

## SCIENTIFIC ABSTRACTS

Skin Disease Education Foundation's

# 42ND ANNUAL HAWAII DERMATOLOGY SEMINAR™

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### PA-01: A case of accentuated delusions in a patient with schizophrenia treated with topical clobetasol

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**BACKGROUND:** Almost fifty percent of patients with schizophrenia experience some type of dermatitis. The standard treatment for dermatitis is a topical corticosteroid. Despite their demonstrated effectiveness, topical corticosteroids are associated with various side effects that may limit their use. These include generalized adverse effects from systemic absorption, such as suppression of the hypothalamic-pituitary-adrenal axis. **OBJECTIVES:** While dose-related, oral corticosteroid-induced psychiatric symptoms, such as psychosis, are well documented, the literature is devoid of topical corticosteroids precipitating psychosis. We hope to provide additional perspective on this phenomenon.

**METHODS:** We present a case of a patient with schizophrenia who developed morphea. She was liberally treated with the potent topical corticosteroid clobetasol, possibly resulting in a supraphysiologic exposure. Subsequently, our patient developed an exacerbation of active-phase symptoms of schizophrenia. **RESULTS:** After clobetasol administration was reduced, these active phase symptoms dissipated.

**LIMITATIONS** (If any): Small sample size, purported first case.

**CONCLUSION:** Given the complex associations between cortisol, the HPA axis, and the development of schizophrenia, it is highly plausible that exogenous glucocorticoids play some role in either an exacerbation of primary psychotic symptoms or an increased susceptibility to them. Our case serves to highlight and association between topical corticosteroids, a therapy commonly used by dermatologic providers, and a rare systemic sequelae to further guide management in complex patients with multiple comorbidities.

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### PA-02: A supporting app for psoriasis patients improves adherence

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**BACKGROUND:** Psoriasis patients' non-adherence to topical treatments is high and leads to poor treatment results. Patient-supporting smartphone applications (apps) exist, but to date their adherence-improving potential have not been documented.

**OBJECTIVE:** To test if a study-specific app as compared to standard treatment improved adherence and reduced psoriasis symptoms short- and long-term.

**METHODS:** An investigator-initiated single-blind randomized controlled trial (RCT) (Trial registration number NCT02858713) encompassing 134 patients was performed. Patients in the intervention group (n = 68) were prescribed a supporting app for 28 days in addition to once-daily study medication calcipotriol/betamethasone dipropionate (Cal/BD) foam prescribed to both intervention and non-intervention group (n = 66). The app provided patients once-daily compulsory treatment reminders and daily information on applied number of treatment sessions and applied amount of prescribed Cal/BD foam. The information on treatment was obtained by chip in an electronic monitor (EM) attached on the Cal/BD foam canister and synchronizing via Bluetooth® to the app. Effect on psoriasis after termination of the intervention was observed in a 22 week follow-up period. In total, 122 patients completed the study. Adherence rates were objectively monitored by the EM detecting treatment sessions. Severity of psoriasis measured by the Lattice system Physician Global Assessment (LS-PGA) and quality of life measured on Dermatology Life Quality Index (DLQI) scales were obtained at all visits.

**RESULTS:** Data was analyzed in an intention to treat analysis. At week 4 more patients in the intervention group were adherent to Cal/BD foam, defined as medication applied ≥80% of

days in the treatment period, compared to patients in the non-intervention group (65% vs. 38%,  $P = 0.007$ ). Improved adherence was associated with a significant reduction in LS-PGA from baseline to week 4 between intervention and nonintervention group (mean 1.86 vs. 1.46,  $P 0.008$ ), but not at follow-up visits week 8 and 26.

**LIMITATIONS:** The app was only tested for a shorter period. Single-blinding posed risk of attrition bias from the investigator.

**CONCLUSION:** This RCT demonstrates that an app significantly improved adherence to the Cal/BD foam and reduced severity of psoriasis. The app only improved severity of psoriasis as long as it was used.

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**DISCLOSURES:** Part of M.T.S.' salary during the trial was paid by funding from LEO Pharma. K. E.A. has received funding from LEO Pharma for the trial. LEO Pharma provided study medication, app, and the electronic monitor (EM) used in the trial. The other authors declare no conflicts of interest.

**FUNDING:** This study was supported by LEO Pharma. The views and opinions expressed therein are those of the authors and do not reflect those of LEO Pharma. LEO Pharma provided the study medication calcipotriol/betamethasone dipropionate (Cal/BD) foam, app and electronic monitor (EM) used in the trial.

**PA-03: A-101, a 40% hydrogen peroxide topical solution, safety and efficacy in adults with seborrheic keratosis: results from the randomized, double-blind, vehicle-controlled, parallel-group Phase 3 study**

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**BACKGROUND:** Seborrheic keratosis (SK) is one of the most common benign skin lesions, affecting over 80 million US citizens, yet there is no Food & Drug Administration (FDA)-approved treatment available.

**OBJECTIVE:** The purpose of this study was to evaluate the safety and efficacy of a proprietary 40% hydrogen peroxide topical solution (A-101) versus its matching vehicle for the treatment of seborrheic keratosis.

**DESIGN:** Subjects with 4 eligible SK lesions, identified by the study investigator, were randomized 1:1 to A-101 or a matching A-101 vehicle. Eligible target lesions were stable, typical SKs, measuring 5-15 mm in both length and width and  $\leq 2$  mm thickness, and were located on the trunk, extremities, and face. Subjects were required to present with  $\geq 1$  lesion on the trunk or extremities and  $\geq 1$  lesion on the face. Treatment was per-

formed by a non-physician sub-investigator in order to maintain blinding on Day 1. During Visit 4 (Day 22), previously treated SK lesions with a Physician's Lesion Assessment score  $> 0$  were re-treated by the study sub-investigator (PLA scale: 0 = clear, 1 = near clear, 2 = thickness  $\leq 1$  mm, and 3 = thickness  $> 1$  mm). At Day 106, the investigator assessed the lesions using the validated PLA.

**RESULTS/SUMMARY:** 450 subjects were enrolled. At Day 106, significantly more subjects receiving A-101 (IntentTo-Treat, ITT population) achieved a PLA score = 0 on all 4 of 4 lesions (4% vs 0%,  $P < 0.002$ ) and 3 of 4 lesions (13.5% vs 0%,  $P < 0.0001$ ) versus vehicle in the primary and secondary endpoints, respectively. In the a priori exploratory analyses (Per-Protocol Population,  $n = 218$ ), significantly higher mean per-subject percentage of lesions achieving clear/near clear (PLA  $\leq 1$ ) was observed in the A-101 arm (47.5% vs 10.2% in the vehicle group;  $P < 0.0001$ ). Additionally, significantly higher mean per-subject percentage of facial lesions achieving clear/near clear (PLA  $\leq 1$ ) was observed in the A-101 arm (64.4% vs 15.0% in the vehicle group at Day 106;  $P < 0.0001$ ) in the ITT population. Adverse events were comparable between groups. Local skin reactions were predominantly mild and had generally resolved by Day 106. At all visits, atrophy, erosion, hypopigmentation, scarring, or ulceration were reported for  $\leq 4\%$  of lesions.

**CONCLUSION:** A-101, a 40% hydrogen peroxide topical solution, is a safe, effective, and well-tolerated treatment for SK. If approved, it would offer the first US FDA-approved topical treatment for SK.

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**PA-04: An observational study of the safety and efficacy of tissue stabilized guided subcision: final data**

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**BACKGROUND:** Tissue stabilized guided subcision (TS-GS) is FDA cleared for the long-term improvement in the appearance of cellulite on the buttocks and thighs, with no loss of benefit for up to 3 years.

**OBJECTIVE:** The purpose of this study is to collect observational data on real-life clinical use of TS-GS cleared for long-term improvement of the appearance of cellulite.

**METHODS:** The study enrolled 53 patients who received treatment. At baseline, day 30, day 90, and day 180, patients completed a questionnaire to assess treatment value, impact on self-confidence and choice of clothing. Global aesthetic improvement scales (GAIS) were completed by the patient and clinician assessing overall aesthetic improvement at day 180.

**RESULTS:** 53 adult female patients have been enrolled and treated. 31 patients received anesthetic solution of 0.1% Lidocaine HCL and 1:1,000,000 Epinephrine or equivalent w/ 10% sodium bicarbonate buffer; 7 patients received this same solution without the buffer. The remaining 15 patients received another solution based on physician's discretion. Average time for anesthesia delivery and tissue release were 25 and 21 minutes, respectively. 81% (n=43) received treatment to both the buttocks and thighs, 13% (n=7) to buttocks only, and 6% (n=3) to thighs only with average areas treated of 24, 18 and 21 areas, respectively. Quality of Life responses (0=not at all affects to 10=very much affects) reflect average scores of 7.4 (baseline), 5.2 (D30), 4.6 (D90) and 5.2 (D180). This shows improvement in patient's level of self-confidence over time when compared to baseline. Average clothing choice scores of 4.5 (D30) 4.5 (D90), and 4.8 (D180) shows no impact of cellulite on clothing choices. The subject GAIS was collected at D180 (n=45) and showed that overall improvement was reported in 91% of subjects. The majority of subjects rated themselves as at least improved (69%). The clinician GAIS collected at D180 showed overall improvement in 96% of these subjects. No serious adverse events were reported. Expected treatment effects were similar to those reported in the pivotal trial supporting FDA clearance.

**CONCLUSIONS:** Results indicate this FDA- cleared long-lasting cellulite treatment that takes an average of under one hour is safe and effective in real-life clinical practice. Patients report an increased level of self-confidence after treatment.

**DISCLOSURES:** All authors have been consultants and/or investigators for Merz North America, Inc. This study was sponsored by Merz North America, Inc.

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#### PA-05: Brodalumab, a human anti-interleukin-17 receptor A monoclonal antibody, shows low immunogenicity in patients with moderate-to-severe psoriasis

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**BACKGROUND:** Brodalumab has demonstrated high efficacy in the treatment of moderate-to-severe plaque psoriasis. Biological therapies sometimes lead to the development of anti-drug antibodies (ADAs), which may affect pharmacokinetics and compromise efficacy and/or safety of the treatment.

**OBJECTIVES:** To investigate the immunogenicity in brodalumab clinical trials.

**METHODS:** Immunogenicity data from a 12-week Phase II study and its 352-week openlabel extension, and three 52-week Phase III studies (AMAGINE-1, -2 and -3) were included. All studies were placebo-controlled, with ustekinumab as a comparator in AMAGINE-2 and -3. A highly sensitive (15 ng/mL) electrochemiluminescent bridging immunoassay with a drug

tolerance threshold of 100.0 µg/mL, defined by a positive control antibody, was used to detect ADAs. Positive samples were tested for 2 neutralising ADAs using a cell-based assay. In the Phase III studies, samples were tested at weeks 0, 4, 12, 24, 48 and 52.

**RESULTS:** Steady-state brodalumab serum concentrations were below the drug tolerance threshold in all samples. 122/4461 brodalumab-treated patients (2.7%) were positive for ADAs at any time after receiving brodalumab; 15 (12%) of which were also positive at baseline. The incidence of ADAs was similar across dosing groups (brodalumab 140 mg: 2.2%; brodalumab 210 mg: 1.9%; variable brodalumab dosing: 3.4%; brodalumab 210 mg after ustekinumab: 2.5%). ADAs were transient in 58 patients (1.4%). No patients had neutralising ADAs, including those who received brodalumab 210 mg after ustekinumab (n=564). There was no evidence of altered pharmacokinetics, loss of efficacy, or changes in the safety profile of brodalumab in subjects who tested positive for binding ADAs. No meaningful differences were observed in the incidence of hypersensitivity or injection site reactions for brodalumab compared with placebo or ustekinumab (hypersensitivity events, week 12 – brodalumab 140 mg: n=39/1491, 2.6%; brodalumab 210 mg: n=26/1496, 1.7%; placebo: n=27/879, 3.1%; ustekinumab: n=8/613, 1.3%; injection site reactions, week 12 – brodalumab 140 mg: n=25/1491, 1.7%; brodalumab 210 mg: n=23/1496, 1.5%; placebo: n=11/879, 1.3%; ustekinumab: n=12/613, 2.0%). The most frequent (≥0.3%) injection site reactions across all brodalumab groups (70, 140, 210 and 280 mg; n=3066) were injection site pain (0.7%), erythema (0.5%) and bruising (0.3%).

**LIMITATIONS:** These analyses were based on a controlled clinical study population and may not be generalizable to a broader population of patients with psoriasis.

**CONCLUSION:** In summary, the incidence of brodalumab-specific immunogenicity in patients with moderate-to-severe psoriasis was low and did not appear to compromise the efficacy, pharmacokinetic, or safety profile of brodalumab, including hypersensitivity and injection-site reactions.

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### PA-06: Change in psoriasis systemic biomarkers following treatment with calcipotriol plus betamethasone dipropionate foam

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**BACKGROUND:** Psoriasis is identified by skin/systemic inflammation, which is driven and maintained by mediators eg interleukin (IL)-17A. Increased cardiovascular (CV) risk is typically associated with moderate-to-severe psoriasis; yet, milder patients may also be at risk. Also, systemic treatment has led to improvement in CV-associated biomarker levels. In the 12-week, Phase III PSO-ABLE study in patients with mild-to-severe psoriasis, fixed combination calcipotriol 50 µg/g (Cal) plus betamethasone dipropionate 0.5 mg/g (BD) foam was significantly more efficacious than Cal/BD gel (Paul et al. J EADV 2016). In this secondary analysis, we assess the systemic pro-inflammatory psoriasis biomarkers IL17A and macrophage-derived chemokine/CCL22 (MDC), and the cardio-protective biomarker adiponectin, before and after treatment with Cal/BD foam in a subgroup of patients with the highest psoriasis severity. We also investigate the possible correlation between the topical efficacy of Cal/BD foam and changes in systemic IL-17A levels.

**MATERIAL/METHODS:** From the PSO-ABLE patient population, we selected 50 Cal/BD foam-treated patients with available serum samples and highest psoriasis severity by baseline mPASI score. We then conducted post-hoc analyses to compare change in IL-17A, MDC, and adiponectin levels from baseline to week 12. Samples were collected in vacutainers and serum was isolated after centrifugation. MDC and adiponectin were measured quantitatively using the HumanMAP platform (Myriad RBM Inc., Austin, TX, USA). IL-17A was quantitatively measured using an ultrasensitive Simoa™ assay (Quanterix, Lexington, MA, USA). Efficacy was assessed by the modified Psoriasis Area and Severity Index (excluding the head; mPASI).

**RESULTS:** The baseline mPASI score and levels of the systemic biomarkers of the 50 patients are described in the Table. A significant improvement in mPASI score was observed after 12 weeks of treatment with Cal/BD foam ( $P<0.0001$ ; Table). Mean levels of IL-17A and MDC decreased significantly from baseline to week 12 ( $P<0.0001$ ) and additionally, Cal/BD foam treatment led to significantly increased levels of adiponectin at week 12 ( $P=0.03$ ; Table). Of note, there was a significant correlation between the improvement in mPASI score and IL-17A levels ( $P=0.04$ ); no significant correlation was observed with the other two biomarkers assessed.

**CONCLUSIONS:** Topical treatment of psoriasis with Cal/BD foam effectively treats the cutaneous manifestations, which can also significantly and positively influence systemic inflammatory and cardioprotective biomarker levels.

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**DISCLOSURES:** Mads Roepke is an employee of LEO Pharma. Cristina Bulai Livideanu has been an investigator for Abbvie,

Amgen, Boehringer Ingelheim, Celgene, Janssen Cilag, LEO Pharma, Lilly, Novartis and Pfizer. Rajesh Kaldete has no conflicts of interest to declare. Carle Paul has been an investigator and consultant for AbbVie, Amgen, Boehringer Ingelheim, Celgene, GSK, Janssen Cilag, LEO Pharma, Lilly, Novartis and Pfizer.

### PA-07: Clinical efficacy and tolerability of a cosmetic growth factor serum for overall facial photodamage

Tan P, Makino E, Mehta R

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**BACKGROUND:** Growth factors (GF) play a crucial role in maintaining firmness and elasticity in the skin as they have been shown to affect different pathways of skin repair and rejuvenation. As the skin ages and is exposed to sun-damage, the cells make less growth factors than cells in youthful skin.

**METHODS:** A 12-week, double-blind, randomized, placebo-controlled study was conducted to assess the efficacy and tolerability of TNS Essential Serum (TNS ES), a serum containing a blend of stable growth factors combined with strong antioxidants, on facial photodamage. Thirty-five males and females aged 44-69 with Fitzpatrick skin types I-V with moderate to severe overall facial photodamage completed the study (Active=19, Placebo=16). Three subjects in the placebo group voluntarily withdrew from the study. Subjects were primarily Caucasian (74%), Asian (17%) and African American (9%). The active group received TNS ES, facial cleanser, moisturizer and SPF 30 physical sunscreen, whereas the placebo group only received facial cleanser, moisturizer and SPF 30 physical sunscreen. Visits at baseline, weeks 2, 4, 8 and 12 included clinical gradings of efficacy parameters using a modified Griffiths' 10-point grading scale, where 0=none (best possible condition), 1-3=mild, 4-6=moderate, and 7-9=severe (worst condition possible), with half points allowed as necessary to differentiate degrees of severity. Efficacy parameters included Overall Photodamage, Global Fine Lines/Wrinkles, Global Coarse Lines/Wrinkles, Skin Tone Evenness and Tactile Roughness. Tolerability assessments, standardized digital photography and subject self-assessment questionnaires were included as well.

**RESULTS:** Twice-daily use of TNS ES showed early improvements at Week 2 and significant long-term improvements at weeks 4, 8, and 12 compared to baseline in all efficacy parameters except for Skin Tone Evenness at weeks 2 and 4 (all  $P\leq 0.031$ ; Wilcoxon signed-rank test; week 2:  $n=19$ , week 4:  $n=17$ , week 8:  $n=18$ , week 12:  $n=19$ ). TNS ES demonstrated significantly greater reductions than the placebo group for fine lines/wrinkles and coarse lines/wrinkles at weeks 4, 8 and 12, and for overall photodamage at weeks 8 and 12 (all  $P\leq 0.04$  treatment comparisons; Wilcoxon ranked-sum test). Both treatments were well-tolerated by subjects with mean scores for all tolerability parameters remaining similar to baseline scores. No treatment-related adverse events were reported for either treatment groups during the study. TNS ES was highly-rated by subjects in self-perceived efficacy. At week 12, 100% of subjects agreed that TNS ES "made my skin feel hydrated" and "made my skin feel smooth and soft". 95% of subjects agreed that the

serum “reduced the appearance of lines/wrinkles around my eyes” and “made my skin look more lifted and firm”.

**CONCLUSION:** This study demonstrates that TNS Essential Serum, a cosmeceutical product containing a high concentration of physiologically balanced GF and strong antioxidants, reversed signs of skin aging significantly more than facial cleanser, moisturizer, and sunscreen alone (placebo treatment).

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**DISCLOSURES:** The authors are employees of Allergan, the sponsor company of this study.

#### **PA-08: Clinical efficacy and tolerability of a hydroquinone-free and retinol-free topical brightening serum on females with facial melasma**

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*Research & Development SkinMedica, an Allergan Company, Irvine, California, USA.*

**BACKGROUND:** Melasma is a common skin problem occurring more often in women than men, and is well known as “the mask of pregnancy”. Oftentimes, the psychosocial impact of melasma decreases one’s quality of life.

**OBJECTIVE:** To assess the cosmetic efficacy and tolerability of a HQ-free and retinol-free serum (Lytera 2.0), a single-center study was conducted in non-pregnant women with mild to severe melasma which was self-perceived as being induced by a previous pregnancy.

**METHODS:** Thirty female subjects aged 30-50 with Fitzpatrick Skin Types II-IV completed the twelve-week study. Subjects used Lytera 2.0, facial cleanser and moisturizer twice-daily, and an all-physical SPF 35 sunscreen once in the morning and as needed. Clinical assessments for Overall Hyperpigmentation and Melasma Area and Severity Index (MASI) were graded by the investigator at all visits (baseline, weeks 4, 8 and 12). Corneometer (hydration) measurements, tewameter (transepidermal water loss) measurements, and an image analysis for L\* (skin brightness) were conducted for each subject. In addition to completion of a subject self-assessment questionnaire for self-perceived efficacy and product attributes at each follow-up visit, a Melasma Quality of Life (MelasQoL) Questionnaire was completed at baseline and week 12 to assess the psychosocial impact of the subjects’ melasma condition.

**RESULTS:** The HQ-free and retinol-free serum demonstrated statistically significant improvement in scores for overall hyperpigmentation and whole face Melasma Area and Severity Index (MASI) at weeks 4, 8, and 12 when compared with baseline (all  $p < 0.001$ ; Wilcoxon Signed-Rank Test). Image analysis for brightness (L\*), standardized photographs, and subject questionnaires supported the investigator assessed reductions at all follow-up visits. Corneometer and tewameter measurements showed an improvement in hydration and skin barrier properties, respectively, for each time point. In addition, the skin brightener was well-tolerated with mean tolerability scores remaining below mild.

**CONCLUSION:** Results from this study support the efficacy and tolerability of this HQ-free and retinol-free serum in improving the appearance of mild to severe facial melasma when used

over the course of 12 weeks by non-pregnant women self-perceived as having pregnancy-induced melasma.

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**DISCLOSURES:** The authors are employees of Allergan, the sponsor company of this study.

#### **PA-09: Combining in-office chemical peel procedures with topical therapy of a comprehensive pigmentation control product for multi-ethnic subjects with moderate to severe facial hyperpigmentation**

Schneider K, Goberdhan L, Makino E, Mehta R.

**BACKGROUND:** Dyschromia is one of the primary complaints for patients with skin of color. Treatments need to achieve a balance between tolerability and efficacy to address existing hyperpigmentation without causing additional damage that could trigger post-inflammatory hyperpigmentation (PIH).

**OBJECTIVE:** An open-label, single-center study was conducted to assess the efficacy of a novel comprehensive pigmentation control serum (LYT2) combined with a series of three very superficial chemical peels (VP) in skin of color subjects.

**METHODS:** Seventeen female and male subjects aged 36 to 69 years with Fitzpatrick Skin Types III-VI and moderate to severe facial hyperpigmentation were enrolled in the 12-week clinical study. Subjects identified as Asian, Hispanic, African American, or Caucasian ethnicities. Subjects received a series of 3 VP treatments every 4 weeks. LYT2 was applied twice-daily in between VP treatments. Investigator assessments for overall hyperpigmentation, overall photodamage, and skin tone unevenness, as well as standardized digital photography and subject self-assessment questionnaires were conducted at all visits (baseline and weeks 4, 8, and 12). In vivo reflectance confocal microscopy (RCM) of a target lesion was conducted (in a subset of subjects) at baseline and week 12.

**RESULTS:** Fourteen subjects completed the study. The treatment regimen provided statistically significant improvements in all efficacy parameters at weeks 8 and 12 (all  $P \leq 0.03$ , student’s t-test). Standardized digital photography and RCM images support the improvements in overall hyperpigmentation observed by the investigator. At the end of treatment, the regimen was highly rated by subjects with 100% of subjects (strongly agree/agree) that the combination “decreased the appearance of uneven skin tone and discolorations” and “reduced the appearance of sun damage.” In addition to this clinical study, independent case studies with this combination treatment regimen at a separate study site were also conducted with results that corroborate the formal clinical study findings.

**CONCLUSION:** The comprehensive results from these studies suggest that the combination of a comprehensive pigmentation control serum with a series of 3 very superficial chemical peels may provide an effective treatment approach for hyperpigmentation in skin of color patients.

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**DISCLOSURES:** The authors are employees of Allergan, the sponsor company of this study.

**PA-10: Concurrent administration of ivermectin 1% cream with brimonidine 0.33% gel improves efficacy and tolerability in treatment of moderate to severe rosacea**

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**BACKGROUND:** Multiple studies have demonstrated the efficacy of ivermectin 1% (IVM) cream (inflammatory lesions) and brimonidine 0.33% (BR) gel (persistent erythema). This prospective study evaluated the efficacy and safety of IVM + BR vs their vehicles in moderate to severe rosacea.

**METHODS:** This was a multicenter, randomized, double-blind, vehicle-controlled study in moderate/severe rosacea (investigator global assessment [IGA]  $\geq 3$ ). Three arms: Active treatment arms (2): 1) Once-daily BR (morning) and IVM (evening) 12 weeks (IVM+BR/12W; n = 49); or 2) Once-daily BR vehicle, 4 weeks, followed by once-daily BR, 8 weeks (morning), and once-daily IVM, 12 weeks (evening; IVM+BR/8W; n = 46). Vehicle arm (1): Once-daily BR vehicle (morning) and IVM vehicle (evening), 12 weeks (n = 95). A general skin care regimen (cleanser/moisturizer/sunscreen) was provided/recommended.

**ASSESSMENTS:** IGA (0-4), Clinician's Erythema Assessment (CEA; 0-4), % change from baseline inflammatory lesion count (ILC), % subjects with 100% IL reduction, subject global rosacea improvement, and facial appearance questionnaire. Adverse events (AEs) were monitored throughout the study.

**RESULTS:** The total IVM+BR population showed superior efficacy (week 12, hour 3; IGA success [clear/almost clear] vs vehicle (55.8% vs 36.8%, P = 0.007); IVM+BR/12W showed better efficacy vs vehicle (61.2% vs 36.8%, P = 0.003) than IVM+BR/8W (50% vs 36.8%, P = 0.135). At week 12, success increased for IVM+BR/12W (32.7%, hour 0 [pre-BR application]; 61.2%, hour 3 [post-BR application] and IVM+BR/8W (28.3%, hour 0; 50%, hour 3). CEA and median percent change in ILC improved with IVM+BR/12W and IVM+BR/8W vs vehicle (P < 0.01). IVM+BR/12W trended towards higher efficacy. Eight treatment-related AEs in 6 subjects (3.2%) were reported (including treatment-related worsening of rosacea: 1 with IVM+BR, 3 with vehicle).

**CONCLUSIONS:** Administration of IVM cream with BR gel demonstrated good efficacy and safety. Early BACKGROUND of BR (day 1; with a complete daily skin care regimen) may benefit efficacy and accelerate treatment success without impairing tolerability.

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**DISCLOSURES:** Dr. Linda Stein Gold has been a paid investigator, speaker, and advisor for Galderma. Dr. Kim Papp has been a paid investigator and advisor for Galderma. Dr. Charles Lynde has been a paid investigator, Dr. Edward Lain has been a paid investigator, speaker, and advisor for Galderma. Dr. Melinda Gooderham has been a paid investigator and advisor Dr. Sandra Johnson has been a paid investigator, speaker, and advisor for Galderma. Nabil Kerrouche is a paid employee of Galderma. Dr. Gregor Schäfer is a paid employee of Galderma. G. Schäfer and N. Kerrouche are employees of Galderma. All other authors are unpaid consultants of Galderma.

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**PA-11: Continuous treatment with secukinumab 300 mg demonstrates sustained efficacy in clearing skin and improving patient-reported outcomes in moderate to severe plaque psoriasis: 2-year results from the CLEAR study**

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**BACKGROUND:** Secukinumab, a fully human monoclonal antibody that selectively neutralizes interleukin 17A, has been shown to have significant efficacy in the treatment of moderate to severe plaque psoriasis and psoriatic arthritis, demonstrating a rapid onset of action and sustained responses, with a favorable safety profile.

**OBJECTIVE:** This 52-week extension of the 52-week CLEAR study in moderate to severe psoriasis evaluated efficacy, safety, and patient-reported outcomes (PROs) over 2 years of continuous treatment with secukinumab.

**METHODS:** In this multicenter, double-blind, parallel-group study (NCT02074982), patients were randomized 1:1 to receive secukinumab 300 mg (n=337) subcutaneously at Baseline, Week 1, 2, 3 and then every 4 weeks from Week 4 to Week 48, or ustekinumab (n=339; dosing per label). Patients in the secukinumab arm who completed 1 year of treatment, and who



continued into the extension, received openlabel secukinumab 300 mg at Week 52 and at 4-week intervals through Week 100. Patients in the ustekinumab arm discontinued from the study after Week 52. For the secukinumab treatment arm, Psoriasis Area Severity Index (PASI) 90, PASI 100, and PRO data, including Dermatology Life Quality Index (DLQI) 0/1 response (representing no impact of skin disease on patients' quality of life), and patients' assessments of itching, pain, and scaling severity (on a 0–10 numeric rating scale) were assessed. In addition, health status was assessed via the EuroQoL 5-Dimension Health Questionnaire 3-Level version (EQ-5D-3L) and visual analog scale (EQ-VAS) (scales: 0–100). Data were reported as observed. No use of concomitant psoriasis medication was allowed during the course of the study.

**RESULTS:** PASI 90 and PASI 100 response rates were sustained from Week 52 up to Week 104 (PASI 90: 78.4% and 74.7%; PASI 100: 48.2% and 47.4%). The proportion of patients with DLQI 0/1 responses remained high over 2 years (71.9% at Week 52 and 66.0% at Week 104). The absolute mean change (reduction) from Baseline in patients' assessments of pain, itching, and scaling were also sustained at Week 52 and Week 104, respectively: pain: –3.2 and –3.4; itching: –5.0 and –4.8; scaling: –5.5 and –5.4. Similarly, mean absolute change (improvement) in EQ-5D VAS (13.7 at Week 52 and 12.4 at Week 104) was sustained over 2 years. The safety profile of secukinumab remained favorable to Week 104, with no new or unexpected safety findings.

**LIMITATIONS:** None

**CONCLUSION:** Continuous treatment with secukinumab 300 mg over 2 years demonstrated sustained efficacy in clearing skin and improving PROs in moderate to severe psoriasis, while maintaining a favorable safety profile. These results were originally presented at the 26th Annual Congress of the European Academy of Dermatology and Venereology; Geneva, Switzerland; September 13–17, 2017

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#### PA-12: Correlations of itch with quality of life and signs of atopic dermatitis across dupilumab trials

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**BACKGROUND:** In phase 3 studies dupilumab improved signs and symptoms (including itch) of atopic dermatitis (AD), with an acceptable safety profile. We present the relationship between peak pruritus Numerical Rating Scale (NRS) scores and Eczema Area and Severity Index (EASI) and Dermatology Life Quality Index (DLQI) scores.

**METHODS:** This post-hoc correlation analysis presents data from three randomized, placebo-controlled, double-blinded, phase 3 trials of dupilumab (LIBERTY AD SOLO 1: NCT02277743; LIBERTY AD SOLO 2: NCT02277769; LIBERTY AD CHRONOS: NCT02260986). Adults with moderate-to-severe AD were randomized 1:1:1 (SOLO 1 & 2) or 3:1:3 (CHRONOS) to dupilumab 300 mg weekly/every two weeks, or placebo. In CHRONOS, all patients received background topical corticosteroids. Data from the SOLO 1 & 2 monotherapy studies were pooled.

**RESULTS:** All 2,119 randomized patients were included (SOLO 1 & 2: n=1,379/CHRONOS: n=740). Across all groups, baseline peak pruritus NRS scores correlated weakly with EASI (Pearson r SOLO 1 & 2: 0.2098/CHRONOS: 0.2050) and moderately with DLQI scores (0.4855/0.4231). Stronger correlations of peak pruritus NRS scores with EASI (0.5642/0.4258) and DLQI (0.6242/0.5396) scores were observed for percent change from

baseline to Week 16 and Week 52 (EASI: 0.3960, DLQI: 0.5647; CHRONOS only).

**CONCLUSIONS:** Weak baseline correlation between peak pruritus NRS and EASI indicates that objective signs alone do not capture the full disease impact of moderate-to-severe AD. In dupilumab trials, post-treatment improvements in itch correlated well with improvements in EASI and DLQI, indicating that dupilumab had a comprehensive, balanced effect on AD signs, symptoms, and quality-of-life measures. Data first presented at the 2017 American College of Allergy, Asthma, and Immunology (ACAAI) annual scientific meeting.

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**DISCLOSURES:** Yosipovitch G: Opko, Trevi, Menlo, Eli Lilly, Novartis, Regeneron Sanofi, Galderma, Sienna – Advisory board; Pfizer, Leo Foundation, Allergan, GSK – Grant/Research Support Eckert L, Plaum S, Pirozzi G: Sanofi – employee, may hold stock and/or stock options in the company. Chen Z, Ardeleanu M, Shumel B, Graham NMH, Gadkari A: Regeneron Pharmaceuticals, Inc. – employees and shareholders.

### PA-13: Dupilumab treatment rapidly improves itch in patients with moderate-to-severe atopic dermatitis

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**BACKGROUND:** In phase 3 studies dupilumab, an anti-interleukin-4 receptor- $\alpha$  monoclonal antibody, significantly improved signs and symptoms (including itch) of moderate-to-severe atopic dermatitis (AD), with an acceptable safety profile. We assessed time to onset of improvement in peak pruritus Numerical Rating Scale (NRS) scores in patients with moderate-to-severe AD.

**METHODS:** This post-hoc analysis presents the least-squares mean percent change from baseline in peak pruritus NRS scores from study Day 2 through Day 15 using pooled data from two randomized, placebo-controlled, double-blind, phase 3 trials of dupilumab (LIBERTY AD SOLO 1: NCT02277743; LIBERTY AD SOLO 2: NCT02277769). In these two studies, adults with moderate-to-severe AD were randomized 1:1:1 to dupilumab 300 mg weekly (qw), 300 mg every 2 weeks (q2w), and placebo. Safety was assessed for the entire treatment period (16 weeks).

**RESULTS:** Data were available for all 1,379 randomized patients

(dupilumab 300 mg qw: n=462; q2w: n=457; placebo: n=460). Dupilumab-treated patients showed significant improvement in mean percentage change from baseline [standard error] in peak pruritus NRS scores vs placebo by Day 2 (dupilumab 300 mg qw/q2w, placebo: -4.0%[0.98]/-4.5%[1.00], -0.6%[1.00]; P<0.025 vs placebo for both). Peak pruritus NRS scores continued to improve for both dupilumab groups vs placebo to Day 15 (-22.5%[1.43]/-24.7%[1.44], -3.4%[1.44]; P<0.0001 vs placebo for both). The most common adverse events were AD exacerbations (13%/13%, 32%), nasopharyngitis (10%/9%, 9%), and injection-site reaction (16%/11%, 6%).

**CONCLUSIONS:** Based on improvement in worst itch scores, treatment with dupilumab showed onset of action as early as Day 2 when compared with placebo.

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### PA-14: Efficacy and safety of 24 weeks of treatment with adapalene 0.3%/benzoyl peroxide 2.5% gel

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**BACKGROUND:** Acne vulgaris (AV) studies, including Phase 3 studies, have rarely evaluated AV treatment for a period longer than 12 weeks. This includes the controlled clinical trials establishing the efficacy and safety of adapalene 0.3%/benzoyl peroxide 2.5% gel (A0.3/BPO2.5) in subjects with moderate and severe AV. However, AV is a chronic disease, and treatment plans longer than 12 weeks are necessary to achieve and maintain control of AV. A recent study evaluated the efficacy and safety of 24 weeks of treatment with A0.3/BPO2.5 in subjects with moderate to severe AV.



**METHODS:** This was Part 1 of an ongoing multicenter, randomized, investigator-blinded, vehicle-controlled, intra-individual comparison study (right/left half-face), of subjects aged 16 to 35 years, with moderate/severe facial AV (Investigator's Global Assessment [IGA] score 3-4;  $\geq 25$  inflammatory lesions [IL]). Subjects received 24 weeks of A0.3/BPO2.5 or vehicle (half-face) and skin care (full-face). Assessments included IGA, acne lesion counts (total, IL, and non-inflammatory [NIL]), and safety/tolerability.

**RESULTS:** Of 67 subjects randomized, 54 (80.6%) completed Part 1 of this ongoing study. Most subjects had moderate AV at baseline (92.5%), with a mean of 40 acne lesions (half-face). At 12 weeks, the AV improvement observed in the current study was highly similar to the Phase 3 studies of A0.3/BPO2.5 in both IGA improvement and lesion reduction. After 24 weeks, a significantly larger percentage of subjects were IGA clear/almost clear with A0.3/BPO2.5 (64.2% vs 19.4% vehicle,  $P < .0001$ ). A0.3/BPO2.5 also demonstrated significantly superior total acne lesion count reduction vs. vehicle at all study visits ( $P < .0001$ ). The 24-week median percent change in IL was -86.7% for A0.3/BPO2.5 vs -57.9% vehicle ( $P < .0001$ ). The 24-week median percent change in NIL was -59.5% for A0.3/BPO2.5 vs -41.4% vehicle ( $P < .01$ ). Local tolerability scores peaked at week 1, and on a scale of 1 to 3, scores were near 1 (mild). After 1 month of treatment, tolerability profiles were similar between A0.3/BPO2.5 and vehicle. Treatment-related AEs were reported by 20.9% of subjects on the A0.3/BPO2.5 side of the face vs 9% with vehicle. Most AEs were mild in intensity, and skin irritation was the most commonly reported related AE (14.9% vs. 6% respectively). Only 2 subjects discontinued the study due to a treatment related AE.

**CONCLUSIONS:** Topical A0.3/BPO2.5 was effective, safe, and tolerable. Significant lesion reduction and IGA improvement vs vehicle was seen at week 1, and improvements in IGA and lesion counts continued for the full 24 weeks of the study. After 24 weeks, 64% of patients achieved an IGA of clear/almost clear using A0.3/BPO2.5.

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**DISCLOSURES:** Dr. Hilary Baldwin has been a paid investigator, speaker, and advisor for Galderma. Dr. Joshua Zeichner has been a paid , speaker, and advisor for Galderma. Dr. Maria Jose Rueda is a paid employee of Galderma. Dr. Jerry Tan has been a paid investigator, speaker, and advisor for Galderma.

#### PA-15: Efficacy and safety of apremilast in systemic- and biologic-naïve patients with moderate plaque psoriasis (52-week results of the UNVEIL study)

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**BACKGROUND:** Patients with moderate plaque psoriasis with psoriasis-involved body surface area (BSA) involvement of  $<10\%$  are often inadequately treated. UNVEIL is a phase IV study that has demonstrated the clinical efficacy and safety of a systemic treatment, oral apremilast, in patients with moderate plaque psoriasis who are naïve to systemic and biologic therapy.

**OBJECTIVE:** To describe efficacy and safety results of UNVEIL through Week 52.

**METHODS:** Patients with chronic plaque psoriasis having a BSA of 5% to 10% and a static Physician's Global Assessment (sPGA) score of 3 (moderate, 0 to 5 scale) who were systemic- and biologic-naïve were randomized (2:1) to apremilast 30 mg twice daily (APR) or PBO for 16 weeks. All patients continued on APR (APR/APR) or were switched to APR (PBO/APR) through Week 52 in an open-label treatment phase. Efficacy was evaluated based on mean percentage change from baseline in the product of the sPGA and BSA (PGAxBSA), as well as the percentage of patients achieving a  $\geq 75\%$  reduction from baseline in PGxBSA (PGxBSA-75) and the percentage of patients achieving sPGA response (an sPGA score of 0 [clear] or 1 [almost clear]). Quality of life was assessed with the Dermatology Life Quality Index (DLQI).

**RESULTS:** Among 221 randomized patients (PBO n=73; APR n=148), baseline mean BSA was 7.2%, PGxBSA was 21.8, Psoriasis Area and Severity Index (PASI) score was 8.1, and DLQI score was 11.0. At Week 16, significantly greater improvement occurred in PGxBSA with APR (-48.1%) vs. PBO (-10.2%;  $P < 0.0001$ ), as well as in other, secondary efficacy end points (i.e., PGxBSA-75 [35.4% vs. 12.3%], sPGA response [30.4% vs. 9.6%], both  $P < 0.0001$ ; mean change from baseline in DLQI total score [-4.8 vs. -2.4],  $P = 0.0008$ ). At Week 52, improvements in all efficacy end points were maintained in APR/APR patients and emerged in PBO/APR patients after switch to APR: mean percentage change from baseline in PGxBSA score was -49.0% (APR/APR) and -42.2% (PBO/APR), PGxBSA-75 was achieved by 37.4% (APR/APR) and 45.3% (PBO/APR) of patients, and sPGA score of 0 (clear) or 1 (almost clear) was achieved by 29.1% (APR/APR) and 35.9% (PBO/APR) of patients. Mean change from baseline in DLQI total score at Week 52 as -4.3 (APR/APR) and -5.1 (PBO/APR). The majority of adverse events (AEs) were mild or moderate in severity. The most common Scientific Abstract with Background, Objective, Methods, Results, Limitations, Conclusion, CORRESPONDENCE and Disclosure AEs (occurring in  $\geq 5\%$  of patients during APR treatment) through Week 52 were diarrhea (28.0%), nausea (19.0%), headache (15.2%), nasopharyngitis (10.4%), upper respiratory tract infection (7.1%), vomiting (5.7%), and decreased appetite (5.2%).

**CONCLUSIONS:** APR was effective in systemic- and biologic-naïve patients with moderate psoriasis, and efficacy was sustained with continued treatment through Week 52. Safety was consistent with the known profile of APR.

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#### PA-16: Efficacy and safety of brodalumab in obese patients with moderate-to-severe plaque psoriasis

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**BACKGROUND:** There is a well-established association between psoriasis and obesity. Obese patients with psoriasis often exhibit decreased efficacy and increased susceptibility

to certain side effects of therapeutic agents, making effective treatment in this population complex and challenging. AMAGINE-1 was a phase 3, multicenter, randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of brodalumab, a fully human anti-interleukin-17 receptor A monoclonal antibody, in patients with moderate-to-severe plaque psoriasis.

**OBJECTIVES:** To evaluate the efficacy and safety of brodalumab in obese and nonobese patients with moderate-to-severe plaque psoriasis.

**METHODS:** Patients were randomized to receive brodalumab 210 mg or placebo every 2 weeks (Q2W) for 12 weeks. After 12 weeks, patients were rerandomized to receive brodalumab 210 mg Q2W or placebo for up to 52 weeks. Skin clearance was monitored by the psoriasis area and severity index (PASI) and the static physician's global assessment (sPGA). Safety was assessed by monitoring exposure-adjusted treatment-emergent adverse event (TEAE) rate per 100 patient-years.

**RESULTS:** Of 659 total patients at the start of the trial, 45% (n=299) were obese (defined as body mass index [BMI]  $\geq 30$  kg/m<sup>2</sup>) and 55% (n=360) were nonobese (defined as BMI  $< 30$  kg/m<sup>2</sup>). Most patients were male with an approximate mean age of 45–48 years. In a post hoc comparison of patients taking brodalumab 210 mg, 59.3% of obese patients reached 90% improvement in PASI score (PASI 90) at week 12 compared with 80.7% of nonobese patients, and 27.8% of obese patients reached PASI 100 at week 12 compared with 55.3% of nonobese patients. Among obese patients taking placebo, none reached PASI 90 or PASI 100 compared with 1.5% and 0.8% of nonobese patients, respectively. Rates of achieving sPGA 0/1 at week 12 were 63.9% among obese patients and 86.8% among nonobese patients. At week 52, clearance rates via PASI 90, PASI 100, and sPGA 0/1 among obese patients continuously treated with brodalumab 210 mg were 71.1%, 52.6%, and 78.9%, respectively, compared with 84.4%, 80.0%, and 86.7%, respectively, in nonobese patients. Through 52 weeks, 370.8 TEAEs per 100 patient-years were reported among obese patients continuously treated with brodalumab 210 mg compared with 388.7 TEAEs per 100 patient-years among nonobese patients.

**LIMITATIONS:** These analyses were based on a controlled clinical study population and may not be generalizable to a broader population of patients with psoriasis.

**CONCLUSIONS:** Higher skin clearance efficacy was associated with brodalumab 210 mg Q2W in nonobese versus obese patients. The safety associated with brodalumab 210 mg Q2W was comparable between nonobese and obese patients.

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### **PA-17: Efficacy and safety of ingenol mebutate gel in field treatment of actinic keratosis on full face, balding scalp, or approximately 250 cm<sup>2</sup> on the chest: a Phase III randomized controlled trial**

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**BACKGROUND:** Ingenol mebutate (IngMeb) is approved for the treatment of actinic keratosis (AK) in areas ≤25 cm<sup>2</sup>; however, some patients may require treatment of areas >25 cm<sup>2</sup>.

**OBJECTIVE:** This Phase III trial (NCT02361216) compared the efficacy and safety of IngMeb gel with vehicle as a field treatment in patients with AK, when applied to affected areas of up to 250 cm<sup>2</sup>.

**METHODS:** This was a randomized, parallel-group, double-blind, vehicle-controlled, 8-week trial. Patients with 5-20 clinically typical, visible and discrete AKs within a selected treatment area of sun-damaged skin on the full face, balding scalp (>25-250 cm<sup>2</sup>), or a contiguous area of approximately 250 cm<sup>2</sup> on the chest applied IngMeb 0.027% gel or vehicle gel once daily for 3 consecutive days. Efficacy assessments at week 8 included complete clearance (AKCLEAR 100), partial clearance (AKCLEAR 75), and reduction in AK count from baseline. Local skin responses (LSRs) and adverse events (AEs) were assessed on days 1 and 4 and at weeks 1, 2, 4, and 8. Treatment Satisfaction Questionnaire for Medication (TSQM) and cosmetic outcomes were assessed at week 8.

**RESULTS:** In total, 729 patients received either IngMeb (n=552) or vehicle (n=177). Median age was 67.5 years; 73.4% were male; and 95.6% had Fitzpatrick skin type I-III. Median AK count at baseline was 12. For IngMeb vs vehicle at week 8, AKCLEAR 100 was 21.4% vs 3.4% (P<.001); AKCLEAR 75 was 59.4% vs 8.9% (P<.001); reduction in AK count was 75.7% vs 12.7% (P<.001). Mean composite LSR score peaked at day 4 with IngMeb (10.8; vehicle 1.6), declined rapidly, and was mini-

mal by week 4. IngMeb showed lower efficacy on the scalp than on the face or chest. Treatment-related AEs occurred in 73.8% and 9.1% of IngMeb and vehicle patients, respectively; serious AEs occurred in 1.5% vs 1.1% (none treatment-related). The most common AEs were application-site pain (63.8% vs 2.3%) and pruritus (36.8% vs 4.0%). TSQM global satisfaction score was significantly higher for IngMeb (41.0-point difference; P<.001). For cosmetic outcomes, "much improved" or "somewhat improved" for overall feel and appearance were reported by 92% and 94% of IngMeb patients, respectively, vs 18% and 19% for vehicle.

**LIMITATIONS:** Patients receiving active treatment were identifiable by the emergence of LSRs, with early onset and rapid resolution.

**CONCLUSIONS:** IngMeb 0.027% gel was superior to vehicle as a field treatment for AK on the full face, balding scalp, or chest areas of approximately 250 cm<sup>2</sup>. LSRs and AEs for IngMeb were as expected. Patient satisfaction was also higher with IngMeb than with vehicle.

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### **PA-18: Efficacy and safety of ixekizumab in a randomized, double-blinded, placebo-controlled, Phase 3b clinical trial in patients with moderate-to-severe genital psoriasis**

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**BACKGROUND:** Genital psoriasis (gen-pso) is common among patients with plaque psoriasis and negatively impacts



quality of life and sexual health. Ixekizumab (IXE), a high-affinity monoclonal antibody that selectively targets interleukin-17A, is approved for the treatment of plaque psoriasis.

**OBJECTIVES:** This study's objective was to evaluate the effect of IXE on gen-pso compared to placebo (PBO) during 12 weeks of treatment.

**METHODS:** Patients with moderate-to-severe gen-pso (N=149) were randomized in a 1:1 ratio to receive either PBO (N=74) or 80 mg IXE every 2 weeks (Q2W) following a starting dose of 160 mg IXE (N=75). The primary endpoint was the percentage of patients achieving a 0 or 1 score in the 6-point static Physician's Global Assessment of Genitalia (sPGA-G [0,1]) at week 12. Major secondary endpoints included the percentage of patients achieving a 0 or 1 score in the 6-point overall sPGA (sPGA [0,1]), a  $\geq 3$ -point improvement on the 11-point genital itch (gen-itch) numeric rating scale (NRS) for patients with a baseline score of  $\geq 3$ , and a 0 or 1 score for the 5-point sexual frequency questionnaire item 2 (SFQitem 2 [0,1]) (indicating that the frequency of sexual activity is never or rarely limited by gen-pso) for patients with a baseline SFQ-item 2 score of  $\geq 2$ . Treatment comparisons were made using logistic regression analysis with non-responder imputation for missing data. Clinicaltrials.gov ID: NCT02718898.

**RESULTS:** IXE Q2W treatment led to significantly greater sPGA-G (0, 1) response rates (73.3%) than PBO (8.1%) at week 12 ( $p < 0.001$ ). Similarly, overall sPGA (0, 1) response rates were significantly greater with IXE Q2W (73.3%) compared to PBO (2.7%,  $p < 0.001$ ). IXE Q2W led to significantly greater gen-itch NRS response rate (59.7%) at week 12 versus PBO (8.3%,  $p < 0.001$ ). Significantly more patients achieved SFQitem 2 (0, 1) with IXE Q2W (78.4%) than PBO (21.4%,  $p < 0.001$ ). Significant improvements in response rates were observed by week 1 for sPGA-G (0,1) ( $p < 0.01$ ), overall sPGA (0,1) ( $p < 0.001$ ), and SFQ-item 2 (0, 1) ( $p < 0.05$ ), and by week 2 for gen-itch NRS ( $p < 0.001$ ). Frequencies of treatment-emergent adverse events (TEAEs) through week 12 were 56.0% and 44.6% in IXE Q2W and PBO groups, respectively; the majority were mild or moderate in severity. Common TEAEs in the IXE Q2W population included upper respiratory tract infections, injection site reactions, headache, oropharyngeal pain, and pruritus. No cases of candidiasis were reported, no deaths occurred, and only one (1.4%) serious adverse event was reported in a patient receiving PBO.

**CONCLUSIONS:** IXE Q2W was superior to PBO for the primary and all major secondary endpoints as early as week 1 and safety outcomes were comparable to previously reported IXE phase 3 trials. These results indicate that IXE is an efficacious treatment of moderate-to-severe gen-pso and minimizes how often gen-pso limits the frequency of sexual activity.

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**DISCLOSURES:** Caitriona Ryan has been a consultant with Abbvie, Dr Reddys, Dermira and Lilly; in addition to these companies, C. Ryan has also been on the Advisory Board for Novartis, UCB and Regeneron; an investigator for Boehringer Ingelheim (BI), Dr Reddys, Dermira, Lilly and Janssen; a speaker for Abbvie, Leo, Lilly, Janssen, Novartis and UCB, and has received honoraria from the above companies except BI. Alan Menter has been a consultant with AbbVie, Afecta, Amgen, Avillion, BI, Eli Lilly, Galderma, Janssen Biotech, Inc, LEO Pharma, Menlo,

Novartis, OrthoDermatologics, Pfizer and Promius; been on the Advisory Board with Abbvie, Afecta, Amgen, BI, Eli Lilly, Janssen Biotech, Inc, LEO Pharma, OrthoDermatologics, Promius; a speaker for AbbVie, Amgen, Janssen Biotech, Inc., LEO Pharma, OrthoDermatologics, and Promius; an investigator for AbbVie, Amgen, BI, Celgene, Dermira, Eli Lilly, Janssen Biotech, Inc., LEO Pharma, Novartis, Pfizer, Regeneron; and has received compensation from the above. Lyn Guenther Guenther Research Inc. and Guenther Medicine Professional Company has received research grant and consulting fee, receptively, from Eli Lilly and Company. Consultancy towards Guenther Medicine Professional Company from Eli Lilly, Abbvie, Amgen, Janssen, Leo Pharma, Merck Frost, Novartis, Pfizer and Valeant. Grants towards Guenther Research Inc for clinical research and PI from Eli Lilly, Amgen, Janssen, Leo Pharma, Novartis, Pfizer, Merck Frosst, Abbvie, BI, and UCB. Honoraria (Speaker) from Eli Lilly, Amgen, Janssen, Leo Pharma, Novartis, Pfizer, and Valeant. Payment for development of educational presentations including service on speaker's bureaus to Guenther Medicine Professional Company from Eli Lilly and Valeant; travel expenses to Guenther Medicine Professional Corporation from Amgen, Valeant and Celgene. Andrew Blauvelt: has received consulting fees to help design the protocol; Oregon Medical Research Center has received grant to perform clinical study. Robert Bissonnette had board membership on Abbvie, Amgen, BI, BMS, Celgene, Eli Lilly, Galderma, GSK Stiefel, Janssen, Leo Pharma, Merck, Novartis and Pfizer; consultancy with Abbvie, Amgen, Celgene, Eli Lilly, Galderma, Incyte, Janssen, Leo Pharma, Merck, Novartis and Xenoport; employment with Innovaderm Research Inc, grants to Institution from Abbvie, Amgen, BI, Celgene, Eli Lilly, Galderma, GSK Stiefel, Immune Tolerance, Incyte, Janssen, Kineta, Leo Pharma, Merck, Novartis and Pfizer; honoraria from Abbvie, Amgen, BI, BMS, Celgene, Eli Lilly, Galderma, GSK Stiefel, Incyte, Janssen, Leo Pharma, Merck and Novartis; payment for speaker activities from Abbvie, Amgen, Celgene, Galderma, Janssen, Leo Pharma, Merck and Novartis; shareholder of Innovaderm Research Inc, travel expenses reimbursed when invited to speak or to participate to board meetings; and was paid (to Institution) for PI Activities. from Abbvie, Amgen, BI, Celgene, Eli Lilly, Galderma, GSK Stiefel, Immune Tolerance, Incyte, Janssen, Kineta, Leo Pharma, Merck, Novartis and Pfizer. Fan Emily Yang has not received any payment/support in kind. Alison Potts Bleakman and her husband are employees of Eli Lilly and own company stock.

#### **PA-19: Efficacy and safety of risankizumab, an IL-23 inhibitor, in patients with moderate-to-severe chronic plaque psoriasis: 16-week Phase 3 IMMhance trial results**

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**ABSTRACT:** Interleukin-23 (IL-23), a key regulator of multiple effector cytokines (including IL-17, IL22, and TNF), is thought to drive the development/maintenance of psoriatic lesions. Risankizumab is a humanized IgG1 monoclonal antibody that inhibits IL-23 by binding its p19 subunit.

In a phase 2 trial, the efficacy/safety of risankizumab was compared with ustekinumab, an IL-12/IL-23 inhibitor, in patients with moderate-to-severe chronic plaque psoriasis. Primary endpoint of PASI90 at week 12 was achieved by significantly higher proportion of patients receiving risankizumab (77%, pooled 90+180mg doses) compared with ustekinumab (40%). In addition, adverse events (AEs) were similar between risankizumab and ustekinumab groups through week 48, suggesting comparable safety profile. Currently, multiple phase 3 studies are in progress to investigate efficacy/safety of risankizumab in patients with moderate-to-severe chronic plaque psoriasis. IMMhance (NCT02672852) is a phase 3 multicenter, randomized, double-blind, placebo-controlled trial, evaluating the efficacy/safety of risankizumab versus placebo in patients with moderate-to-severe chronic plaque psoriasis. The initial 16-week placebocontrolled period was followed by randomized withdrawal and subsequent re-treatment with risankizumab. Randomization was stratified by weight and prior TNFi-exposure. Co-primary endpoints were percentages of patients achieving PASI90 and sPGA0/1 at week 16; missing data were imputed as non-responders. At baseline, 507 patients at 60 sites were randomized 4:1 to receive either risankizumab (150mg at weeks 0 and 4) or placebo during 16-week placebo-controlled period. Baseline demographics and disease characteristics from a preliminary analysis of the study database are presented here. Mean age was 49.2 years and mean weight was 92.0kg; 70.2% of patients were male. A history of diagnosed or suspected psoriatic arthritis was reported in 34.5% of patients and prior TNFi therapy was reported in 36.5% of patients. Mean baseline PASI and BSA were 20.1 and 26.1%, respectively. Efficacy and safety data from the IMMhance trial through 16 weeks (not yet available at time of abstract submission) will be presented.

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**PA-20: Efficacy of a halobetasol 0.01% lotion in the treatment of moderate-to-severe plaque psoriasis: results of 2 Phase 3 randomized controlled Trials**

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**BACKGROUND:** Psoriasis is a chronic, immune-mediated disease that varies widely in its clinical expression. Treatment options focus on relieving symptoms, reducing inflammation, induration, and scaling, and controlling the extent of the disease. Topical corticosteroids are the mainstay of treatment, however long-term safety remains a concern, particularly with the more potent formulations.

**OBJECTIVE:** To investigate the efficacy of a once-daily application of halobetasol propionate (HP) 0.01% lotion in comparison with its vehicle in subjects with moderate-to-severe plaque psoriasis.

**METHODS:** Two multicenter, randomized, double-blind, vehicle-controlled Phase 3 studies in moderate or severe psoriasis (N=285). Subjects randomized (2:1) to receive HP or vehicle, once-daily for 8 weeks. Efficacy assessments included treatment success (defined as at least a 2-grade improvement from baseline in the IGA score and a score of 'clear' or 'almost clear'), impact on individual signs of psoriasis (erythema, plaque elevation, and scaling) at the target lesion, and reduction in Body Surface Area (BSA)

**RESULTS:** HP lotion demonstrated statistically significant superiority over vehicle. At Week 8, 36.5% (Study 1) and 38.4% (Study 2) of subjects were treatment successes compared with 8.1% and 12.0% in the vehicle (p<0.001) arms respectively. HP lotion was superior to vehicle in reducing the psoriasis signs of erythema, plaque elevation, and scaling at the target lesion. At Week 8, a 2-grade improvement was achieved by 46.7% and 56.3% of subjects for erythema, 52.5% and 62.7% for plaque elevation, and 59.4% and 63.1% for scaling (all P<0.001 versus

vehicle). In addition, there was a 34.2% and 36.2% reduction in mean BSA.

**CONCLUSIONS:** Despite a concentration one-fifth of that currently available, halobetasol propionate 0.01% lotion was consistently more effective than its vehicle in achieving treatment success, reducing psoriasis signs of erythema, plaque elevation, and scaling at the target lesion, and reducing BSA.

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**DISCLOSURES:** Boni Elewski has received honoraria and grants while serving as a consultant and investigator for the following companies: Valeant Pharmaceuticals International Inc, Anacor Pharmaceuticals, Inc, Meiji Seika Pharma Co, and Viamet Pharmaceuticals, Inc. Wendy Cantrell has no conflicts to disclose Mark Lebwohl is an employee of Mount Sinai, which receives research funds from Amgen Inc, Anacor Pharmaceuticals, Boehringer Ingelheim, Celgene Corporation, Eli Lilly, Janssen Biotech, Inc, Kadmon Corporation, LEO Pharma, MedImmune, Inc, Novartis, Pfizer, Inc, Sun Pharmaceutical Industries, Ltd, and Valeant Pharmaceuticals North America LLC. Lawrence Green is an investigator, consultant, and or speaker for Amgen, Abbvie, Celgene, Janssen, Merck, Novartis, and Valeant. Jeff Sugarman is a Consultant and Principle investigator in research studies sponsored by Promius and Valeant Pharmaceuticals. Principle investigator in research studies sponsored by Leo Pharmaceuticals Linda Stein Gold is an investigator, advisor and speaker for Valeant and Leo. David Pariser is a consultant for Bickel Biotechnology, consultant for Biofrotera AG, consultant for Celgene, consultant for Dermira, consultant for DUSA Pharmaceuticals, consultant/principal investigator for Leo Pharma, consultant for Novartis, advisor for Pfizer, consultant for Promius Pharmaceuticals, consultant for Regeneron, Consultant for TheraVida, consultant for Valeant, principle investigator for Abbott laboratories, Amgen, Bickel, Celgene, Eli Lilly, Leo, Novartis, Novo Nordisk, Ortho Dermatologics, Peplin, Pfizer, and received grants/research funding from Photocure ASA, Promius, Regeneron, Stiefel, and Valeant Neal Bhatia has served as an adviser for Valeant Pharmaceuticals Fran Cook-Bolden has served as an investigator and adviser for Valeant Pharmaceuticals Jennifer Soung has received research, speaking and/or consulting support from a variety of companies including Janssen, Eli Lilly, Amgen, AbbVie, Merz, Pfizer Inc, Galderma, Valeant, National Psoriasis Foundation, Cassiopea, Celgene, Actavis, Actelion, and GSK. Stephen Tying has served as an investigator for Valeant Pharmaceuticals and received grants from Amgen Drs Pillai, Lin, Qurewshi, Alexander, Israel and Yawn; and Ms Jacobson, Harris, Martin and Mathew are employees of Valeant Pharmaceuticals.

**PA-21: Efficacy of a halobetasol 0.01%/tazarotene 0.045% fixed combination in the treatment of moderate-to-severe plaque psoriasis: results of 2 Phase 3 randomized controlled trials**

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**BACKGROUND:** Psoriasis is a chronic, immune-mediated disease that varies widely in its clinical expression. Treatment options focus on relieving symptoms, reducing inflammation, induration, and scaling, and controlling the extent of the disease. Topical corticosteroids are the mainstay of treatment, however long-term safety remains a concern, particularly with the more potent formulations. Combination therapy with a corticosteroid and tazarotene may improve psoriasis signs providing a superior safety profile, potentially reducing the occurrence of cutaneous adverse events of each individual component.

**OBJECTIVE:** To investigate the efficacy of a once-daily application of a fixed combination halobetasol propionate 0.01% and tazarotene 0.045% (HP/TAZ) lotion in comparison with its vehicle in subjects with moderate-to-severe plaque psoriasis.

**METHODS:** Two multicenter, randomized, double-blind, vehicle-controlled Phase 3 studies in moderate or severe psoriasis (N=418). Subjects randomized (2:1) to receive HP/TAZ or vehicle, once-daily for 8 weeks. Efficacy assessments included treatment success (defined as at least a 2-grade improvement from baseline in the IGA score and a score of 'clear' or 'almost clear'), impact on individual signs of psoriasis (erythema, plaque elevation, and scaling) at the target lesion, and reduction in Body Surface Area (BSA)

**RESULTS:** HP/TAZ lotion demonstrated statistically significant superiority over vehicle as early as 2 weeks. At Week 8, 35.8% (Study 1) and 45.3% (Study 2) of subjects had treatment success compared with 7.0% and 12.5% in the vehicle ( $p < 0.001$ ) groups respectively. HP/TAZ lotion was superior to its vehicle in reducing the psoriasis signs of erythema, plaque elevation, and scaling at the target lesion. At Week 8, a 2-grade improvement was achieved by 44.2% and 49.6% of subjects for erythema, 59.3% and 59.7% for plaque elevation, and 59.4% and 62.9% for scaling (all  $P < 0.001$ ). In addition, there was a 32.8% and 42.5% reduction in mean BSA.

**CONCLUSIONS:** HP/TAZ lotion was consistently more effective than its vehicle in achieving treatment success, reducing psoriasis signs of erythema, plaque elevation, and scaling at the target lesion, and reducing BSA.

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**DISCLOSURES:** Boni Elewski has received honoraria and grants while serving as a consultant and investigator for the following companies: Valeant Pharmaceuticals International Inc, Anacor Pharmaceuticals, Inc, Meiji Seika Pharma Co, and Viamet Pharmaceuticals, Inc. Wendy Cantrell has no conflicts to disclose Mark Lebwohl is an employee of Mount Sinai, which receives research funds from Amgen Inc, Anacor Pharmaceuticals, Boehringer Ingelheim, Celgene Corporation, Eli Lilly, Janssen Biotech, Inc, Kadmon Corporation, LEO Pharma, MedImmune, Inc, Novartis, Pfizer, Inc, Sun Pharmaceutical Industries, Ltd, and Valeant Pharmaceuticals North America LLC. Lawrence Green is an investigator, consultant, and or speaker for Amgen, Abbvie, Celgene, Janssen, Merck, Novartis, and

Valeant. Jeff Sugarman is a Consultant and Principle investigator in research studies sponsored by Promius and Valeant Pharmaceuticals. Principle investigator in research studies sponsored by Leo Pharmaceuticals Linda Stein Gold is an investigator, advisor and speaker for Valeant and Leo. David Pariser is a consultant for Bickel Biotechnology, consultant for Biofrotera AG, consultant for Celgene, consultant for Dermira, consultant for DUSA Pharmaceuticals, consultant/principal investigator for Leo Pharma, consultant for Novartis, advisor for Pfizer, consultant for Promius Pharmaceuticals, consultant for Regeneron, Consultant for TheraVida, consultant for Valeant, principle investigator for Abbott laboratories, Amgen, Bickel, Celgene, Eli Lilly, Leo, Novartis, Novo Nordisk, Ortho Dermatologics, Peplin, Pfizer, and received grants/research funding from Photocure ASA, Promius, Regeneron, Stiefel, and Valeant Neal Bhatia has served as an adviser for Valeant Pharmaceuticals Fran Cook-Bolden has served as an investigator and adviser for Valeant Pharmaceuticals Jennifer Soung has received research, speaking and/or consulting support from a variety of companies including Janssen, Eli Lilly, Amgen, AbbVie, Merz, Pfizer Inc, Galderma, Valeant, National Psoriasis Foundation, Cassiopea, Celgene, Actavis, Actelion, and GSK. Stephen Tyring has served as an investigator for Valeant Pharmaceuticals and received grants from Amgen Drs Pillai, Lin, Qurewshi, Alexander, Israel and Yawn; and Ms Jacobson, Harris, Martin and Mathew are employees of Valeant Pharmaceuticals.

#### **PA-22: Efficacy of guselkumab in previously treated patients with moderate-to-severe plaque psoriasis: An analysis from VOYAGE 1 and VOYAGE 2**

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**BACKGROUND/OBJECTIVES:** To determine the efficacy of guselkumab (GUS) in patients with a history of previous use of psoriasis (PsO) treatments.

**METHODS:** Using pooled data from VOYAGE 1 and VOYAGE 2, an analysis was conducted in patients with "no previous use" vs. those with "previous use" of PsO treatments [non-biologic systemics, biologics, nonbiologic systemics or biologics, anti-tumor necrosis factor (TNF) agents etanercept {ETN} and infliximab {IFX}] using the Investigator Global Assessment (IGA) 0/1 and Psoriasis Area and Severity Index (PASI) 90 efficacy measures through Week 24.

**RESULTS:** A total of 1829 patients with moderate-severe PsO were included in this analysis (422 placebo [PBO], 825 GUS, and 582 adalimumab [ADA]). Significantly higher (all  $p < 0.001$ ) proportions of patients in the GUS vs. PBO group achieved IGA

0/1 and PASI 90 at Week 16, both among patients with previous use and among those with no previous use of the above treatments. Similarly, significantly higher proportions of patients in the GUS vs. ADA groups achieved IGA 0/1 and PASI 90 at Week 24 (all  $p < 0.001$ ), both among patients with previous use and among those with no previous use of the above treatments. Overall, IGA 0/1 and PASI 90 results were similar between GUS-treated patients with and without previous use of each type of PsO treatment at Week 16 and Week 24; however, IGA 0/1 and PASI 90 results were lower among ADA-treated patients with previous use of biologics or anti-TNF agents than those without previous use of these agents.

**CONCLUSIONS:** GUS was superior to both PBO at Week 16 and to ADA at Week 24 in patients regardless of previous use of PsO treatments through Week 24. Prior use of anti-TNF therapy was associated with notably decreased clinical responses to ADA, but not to GUS.

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**DISCLOSURES:** Drs. Michael Song, Yasmine Wasfi, Bruce Randazzo, Shu Li and Yaung-Kaung Shen are all employees of Janssen Research & Development, LLC. Dr. Blauvelt has served as a scientific adviser and clinical study investigator for AbbVie, Amgen, Boehringer Ingelheim, Celgene, Dermira, Eli Lilly and Company, Genentech/Roche, GlaxoSmithKline, Janssen, Leo, Merck Sharp & Dohme, Novartis, Pfizer, Purdue Pharma, Regeneron, Sandoz, Sanofi Genzyme, Sun Pharma, UCB, and Valeant, and as a paid speaker for Eli Lilly and Company, Regeneron, and Sanofi Genzyme.

#### PA-23: Gastrointestinal symptoms are common in U.S. patients with moderate-severe psoriasis

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**BACKGROUND/OBJECTIVE:** Patients with moderate-to-severe plaque psoriasis (PsO) are at increased risk of developing inflammatory bowel disease (IBD). A survey was conducted to evaluate the prevalence of gastrointestinal symptoms in PsO patients.

**METHODS:** An electronic survey was available to U.S. PsO patients with data collected from Jan/Feb. 2017. Patients with moderate-to-severe plaque PsO and healthy controls (HC), with common co-morbidities allowed in both groups qualified for inclusion in the survey. Psoriasis patients were further categorized as those without recent exposure to biologic therapy (PsO-) vs those with recent (within 4 months) biologic exposure (PsO+). GI symptoms and signs, including frequency and severity, were compared across groups. CalproQuest (CPQ) scores, which have recently been proposed as a tool to identify patients with elevated fecal calprotectin levels and increased risk for IBD, were also calculated. Patients with inflammatory

bowel disease (IBD), inflammatory bowel syndrome (IBS), or other gastrointestinal (GI) diagnoses with symptoms that overlap with IBD were excluded.

**RESULTS:** Overall, 915 patients with self-reported moderate-severe PsO and 1,411 healthy controls participated. Demographics were generally comparable between groups. GI symptoms and signs were significantly more prevalent in the PsO- and PsO+ groups vs the HC group, respectively: pain- 20.6% and 36.9% vs 10.5%; fullness/bloating- 37.2% and 48.4% vs 25.3%; and diarrhea (16.3% and 29.3% vs 12.2% (all  $p$ -values=0.002 except diarrhea for PsO- vs HC,  $p=0.023$ ). Mucous and blood in the stool followed a similar pattern. A significantly greater percentage of PsO- and PsO+ patients had positive CPQ scores vs HCs, with the greatest percentage of positive CPQ scores in the PsO+ group.

**CONCLUSION:** GI symptoms and signs are common in patients with moderate-to-severe PsO, more so than in healthy controls. This suggests that physicians caring for patients with PsO may consider assessing for GI symptoms and signs, and monitoring for their progression with treatment of PsO to identify patients potentially at risk for developing IBD.

**DISCLOSURES:** Steve Fakhazadeh, Jill Abell, Timothy Hoops, Bhaskar Srivastava, Erik Muser, Danielle Dungee and Sean Quinn, are all employees of Janssen Research & Development, LLC. Steven Feldman, Megan Leonie Perkins and Michael Kappelman are all consultants for Janssen Research & Development, LLC.

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#### PA-24: Genetic differences between extrinsic and Intrinsic Atopic dermatitis in Koreans

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**BACKGROUND:** Atopic Dermatitis (AD) affects about 20% of children and ~3% of adults throughout the world. It is a complex disease with variable symptoms and its causes are not clearly determined. Recent advances using genetic approach on AD discovered predisposing risk factors affecting epidermal defense barrier complexes or the immune system, suggesting an underlying mechanism for AD development. The current treatment for AD mainly focuses on the alleviation of the symptoms.

**OBJECTIVE:** In the adjourning era of the precision medicine, we seek to find out the genetic differences between extrinsic and intrinsic AD in the hope to develop a better (precise) treatment for each type of AD.

**METHODS:** The current study included 40 ADe patients, 40 ADi patients and 164 normal individuals. Genomic DNAs were extracted from peripheral blood MCs and exome sequencing was carried out using NGS technology. SNPs were determined based on marker QC criteria which included HWE  $p$  value  $> 0.0001$  and call rate  $> 0.9$ . Association was determined based on the statistical analyses; Chi-square and Cochran-Armitage Trend test for parametric method were employed where it fits and Jonckheere-Terpstra TEST was used for non-parametric method.

**RESULTS:** Total of 15 genes was found to be associated with AD compared to the controls. While there were 8 genes specifically associated with ADe compared to normal controls, only one gene with ADi. This one gene was associated with both ADe and ADi but there was no other gene differed between ADe and ADi.

**LIMITATIONS:** Based on our findings, the limited number of patients must have caused lack of genes differed between ADe and ADi.

**CONCLUSION:** NGS can be utilized to detect genetic differences in AD patients, which facilitates development of precise treatment for each individual suffered from AD in near future.

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### PA-25: Halobetasol 0.01%/tazarotene 0.045% lotion in the treatment of moderate-to-severe plaque psoriasis: maintenance of therapeutic effect after cessation of therapy

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**BACKGROUND:** Psoriasis is a chronic, immune-mediated disease that varies widely in its clinical expression. Topical corticosteroids (TCS) are the mainstay of treatment, however long-term safety remains a concern, limiting use. Combination therapy with tazarotene may improve psoriasis signs at a lower TCS concentration providing a superior safety profile.

**OBJECTIVE:** To investigate the maintenance of effect of a once-daily application of a fixed combination halobetasol propionate 0.01% and tazarotene 0.045% (HP/TAZ) lotion in comparison with its active ingredients and vehicle in patients with moderate-to-severe plaque psoriasis.

**METHODS:** Multicenter, randomized, double-blind, vehicle-controlled Phase 2 study in moderate or severe psoriasis (N=212). Patients randomized (2:2:2:1 ratio) to receive HP/TAZ, individual monads, or vehicle, once-daily for 8 weeks with a 4-week posttreatment follow-up. Efficacy assessments included treatment success (defined as at least a 2-grade improvement from baseline in the IGA score), and impact on individual signs of psoriasis (erythema, plaque elevation, and scaling) at the target lesion.

**RESULTS:** At the end of the 4-week posttreatment period, 38.2% of patients who had been treated with HP/TAZ were treatment successes; compared with 21.0%, 14.9% and 6.9% of patients who had been treated with HP (P=0.042), TAZ (P=0.009), or vehicle (P=0.002). HP/TAZ lotion was also superior in reducing the psoriasis signs of erythema, plaque elevation, and scaling at the target lesion. At the end of the 4-week posttreatment period, 49.1%, 54.4% and 54.5% of patients were treatment successes (erythema, plaque eleva-

tion, and scaling respectively); compared with 38.7%, 48.4%, and 48.4% of patients who had been treated with HP, 29.8% (P=0.049), 31.9% (P=0.022), and 23.4% (P=0.001) of patients who had been treated with TAZ, and 13.8% (P=0.002), 20.7% (P=0.003), and 20.7% (P=0.003) treated with vehicle. Side effects such as skin atrophy were minimal, and tended to resolve during the posttreatment period.

**CONCLUSIONS:** In conclusion, HP 0.01%/TAZ 0.045% lotion provides synergistic and sustained efficacy following 8 weeks' therapy and 4 weeks' posttreatment follow-up.

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**DISCLOSURES:** Boni Elewski has received honoraria and grants while serving as a consultant and investigator for the following companies: Valeant Pharmaceuticals International Inc, Anacor Pharmaceuticals, Inc, Meiji Seika Pharma Co, and Viamet Pharmaceuticals, Inc. Wendy Cantrell has no conflicts to disclose Mark Lebwohl is an employee of Mount Sinai, which receives research funds from Amgen Inc, Anacor Pharmaceuticals, Boehringer Ingelheim, Celgene Corporation, Eli Lilly, Janssen Biotech, Inc, Kadmon Corporation, LEO Pharma, MedImmune, Inc, Novartis, Pfizer, Inc, Sun Pharmaceutical Industries, Ltd, and Valeant Pharmaceuticals North America LLC. Lawrence Green is an investigator, consultant, and or speaker for Amgen, Abbvie, Celgene, Janssen, Merck, Novartis, and Valeant. Jeff Sugarman is a Consultant and Principle investigator in research studies sponsored by Promius and Valeant Pharmaceuticals. Principle investigator in research studies sponsored by Leo Pharmaceuticals Linda Stein Gold is an investigator, advisor and speaker for Valeant and Leo. David Pariser is a consultant for Bickel Biotechnology, consultant for Biofrotera AG, consultant for Celgene, consultant for Dermira, consultant for DUSA Pharmaceuticals, consultant/principal investigator for Leo Pharma, consultant for Novartis, advisor for Pfizer, consultant for Promius Pharmaceuticals, consultant for Regeneron, Consultant for TheraVida, consultant for Valeant, principle investigator for Abbott laboratories, Amgen, Bickel, Celgene, Eli Lilly, Leo, Novartis, Novo Nordisk, Ortho Dermatologics, Peplin, Pfizer, and received grants/research funding from Photocure ASA, Promius, Regeneron, Stiefel, and Valeant Neal Bhatia has served as an adviser for Valeant Pharmaceuticals Fran Cook-Bolden has served as an investigator and adviser for Valeant Pharmaceuticals Jennifer Soung has received research, speaking and/or consulting support from a variety of companies including Janssen, Eli Lilly, Amgen, AbbVie, Merz, Pfizer Inc, Galderma, Valeant, National Psoriasis Foundation, Cassiopea, Celgene, Actavis, Actelion, and GSK. Stephen Tying has served as an investigator for Valeant Pharmaceuticals and received grants from Amgen Drs Pillai, Lin, Qurewshi, Alexander, Israel and Yawn; and Ms Jacobson, Harris, Martin and Mathew are employees of Valeant Pharmaceuticals.

### PA-26: Immediate and long-term efficacy of a two-step topical hyaluronic acid lip treatment

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**BACKGROUND:** Lips are a key defining feature of the face and play an important role in conveying one's age, attractiveness and health. Prominent signs of lip aging include loss of volume, color and definition as well as increases in lines/wrinkles and uneven skin texture.

**OBJECTIVE:** A novel, topical two-step lip treatment product (HA5 LS) was developed to address the key aging features of the lip by providing both immediate effects and intrinsic long-term effects. Step 1 (smoothing formulation for long-term effects) contains five types of hyaluronic acid (HA) and a unique technology (VITISENSCE™), including a blend of a flower stem cell extract, marine micro-organism polysaccharides and peptides to support endogenous epidermal HA while minimizing HA degradation. Step 2 (lip plumping formulation for instant effects) contains a blend of emollients, rich fatty acids and benzyl nicotinate to support lip skin barrier, volume and color.

**METHODS:** To assess both the instant and long-term effects on lip appearance of HA5 LS, a single-center, open-label clinical study was conducted in female subjects presenting with mild to moderate lip dryness and mild to severe lip condition. Subjects were self-perceived and clinically determined to have average-size lips, and must have been non-smokers who have not smoked within the last 5 years. Subjects were instructed to apply HA5 LS at least three times a day to ensure coverage 8 hours a day for four weeks. Clinical assessments for efficacy and tolerability were conducted at baseline, baseline post-application, week 2 and week 4. Standardized digital photography, subject self-assessment questionnaires, lip wrinkle image analysis and instrumentation measurements for skin hydration (Corneometer CM 825) and lip plumpness (digital caliper) were also conducted.

**RESULTS:** Thirty-one female subjects aged 22-40 years completed the study. HA5 LS provided instant and long-term effects, achieving significant improvements in all clinical grading parameters including Overall Lip Condition, Lip Texture/Visual Roughness, Lip Plumpness, Lip Color/Rosiness, Overall Lip Definition/Lip Contour, Lip Lines/Wrinkles, Scaling at baseline post-application, week 2 and week 4, as well as Cupping at baseline-post application and week 4 (all  $p \leq 0.026$ ; Wilcoxon signed-rank test). Instrumentation measurements for hydration and lip thickness at weeks 2 and 4 were also significant (all  $p \leq 0.032$ ; paired t-test). HA5 LS was well-tolerated and highly-rated by subjects throughout the study duration.

**CONCLUSION:** Results from this study suggest that HA5 LS addresses the key features of lip aging, providing both instant and long-term benefits.

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**DISCLOSURES:** The authors are employees of Allergan, the sponsor company of this study.

#### PA-27: Impact on quality of life and satisfaction with apremilast in patients with moderate plaque psoriasis: 52-week results of the UNVEIL study

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**BACKGROUND:** UNVEIL is the first prospective, randomized, placebo (PBO)-controlled trial to demonstrate the clinical efficacy and safety of a systemic treatment, oral apremilast, in patients with moderate plaque psoriasis (psoriasis-involved body surface area [BSA] 5% to 10%) who are naive to systemic and biologic therapy.

**OBJECTIVE:** To describe improvements in QOL, pruritus, and medication satisfaction over 52 weeks.

**METHODS:** Patients with chronic plaque psoriasis, BSA of 5% to 10%, and static Physician's Global Assessment (sPGA) score of 3 (moderate, 0 to 5 scale) who were systemic- and biologic-naive were randomized (2:1) to apremilast 30 mg twice daily (APR) or PBO for 16 weeks. At Week 16, all patients continued on APR (APR/APR) or were switched from PBO to APR (PBO/APR) through Week 52 in an open-label treatment phase. Assessments included the Dermatology Life Quality Index (DLQI), pruritus visual analog scale (VAS; 0 to 100 mm), and Treatment Satisfaction Questionnaire for Medication (TSQM) version II.

**RESULTS:** Among 221 randomized patients (PBO n=73; APR n=148), baseline mean scores were 8.1 for the Psoriasis Area and Severity Index, 7.2% for BSA, 11.0 for DLQI, and 56.6 mm for pruritus VAS. At Week 16, significantly greater improvement from baseline in DLQI total score occurred with APR vs. PBO (-4.8 vs. -2.4, respectively;  $P=0.0008$ ), and significantly more patients with a baseline DLQI total score  $>5$  achieved the minimal clinically important difference (MCID) of  $\geq 5$ -point improvement with APR vs. PBO (63.8% vs. 34.5%;  $P=0.0009$ ). Pruritus VAS (-19.2 mm vs. -10.2 mm;  $P=0.0016$ ) and TSQM global satisfaction (63.2 vs. 48.7;  $P<0.0001$ ) and effectiveness (57.3 vs. 38.8;  $P<0.0001$ ) ratings were also significantly improved with APR vs. PBO. At Week 52, PBO/APR and APR/APR patients had mean DLQI improvements from baseline of -5.1 and -4.4, respectively, and 55.6% and 59.4% of patients achieved DLQI MCID. PBO/APR and APR/APR patients had mean change from baseline in pruritus VAS scores of -25.3 mm and -20.8 mm, respectively. Mean TSQM global satisfaction (59.2 and 59.9) and effectiveness (57.7 and 54.1) ratings were sustained in PBO/APR and APR/APR patients, respectively. The most common adverse events (AEs; occurring in  $\geq 5\%$  of patients during APR treatment) were diarrhea (28.0%), nausea (19.0%), headache (15.2%), nasopharyngitis (10.4%), upper respiratory tract infection (7.1%), vomiting (5.7%), and decreased appetite (5.2%). AE incidence did not increase with longer exposure to APR.

**CONCLUSION:** QOL and pruritus improvements were sustained and medication satisfaction was high with APR over 52 weeks in systemic- and biologic-naive patients with moderate psoriasis. Safety and tolerability were consistent with the known safety profile of APR.

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**DISCLOSURES:** Linda Stein Gold has served as an investigator and consultant for Celgene Corporation, LEO Pharma,

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#### **PA-28: Improvement in scalp and nails with Apremilast in patients with moderate plaque psoriasis naive to systemic and biologic therapy: 52-week results of the UNVEIL study**

Jackson J<sup>1</sup>, Alikhan A<sup>2</sup>, Lebwohl M<sup>3</sup>, Gold L<sup>4</sup>, Goncalves J<sup>5</sup>, Levi E<sup>5</sup>, Bagel J<sup>6</sup>

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**BACKGROUND:** Scalp and nail psoriasis are difficult-to-treat manifestations of plaque psoriasis that often are disproportionately more distressing to patients than other areas. UNVEIL is the first prospective, randomized, placebo (PBO)-controlled trial to demonstrate the clinical efficacy and safety of a systemic treatment, oral apremilast, in systemic- and biologic-naïve patients with moderate plaque psoriasis (body surface area [BSA]=5%–10% and static Physician's Global Assessment [sPGA]=3 [moderate]).

**OBJECTIVE:** To report results for UNVEIL patients with baseline scalp and/or nail involvement.

**METHODS:** Patients were randomized (2:1) to apremilast 30 mg twice daily (APR) or PBO for 16 weeks. At Week 16, all patients continued on APR (APR/APR) or were switched from PBO to APR (PBO/APR) through Week 52. Improvements in scalp and nail psoriasis were assessed through Week 52 in patients with baseline Scalp Physician Global Assessment (ScPGA) ≥1 and Nail Psoriasis Severity Index (NAPSI) ≥1 in the target nail. Main-

tenance of ScPGA 0 (clear) or 1 (minimal) and ≥50% reduction from baseline in NAPSI score (NAPSI-50) at Week 52 in APR/APR patients was assessed.

**RESULTS:** Among UNVEIL patients, 75.6% had scalp psoriasis and 37.6% had nail psoriasis at baseline. At Week 16, more patients treated with APR (38.4%) achieved ScPGA 0 (clear) or 1 (minimal) with a ≥2-point reduction from baseline than those receiving PBO (20.0%;  $P<0.05$ ). At Week 52, 46.9% of PBO/APR patients and 47.7% of APR/APR patients achieved ScPGA 0 or 1 with a ≥2-point reduction from baseline. At Week 16, mean percentage change from baseline in NAPSI score was –10.5% (PBO) and –28.9% (APR;  $P=0.12$ ); NAPSI-50 was achieved by 18.5% (PBO) and 26.8% (APR) of patients ( $P=0.50$ ). At Week 52, mean percentage change from baseline in NAPSI score was –52.7% (PBO/APR) and –51.9% (APR/APR); 69.6% and 62.5% of patients, respectively, achieved NAPSI-50. During Weeks 0 to 16, the most common adverse events (AEs; ≥5% of patients in either treatment group) were diarrhea, headache, nausea, upper respiratory tract infection, decreased appetite, and vomiting. AE incidence did not increase with APR exposure through Week 52, and no new safety or tolerability issues were observed.

**CONCLUSION:** In systemic- and biologic-naïve patients with moderate plaque psoriasis (BSA=5%–10% and sPGA=3) who received APR, improvements in scalp and nail psoriasis were noted at Week 16; these patients continued to improve on APR treatment up to 52 weeks. Safety and tolerability were consistent with other published studies.

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#### **PA-29: IncobotulinumtoxinA versus onabotulinumtoxinA in the treatment of glabellar facial lines: A multicenter, randomized, double-blinded trial**

Kane M, Gold M, Coleman W, Jones D, Tanghetti E, Alster T, Rohrer T, Burgess C, Shamban A

**BACKGROUND:** IncobotulinumtoxinA and onabotulinumtoxinA are indicated for the temporary improvement in the appearance of glabellar frown lines (GFL). The study presented here is the first randomized, parallel-group study available to date which directly compares the efficacy of incobotulinumtoxinA and onabotulinumtoxinA for the treatment of GFL at the Food and Drug Administration–recommended dose of 20 units (U).

**OBJECTIVE:** To evaluate the efficacy of incobotulinumtoxinA compared with onabotulinumtoxinA for the treatment of glabellar frown lines (GFL) at a dose of 20 U.

**METHODS:** A total of 250 females with moderate-to-severe GFLs on the Facial Wrinkle Scale (FWS) were enrolled in this randomized, double-blind, parallel-group study. Subjects received 20 U of either incobotulinumtoxinA (N=122) or onabotulinumtoxinA (N=128) injected into the glabellar complex at 5 injection points. The primary endpoint was defined as a  $\geq 1$ -point improvement from baseline on the FWS at maximum frown 1-month post-treatment as rated by independent panel review (IPR) using standardized subject photographs. Equivalence of treatment effect for incobotulinumtoxinA and onabotulinumtoxinA was determined by comparing response rates (ie,  $\geq 1$ -point improvement from baseline on the FWS); the prespecified equivalence margin was 15%. A two-sided 95% Newcombe-Wilson confidence interval (CI) was computed around the difference in response to treatment between the 2 treatment groups. Secondary endpoints included:  $\geq 1$ -point improvement at all other visits (assessed by IPR and by the treating Investigator); subject assessment of treatment satisfaction at all visits; subject-reported time of onset and of maximum treatment effect. Adverse events were monitored throughout the study.

**RESULTS:** A  $\geq 1$ -point improvement was observed in 95.7% and 99.2% of subjects in the incobotulinumtoxinA and onabotulinumtoxinA treatment groups, respectively, meeting the primary endpoint. The difference in response rate (95% CI) was -3.5% (-7.5% to 0.6%), thus demonstrating equivalence between the 2 products. At all time points, similar response rates on the FWS were observed for both groups; additionally, subject-reported satisfaction, treatment onset, and peak effect were similar between the groups. A total of 11.5% of incobotulinumtoxinA subjects and 14.1% of onabotulinumtoxinA subjects experienced at least 1 AE, with headache as the most common. No differences in safety profiles between the groups were observed.

**CONCLUSION:** IncobotulinumtoxinA and onabotulinumtoxinA demonstrated equivalence in the treatment of GFL at the 20 U dose at 1 month (primary endpoint). Similar safety and efficacy was observed for both products through 4 months after treatment.

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### PA-30: Long-term efficacy of brodalumab for the treatment of moderate-to-severe psoriasis: data from a pivotal Phase 3 clinical trial

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**BACKGROUND:** Brodalumab is a fully human anti-interleukin-17 receptor A monoclonal antibody that antagonizes the action of specific inflammatory cytokines involved in psoriasis. Pivotal phase 3 clinical trials demonstrated the efficacy and safety of brodalumab through 52 weeks of treatment in patients with moderate-to-severe psoriasis. Thus, analysis was undertaken to evaluate the efficacy of brodalumab in psoriasis from week 52 through week 120. Data were derived from the long-term, openlabel extension study of a 52-week, randomized, double-blind, placebo- and active comparator-controlled clinical trial (AMAGINE-2).

**OBJECTIVES:** To evaluate the long-term efficacy of brodalumab, as assessed by the psoriasis area and severity index (PASI) and the static physician's global assessment, in patients with moderate-to-severe psoriasis through 120 weeks.

**METHODS:** Patients received brodalumab 210 mg or 140 mg every 2 weeks (Q2W), ustekinumab, or placebo during a 12-week induction phase, followed by a maintenance phase through week 52. During the maintenance phase, patients receiving brodalumab were re-randomized to a different dose and interval of brodalumab (210 mg or 140 mg Q2W, Q4W, or Q8W), patients receiving placebo were switched to brodalumab 210 mg Q2W, and patients receiving ustekinumab continued on ustekinumab. At week 52, patients who received brodalumab during the maintenance phase continued receiving their maintenance dose of brodalumab, and patients who were taking ustekinumab switched to brodalumab 210 mg Q2W. Data are presented for patients who received brodalumab 210 mg Q2W (the FDA-approved dose) through week 120 of the long-term extension phase.

**RESULTS:** A total of 1392 patients received brodalumab 210 mg Q2W in the long-term extension phase. At week 52, rates (95% confidence interval [CI]) of these patients for PASI 75% improvement (PASI 75), PASI 90, and PASI 100 were 90.6% (88.9%-92.2%), 77.6% (75.2%-79.9%), and 53.3% (50.5%-56.0%), respectively. Similarly, at week 120, corresponding responder rates (95% CI) were 88.4% (86.0%-90.6%), 76.8% (73.6%-79.7%), and 56.2% (52.7%-59.7%), respectively. Success rates (95% CI), based on static physician's global assessment score of 0 or 1, were 79.2% (76.8%-81.4%) and 76.6% (73.5%-79.6%) at weeks 52 and 120, respectively.

**LIMITATIONS:** The results of these analyses were based on a controlled clinical study population and may not be generalizable to the broader population of patients with psoriasis.

**CONCLUSION:** Treatment with brodalumab resulted in substantial psoriatic lesion clearing for more than 2 years in most patients with moderate-to-severe psoriasis.

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### PA-31: Long-term safety and effectiveness of adalimumab for moderate to severe psoriasis: Results from the eight-year interim analysis of the ESPRIT registry

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**BACKGROUND:** ESPRIT is a 10-year international prospective observational registry evaluating the long-term safety/effectiveness of originator adalimumab (ADA) in adult patients with moderate-to-severe chronic plaque psoriasis. Interim analyses over the initial 8 years of the registry are reported.

**METHODS:** ESPRIT enrolled patients continuing ADA treatment from a current prescription or previous study participation, or initiating ADA  $\leq 4$  weeks of entering the registry (New Prescription Population [New-Rx]). The All-Treated Population (All-Rx) received at least 1 ADA dose in this registry. Incidence rates (IR) for all treatment-emergent adverse events (All-TEAEs) occurring from initial dose through 70 days after last ADA dose (excluding AEs during treatment interruptions) are reported as events per 100 pt-years of total ADA exposure (E/100PY), including pre-registry exposure. Physician's Global Assessment (PGA) was used to evaluate effectiveness in as-observed population.

**RESULTS:** 6045 patients (All-Rx, 58% male; mean age: 47 years; mean weight: 90 kg) were enrolled and dosed repre-

sented 25,268.1 PY of overall total ADA exposure, including 2554 (42.2%) New-Rx patients (54% male; mean age: 46 years; mean weight: 90 kg). Median duration of total ADA exposure was 1430 days (range 14–5161) and 658 days (range 14–2947) for All-Rx and New-Rx, respectively. After 8 years, registry discontinuation rate was 39.4% (All-Rx) and 46.3% (New-Rx); most frequent reason for discontinuing was being lost to follow up (18.2% and 23.9%, respectively). IR (E/100PY) for All-TEAEs (All-Rx) was: overall 22.0; serious AEs 4.5; malignancies 1.1, nonmelanoma skin cancer 0.7; serious infections (SI) 1.0, active TB <0.1; congestive heart failure <0.1; lupus-like reactions/systemic lupus <0.1; demyelinating disorder <0.1. IR for All-TEAEs (All-Rx) leading to death was 0.2 E/100PY. Standardized mortality ratio (All-Rx) was 0.34 (95% CI, 0.25–0.46), indicating observed number of deaths was below expected in an age-, sex- and country-matched population. All-Rx patients achieving PGA 'clear' or 'minimal' at 12, 24, 36, 48, 60, 72, 84, and 96 months in the registry were 2635/4624 (57.0%), 2376/4048 (58.7%), 2090/3537 (59.1%), 1994/3185 (62.6%), 1496/2415 (61.9%), 1114/1745 (63.8%), 428/653 (65.5%), and 9/20 (45.0%), respectively.

**CONCLUSIONS:** No new safety signals were observed with ADA treatment during this 8-year interim analysis; safety was consistent with known safety profile of ADA. IR of SI and malignancies remained stable with up to >8 years of overall exposure to ADA. The number of TE deaths in the registry was below the expected rate compared with the general population. As-observed effectiveness of ADA remained stable through 96 months.

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**PA-32: Long-term safety of adalimumab (HUMIRA) in adult patients from global clinical trials across multiple indications: An updated analysis in 29,987 patients representing 56,951 patient-years**

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**BACKGROUND:** Adalimumab is an anti-tumor necrosis factor- $\alpha$  (TNF- $\alpha$ ) agent indicated for the treatment of immune-mediated diseases. The long-term safety of adalimumab was previously reported in 23,458 patients representing up to 12 years of clinical trial exposure in rheumatoid arthritis (RA), juvenile idiopathic arthritis, ankylosing spondylitis (AS), psoriatic arthritis (PsA), plaque psoriasis (Ps), and Crohn's disease (CD). Here we report an updated analysis examining the long-term safety of adalimumab in adult patients with RA, AS, non-radiographic axial spondyloarthritis (nr-axSpA), peripheral SpA (pSpA), PsA, Ps, hidradenitis suppurativa (HS), CD, ulcerative colitis (UC), and non-infectious uveitis (UV).

**METHODS:** Safety data from 78 clinical trials of adalimumab (RA, 33; AS, 5; nr-axSpA, 2; pSpA, 1; PsA, 3; Ps, 13; HS, 3; CD, 11; UC, 4; UV, 2; other, 1) were included in these analyses, including randomized controlled, open-label, and long-term extension studies conducted in Europe, North America, South America, Asia, Australia, New Zealand, and South Africa through December 31, 2016. Adalimumab postmarketing surveillance data were not included in this analysis. Safety assessments included all adverse events (AEs) and serious AEs (SAEs) that occurred after the first adalimumab study dose and up to 70 days (5 half-lives) after the last study dose.

**RESULTS:** This analysis included 29,987 patients, representing 56,951 patient-years of exposure. The majority of adalimumab exposure was in RA studies (24,922 PYs). The most frequently reported SAE of interest was infection (highest incidences in CD: 6.9, RA: 4.6, UV: 4.1, and UC: 3.5). The overall standardized mortality ratio was 0.65, 95% CI [0.5, 0.74]. For most of the adalimumab populations (AS, PsA, Ps, UC, CD, and RA), the observed number of deaths was below what would be expected in an age- and sex-adjusted population. For HS, nr-axSpA, pSpA, and UV studies, the small size of these trials precluded accurate assessment of the standardized mortality ratio, and the 95% CIs all included 1.0.

**CONCLUSION:** This analysis of data from clinical trials of adalimumab demonstrated an overall safety profile consistent with previous findings and with the TNF inhibitor class. No new safety signals or tolerability issues with adalimumab treatment

were identified and, for most indications, the mortality rate was below what would be expected in an age- and sex-adjusted population. Efficacy and safety data continue to support the well-established benefits of adalimumab for the approved indications.

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**PA-33: LYP-like lymphomatoid drug reaction associated with cetuximab treatment for squamous cell carcinoma of the tongue**

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**BACKGROUND:** Cetuximab is a monoclonal antibody which targets the epidermal growth factor receptor (EGFR), inhibiting cellular proliferation, differentiation and growth while also inducing the apoptosis of malignant cells<sup>1</sup>. Cetuximab is currently approved by the Food and Drug Administration for the treatment of colorectal adenocarcinoma and squamous cell carcinoma of the head and neck

**OBJECTIVES:** A variety of adverse cutaneous reactions including papulopustular eruptions, xerosis, paronychia, pyogenic granulomas, alopecia, trichomegaly, Stevens-Johnson syndrome, and toxic epidermal necrolysis<sup>1</sup> have been reported to occur in association with cetuximab therapy. We present a case of a cetuximab-associated with cutaneous CD30+ LYP-like eruption in a patient with squamous cell carcinoma of the tongue.

**METHODS:** By clinical follow up we observed that on initial

examination there were numerous erythematous papules and nodules involving the patients' anterior scalp, glabella forehead, and left thigh. At two-month follow up, there were additional papules involving the right upper back and left posterior shoulder but there was complete resolution of the facial and thigh papules.

**RESULTS:** Immunohistochemistry revealed cells positive for CD30, CD3, CD45 and negative for Melan A and wide spectrum cytokeratin consistent with a CD30+ lymphoproliferative process. At 6 month followup, the patient reported complete resolution of his symptoms. Limitations (If any): Isolated case, purported first observable case

**CONCLUSIONS:** Medication associated pseudolymphomas have been reported with other chemotherapeutic agents such as cyclophosphamide, prednisone, vincristine and idarubicine. To our knowledge cetuximab is one that has not been documented in the literature thus far<sup>2</sup>. It is of importance that providers be aware of the benign course of Cetuximab induced LYP (Lymphomatoid Papulosis) like reactions, which contrast with the increased risk of malignancy in patients with primary cutaneous CD30+ lymphoproliferative disorders, such as primary LYP.

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#### **PA-34: Multicenter pivotal study of the safety and effectiveness of a tissue stabilized guided subcision procedure for the treatment of cellulite- 3 Year Update**

Kaminer M, Coleman III W, Weiss R, Robinson D, Coleman IV W

**BACKGROUND:** Tissue release (subcision) for cellulite has been practiced for decades with limited success. A novel procedure has been developed which stretches and stabilizes tissue while providing integrated anesthesia delivery and precise depth control of minimally-invasive tissue release.

**OBJECTIVE:** To assess the safety and efficacy of tissue stabilized-guided subcision (TS-GS) system for the treatment of cellulite on the buttocks and thighs.

**METHODS:** A pivotal prospective multi-centered safety and effectiveness study enrolled 55 subjects. Subjects served as their own controls, underwent a single treatment and were followed at regular intervals out to 3 years. Effectiveness was evaluated by blinded, independent physician evaluators using randomized (before/after) professional photographs and a novel, validated 5 point severity scale. Adverse events were monitored throughout the study.

**RESULTS:** Treatments were well tolerated with minor expected side effects that resolved quickly. A rapid and pronounced improvement in the appearance of cellulite was observed. A total of 45 subjects completed the 3-year follow-up. The mean

reduction in cellulite severity at 3 years was 2.0 points on the validated scale ( $P < 0.0001$ ), and masked evaluator improvement was 97%. At 3 years, evaluators rated 100% of subjects as having noticeable improvement, and 93% of subjects were either satisfied or very satisfied.

**CONCLUSIONS:** Tissue release at precise depths leads to significant, lasting improvement in cellulite. Results presented here demonstrate that a single treatment the TS-GS release system improved the appearance of cellulite on the thighs and buttocks through 3 years of follow-up with minimal adverse effects. This study supported the FDA- clearance of the device as an effective and safe treatment for the long-term improvement in the appearance of cellulite of the buttocks and thighs with no diminishment of benefit for up to 3 years.

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#### **PA-35: Paraneoplastic dermatomyositis leading to restaging of endometrial carcinoma**

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**BACKGROUND:** Dermatomyositis (DM) is a rare autoimmune condition that primarily involves a patient's skin and muscles. It affects approximately 1/100,000 people.<sup>1,2</sup> Studies have shown that DM is associated with an underlying malignancy in 27-45% of patients.<sup>3,4</sup>

**CASE:** 61-year-old African American female with history of stage 1b serous endometrial cancer s/p hysterectomy (Oct 2015) presented to dermatology clinic in November 2015 with rash for one month. The rash was pruritic and painful and affected her scalp, face, neck, back, chest, and all four extremities. Previous trials of oral/intramuscular steroids and topical antibiotics produced unsatisfactory improvement. Three days later, she was admitted to the hospital for pain due to worsening rash. She was found to have elevated creatinine phosphokinase of 1113 IU/L and was discharged the next day on high dose oral steroids, antibiotics, and steroid cream. An autoimmune workup was within normal limits. A skin biopsy was consistent with a highly inflammatory connective tissue disease. Her clinical presentation, elevated CPK, and skin biopsy were thus most consistent with paraneoplastic dermatomyositis. It was unclear why her symptoms were persisting despite presumed removal of the cancer. She was seen at the dermatology clinic multiple times before again being readmitted to the hospital in late November with intractable pain from worsening, desquamating rash. During her hospital stay, she was started on hydroxychloroquine to treat her condition. A muscle biopsy of the quadriceps showed nonspecific muscle atrophy. Given the severity of her dermatomyositis, a workup for metastatic disease was warranted. A PET scan revealed metastasis to the left para-aortic lymph node which was later confirmed with CT-guided biopsy. Oncology was consulted at this time.



**METHODS/RESULTS:** N/A as this is a case report.

**LIMITATIONS:** As a case report this work only contributes one patient's story to the literature and thus has very limited power.

**CONCLUSIONS:** Paraneoplastic dermatoses are the second most common paraneoplastic syndrome; only endocrine syndromes are more common.<sup>5</sup> It is important to recognize paraneoplastic syndromes in order to diagnose potential underlying malignancies or in the case of the patient presented here, to look for metastatic disease. Additionally, it has been suggested by a small case series that severe dermatomyositis, such as erosive or vesiculobullous dermatomyositis, could be associated with higher rate of malignancy and/or a poor prognosis.<sup>6</sup> We present a case of a patient who was determined to have stage 1b endometrial carcinoma s/p hysterectomy which was subsequently discovered to have lymph node-involvement. Investigation for metastatic disease was only pursued because of her severe, treatment-resistant dermatomyositis.

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**DISCLOSURES:** The authors have nothing to disclose.

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#### PA-36: Prevalence of gastrointestinal disorders in rosacea: The role of systemic antibiotics

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**BACKGROUND:** Rosacea has been associated with increased prevalence of gastrointestinal (GI) diseases. However, this association maybe mediated by antibiotic usage for its treatment. We compared oral doxycycline dosages [subantimicrobial dose (SD) of 40 mg to conventional doses of 50 or 100 mg] for GI disease prevalence.

**METHODS:** This cross-sectional study of individuals aged 30-64 with a history of rosacea between 2007-2015 from the Humana claims database (N = 77,117) analyzed the association between doxycycline treatments and prevalence of 11 GI diseases (malabsorption, celiac disease, irritable bowel syndrome, small intestinal bacterial overgrowth, H. pylori infection,

gastroesophageal reflux, gastritis, peptic ulcers, ulcerative colitis, Crohn's disease, and infectious colitis), using multivariable logistic regression (age and gender adjusted).

**RESULTS:** Conventional dose doxycycline was associated with higher prevalence of GI disease than no doxycycline (adjusted odds ratio [aOR] 1.53, P < .0001). SDdoxycycline was associated with lower GI disease prevalence versus 100 mg (aOR 0.62, P < 0.0001) and 50 mg doxycycline (aOR 0.80, P < .0001). GI diseases were not significantly different with SD-doxycycline relative to no doxycycline (aOR 0.88, P = NS).

**CONCLUSIONS:** Rosacea patients prescribed SD-doxycycline had fewer overall GI diseases than those on 100 mg or 50 mg doses of doxycycline; furthermore, no significant difference was seen in GI disease prevalence between SD and no doxycycline. The data suggests that conventional dose doxycycline usage may contribute to the previously reported associations between rosacea and GI disease.

**CONFLICT OF INTEREST:** Dr. Hester Gail Lim has no relevant conflicts of interest to disclose. Dr. Alexander Fischer has no relevant conflicts of interest to disclose. Dr. Marie-Jose Rueda is a paid employee of Galderma. Dr. James Kendall is a former employee of Galderma. Dr. Sewon Kang has been a paid investigator and advisor for Galderma. Dr. Anna L. Chien has been a paid advisor for Galderma.

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**DISCLOSURES:** Galderma is the maker of Oracea® Capsules. Marie-Jose Rueda is an employee of Galderma. James Kendall is a former employee and paid consultant of Galderma. Sewon Kang is an investigator for Galderma. Sewon Kang and Anna Chien are paid consultants of Galderma.

#### PA-37: Prevention and reduction of atrophic acne scars in moderate to severe acne subjects treated with topical adapalene 0.3%/benzoyl peroxide 2.5% gel

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**BACKGROUND/OBJECTIVES:** Few clinical trials have investigated the effect of a topical acne treatment on scarring. The main objective of this study was to evaluate the effect of adapalene 0.3%/benzoyl peroxide 2.5% (A0.3/BPO2.5) gel versus vehicle gel on the risk of formation of atrophic acne scars in subjects with moderate to severe acne vulgaris.

**METHODS:** This was a multicenter, randomized, investigator-blinded, vehiclecontrolled study using intra-individual comparison (right half-face vs left half-face) in subjects (16 to 35 y) with moderate to severe acne vulgaris on the face (Investigator's

Global Assessment [IGA] score 3 or 4;  $\geq 25$  inflammatory lesions;  $\geq 10$  atrophic acne scars). Subjects received 24 weeks of A0.3/BPO2.5 gel or vehicle gel on each half-face and skin care on both sides. Assessments included investigator atrophic acne scar count, Scar Global Assessment (SGA), acne lesion count, IGA, subject acne-related scars self-evaluation and questionnaire, as well as local tolerability and safety.

**RESULTS:** Of 67 subjects randomized, 54 (80.6%) completed the study. At baseline, most subjects had moderate acne (92.5%) with mild (62.7%) or moderate scars (29.9%); mean of 40 acne lesions and 12 scars per half-face. A0.3/BPO2.5 gel was significantly superior to vehicle gel in reducing acne scar counts from W1 (all  $p < .01$ ). By W24, the total atrophic scar count had decreased by 15.5% for A0.3/BPO2.5 gel compared to an increase of 14.4% for vehicle, and the difference was 4 scars (9.5 scars A0.3/BPO2.5 vs. 13.3 vehicle per half-face,  $p < .0001$ ). Percentages clear/almost clear on SGA at W24 were 32.9% for A0.3/BPO2.5 gel vs. 16.4% vehicle ( $p < .01$ ) and this was corroborated by subject assessment of their scars. The reduction in acne lesions was significantly superior for A0.3/BPO2.5 gel vs. vehicle at all study visits and the median % change in inflammatory acne lesions at 24W was -86.7% for A0.3/BPO2.5 vs. -57.9% vehicle ( $p < .0001$ ). Significantly more subjects were IGA clear/almost clear on the A0.3/BPO2.5 gel side after 24 weeks (64.2% vs. 19.4% vehicle,  $p < .0001$ ). Treatment-related AEs were reported by 20.9% subjects on the A0.3/BPO2.5 side vs. 9% vehicle side, most commonly skin irritation (14.9% vs. 6% respectively).

**CONCLUSIONS:** Topical A0.3/BPO2.5 gel demonstrated early onset of effect from W1 on acne lesions and acne scars. After 24 weeks of continuous treatment, significantly less atrophic acne scars and acne lesions were observed compared to the vehicle side.

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**DISCLOSURES:** Dr. Brigitte Dreno has been a paid investigator, speaker, and advisor for Galderma. Dr. Robert Bissonnette has been a paid investigator, speaker, and advisor for Galderma. Dr. Angélique Gagné-Henley has been a paid investigator for Galderma. Dr. Benjamin Barankin has been a paid investigator for Galderma. Dr. Charles Lynde has been a paid investigator for Galderma. Nabil Kerrouche is a paid employee of Galderma. Dr. Jerry Tan has been a paid investigator, speaker, and advisor for Galderma. **FUNDING:** This study was funded by Galderma R&D. JT, RB, AGH, BB, CL, BD have been investigators for Galderma and have also been advisory board members and/or speakers for Galderma. NK is an employee of Galderma.

### PA-38: Radiographic progression of structural joint damage in patients with active psoriatic arthritis treated with ixekizumab over 52 weeks

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**BACKGROUND:** Ixekizumab (IXE), an anti-interleukin-17A monoclonal antibody, was shown to be superior to placebo (PBO) in clinical responses and inhibiting the progression of structural joint damage in patients (pts) with psoriatic arthritis (PsA) treated for 24 weeks (wks). 1

**OBJECTIVE:** To assess progression of structural joint damage in pts with PsA with IXE for up to 52 wks.

**METHODS:** Biologic disease-modifying antirheumatic drug (DMARD)-naïve pts with active PsA (N=417) entered into SPIRIT-P1 (NCT01695239), a double-blind phase 3 trial. Patients must have had  $\geq 1$  joint erosion on the hand and foot x-rays confirmed by central reading or have had a C-reactive protein level  $> 6$  mg/L at screening. A total of 417 pts were randomized to IXE 80 mg every 2 wks (Q2W; N=103) or 4 wks (Q4W; N=107) following a 160 mg initial dose, PBO (N=106), or adalimumab 40 mg every 2 wks (ADA; active reference arm; N=101) for 24 wks. In the Extension Period (EXT; Wks 24-52), pts on PBO and ADA were re-randomized (1:1) to IXEQ2W or IXEQ4W at Wk 16 (inadequate responders) or Wk 24; pts on ADA underwent a washout prior to IXE treatment. All pts were assessed for structural joint damage using the van der Heijde modified PsA Total Sharp Score (mTSS, 0-528 scale). Two readers blinded to timepoint independently scored X-rays at wks 0, 24 and 52 and clinical data (average of readers). Data from mTSS was excluded from the pre-specified analysis if the radiograph was taken after the scheduled visit date. In a post-hoc analysis, mTSS from a radiograph taken after the scheduled visit date was interpolated and considered as observed data. Any missing data at Wk 52, in either presentation, were imputed using a linear extrapolation if they had  $\geq 1$  postbaseline value.

**RESULTS:** Of the pts had active PsA at Week 0, 381 pts (91.3%) entered the EXT, with 374 (98.2%) having radiographs collected during the EXT. Week 52 mean (SD) mTSS change from baseline were 0.54 (2.11) and 0.09 (1.0) for pts randomized to IXEQ4W and IXEQ2W at baseline, respectively. Similarly, post-hoc analysis changes at Wk 52 were 0.47 (1.9) and 0.09 (0.9) for the IXEQ4W and IXEQ2W groups, respectively. The majority of pts on IXEQ2W or IXEQ4W exhibited no structural progression through 1 year of IXE treatment. In pts who switched from PBO or ADA to IXE, the Wk 52 mean change from baseline mTSS values scores ranged from -0.03 to 0.41.

**CONCLUSIONS:** Over a 52 wk period, minimal changes in mTSS were observed in pts with PsA entering the EXT and treated with IXEQ2W or IXEQ4W.

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PRESENTER (NON-AUTHOR): David A Amato

**DISCLOSURES:** Désirée van der Heijde, Director of Imaging Rheumatology bv, has as received consulting fees AbbVie, Amgen, Astellas, AstraZeneca, BMS, Boehringer Ingelheim, Celgene, Daiichi, Eli-Lilly, Galapagos, Gilead, Glaxo-Smith-Kline, Janssen, Merck, Novartis, Pfizer, Regeneron, Roche, Sanofi, Takeda, UCB. Masato Okada has received grant and personal fee from Eli Lilly and Company during the conduct of the study. Personal fees received from Santen Pharmaceutical, Mitsubishi Tanabe Pharma, Pfizer and Abbott Japan outside the submitted work. Chin Lee is an employee of Eli Lilly and Company and holds stock. Catherine L. Shuler is an employee of Eli Lilly and Company and holds stock. Suchitrita Rathmann is an employee of Eli Lilly and Company and holds stock. Chen-Yen Lin

is an employee of Eli Lilly and Company and holds stock. Philip Mease is a consultant, speaker and has received grant from AbbVie, Amgen, Bristol Myers Squibb, Celgene, Janssen, Novartis, Pfizer, and UCB. Received research grant and is consultant for Lilly and Sun. He is speaker for Genentech.

### PA-39: Real-world treatment and patient-specific characteristics of actinic keratosis in the United States

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**BACKGROUND:** Actinic keratosis (AK) is a sun-damage-induced field disease, which manifests as clinical and subclinical lesions. If left untreated, AK may progress to squamous cell carcinoma. Multiple treatment options are available. The purpose of this study was to understand and describe real-world treatment patterns, and patient-specific characteristics of AK in the United States (US).

**STUDY DESCRIPTION:** A retrospective medical chart review first determined what information related to AK was available in US patient records by 10 providers treating AK in a feasibility phase. Thereafter a total of 86 providers across the US provided medical records for 429 patients with a diagnosis of AK during a period of 12 months. The results were analyzed descriptively.

**RESULTS:** The mean age at index AK diagnosis was 59.9 ( $\pm 12.4$  SD) years. The Olsen Grading Scale (OGS) at baseline was OGS I for 136 patients (44.0%); 155 patients (50.2%) had OGS II and 18 patients (5.8%) had OGS III. In the first treatment cycle, 218 patients received a procedure (cryotherapy, phototherapy or Mohs surgery), 162 received topical therapy, and 49 had a combination of procedure and topical. A second treatment cycle was not initiated within the 12 months for 116 (53.2%) patients receiving a procedure in the first treatment cycle, 106 (65.4%) receiving topical therapy, and 23 patients (46.9%) treated with combination therapy. Independent of the number of treatment cycles during the study period, 171 patients (39.9%) received a procedure only to treat the AK index diagnosis, 150 (35.0%) received topical therapy only, and 108 (25.2%) received a combination of procedure and topical. Efficacy assessment was based on the best response to treatment independent of the number of treatment cycles. Complete and partial clearance were achieved by 37.6% and 62.4% of patients treated with procedure only, 25.0% and 61.4% treated with topical only, and 18.3% and 56.6% treated with a combination of procedure and topical. For patients with more than five AK lesions at baseline complete and partial clearance were achieved by 0% and 44.8% receiving a procedure only ( $n=29$ ) and 9.7% and 71% treated with topicals only ( $n=31$ ).

**CONCLUSION:** This chart review study, although with limitations, provides a level of understanding of how AK lesions are treated in a real-world setting. A procedure alone is the most common treatment approach, though most patients with AK received a topical treatment. With more than five AK lesions at baseline, procedure-only treatment became less effective;

the opposite effect was seen with topical-only treatment, which showed a higher partial response to treatment with more than five AK lesions.

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**DISCLOSURES:** This study was funded by LEO Pharma.

### PA-40: Results from a survey of United States community dermatologists regarding their patients with chronic pruritus

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**BACKGROUND:** Chronic pruritus is a symptom of many diseases and is often referenced as the most common skin complaint in dermatology. Pruritus is strongly associated with a disruption in quality of life due to sleep disturbances and increased levels of depression and distress. However, despite the prevalence and impact of chronic pruritus, data on the epidemiology of this condition in the United States (US) are limited, including information related to severity, duration, and the frequency of pruritus experienced by patients seeking medical therapy.

**OBJECTIVES:** To utilize data from a survey of practicing community dermatologists in the US to better understand the characteristics of patients presenting with chronic pruritus, current treatment practices, and the dermatologists' perception of unmet medical needs for this population.

**METHODS:** US-based dermatologists, excluding medical residents, registered in the American Medical Association Masterfile database were selected to participate in an online screening survey, and were eligible to participate in the final survey if they managed  $\geq 10$  patients with chronic pruritus annually. The final 55-question survey was developed by Biomedical Insights, Inc. (San Francisco, CA) and validated via pilot testing. From March 27, 2015, to April 10, 2015, the final survey was administered, with compensation for participants. The survey data were cleaned and summarized as arithmetic means, weighted means, and 95% confidence intervals.

**RESULTS:** Out of the 291 dermatologists who responded to the screener, 275 qualified for the survey and 212 were included in this analysis. The majority (89%) identified their primary specialization as "General Dermatology"; 50% stated they practiced as part of a group dermatology practice, 15% as part of a multispecialty group, 5% in an academic setting, and <1% in the Veterans' Administration system or "Other." Among 9 dermatologic conditions sampled (chronic itch, prurigo nodularis, urticaria, atopic dermatitis, skin ulcers and wounds, eczema, rosacea, psoriasis, and acne), chronic pruritus was rated as having the highest average level of unmet need (8.6 out of 10). When estimating the incidence rate of chronic pruritus, most



respondents included patients with “unspecified chronic itch” (97%) and “multifactorial chronic itch” (92%) in their estimate; less commonly included were patients with “chronic itch in eczema” (57%), “chronic itch in atopic dermatitis” (55%), and “chronic itch in psoriasis” (32%). Their patients with chronic pruritus are predominantly middle-aged or older; 27% of patients are aged 45-64 years and 32% are aged 65-84 years. Many dermatologists indicated that elderly patients represent a population with a higher unmet need. Most respondents indicated that their patients’ chronic pruritus is moderate to very severe (38% moderate, 27% severe, 13% very severe). Specifically, for patients identified as having severe/very severe chronic pruritus, dermatologists were “confident” that the underlying cause(s) of chronic pruritus had been identified in 35% of patients, with 32% having pruritus arising from  $\geq 2$  causes. They indicated that among their patients with severe/very severe pruritus, 80% have experienced it for  $>6$  months and 19% for  $>5$  years. In addition, the dermatologists reported that 44% of their patients experience symptoms year-round. First-line pruritus therapy mainly consists of antihistamines (78%) and corticosteroids (76%), while second-line therapy is typically ultraviolet (UV) phototherapy (42%). For patients who do not respond to first- and second-line therapy, the most common third-line therapies are UV phototherapy, antidepressants, and anticonvulsants (19% for each), and the most common fourth-line therapy is immunosuppressants (21%). Respondents indicated that 36% of their patients fail to improve to mild or resolved chronic pruritus after all treatment attempts.

**LIMITATIONS:** Since this study was voluntary, those who chose to participate may not be a truly representative sample of US practicing dermatologists.

**CONCLUSIONS:** The relatively high prevalence of chronic pruritus, high number of patients with severe/very severe symptoms, and high level of unmet need necessitate the development of alternative treatments for this patient population.

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**DISCLOSURE:** Stuart Sedlack: Former employee of Velocity Pharmaceutical Development and Menlo Therapeutics Inc (formerly Tigercat Pharma, Inc), and received compensation and owned stock in Menlo Therapeutics Inc. Gil Yosipovitch: Received grants from Menlo Therapeutics, Tioga, GlaxoSmithKline, the LEO Foundation, and Allergan; served as an advisory board member for Menlo Therapeutics (formerly Tigercat Pharma, Inc), Trevi, Sanofi Regeneron, Eli Lilly, Galderma, and Sienna; and served as a consultant for OPKO, Eli Lilly, Tioga, CARA, Sienna, Almiral, Sun Pharma, and Novartis. Matthew B. Kerby: Has received personal fees from Velocity Pharmaceutical Development and is an employee of and owns stock in Menlo Therapeutics (formerly Tigercat Pharma, Inc). Paul C. Nagle: Is an employee and Partner at BioMedical Insights Inc; received consulting fees, honoraria, and travel support from Menlo Therapeutics, received grants from Menlo Therapeutics that were paid to his institution. Sonja Ständer: Received grants from Menlo Therapeutics (formerly Tigercat Pharma, Inc), Dermasence, Trevi, and Vanda; and served as an advisory board member for Menlo Therapeutics (formerly Tigercat Pharma, Inc), Almiral, Astellas, Beiersdorf, Celgene, Chugai Pharma, Creabilis, Daiichi Sankyo, Galderma, Kiniksa, Kniepp, Maruho, Merz, NeRRRe Therapeutics, Novartis, Pierre Fabre, Sienna, and Ziarc

**FUNDING:** This study was sponsored by Menlo Therapeutics Inc (formerly Tigercat Pharma, Inc).

#### **PA-41: Safety and tolerability of a halobetasol 0.01% lotion in the treatment of moderate-to-severe plaque psoriasis: Results of 2 Phase 3 randomized controlled trials**

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**BACKGROUND:** Psoriasis is a chronic, immune-mediated disease that varies widely in its clinical expression. Treatment options focus on relieving symptoms, reducing inflammation, induration, and scaling, and controlling the extent of the disease. Topical corticosteroids are the mainstay of treatment, however long-term safety remains a concern, particularly with the more potent formulations, limiting their use to two weeks.

**OBJECTIVE:** To investigate the safety and tolerability of a once-daily application of halobetasol propionate 0.01% lotion in comparison with its vehicle in subjects with moderate-to-severe plaque psoriasis.

**METHODS:** Two multicenter, randomized, double-blind, vehicle-controlled Phase 3 studies in moderate or severe psoriasis (N=285). Subjects randomized (2:1) to receive HP or vehicle, once-daily for 8 weeks. Safety and adverse events (AEs) were evaluated throughout.

**RESULTS:** The most frequently reported treatment related AEs with HP was application site pain (0.7%), compared with 2.8% for vehicle. The majority of AEs were mild or moderate. There were only three serious AEs (SAEs) reported following HP treatment (1.1%). None of the SAEs were treatment related (Staphylococcal infection and severe sepsis, diverticulitis, and hypertensive crisis). By Week 8, mean baseline scores for itching, dryness and burning/stinging had reduced by 60.1%, 50.2% and 78.3% respectively (pooled data). There were no reports of telangiectasia, or folliculitis in subjects treated with HP, and no new reports of skin atrophy or striae.

**CONCLUSIONS:** An 8-week treatment regimen of halobetasol propionate 0.01% lotion was well-tolerated, with a low incidence of treatment related AEs.

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**DISCLOSURES:** Boni Elewski has received honoraria and grants while serving as a consultant and investigator for the following companies: Valeant Pharmaceuticals International Inc, Anacor Pharmaceuticals, Inc, Meiji Seika Pharma Co, and Viamet Pharmaceuticals, Inc. Wendy Cantrell has no conflicts to disclose Mark Lebwohl is an employee of Mount Sinai,

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**PA-42: Safety and tolerability of a halobetasol 0.01%/tazarotene 0.045% fixed combination in the treatment of moderate-to-severe plaque psoriasis: Results of 2 Phase 3 randomized controlled trials**

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**BACKGROUND:** Psoriasis is a chronic, immune-mediated disease that varies widely in its clinical expression. Treatment options focus on relieving symptoms, reducing inflammation, induration, and scaling, and controlling the extent of the disease. Topical corticosteroids are the mainstay of treatment, however long-term safety remains a concern, particularly with the more potent formulations. Combination therapy with a corticosteroid and tazarotene may improve psoriasis signs at a lower corticosteroid concentration providing a superior safety profile.

**OBJECTIVES:** To investigate the safety and tolerability of a once-daily application of a fixed combination halobetasol propionate 0.01% and tazarotene 0.045% (HP/TAZ) lotion in comparison with its vehicle in subjects with moderate-to-severe plaque psoriasis.

**METHODS:** Two multicenter, randomized, double-blind, vehicle-controlled Phase 3 studies in moderate or severe psoriasis (N=418). Subjects randomized (2:1) to receive HP/TAZ or vehicle, once-daily for 8 weeks. Safety and treatment emergent adverse events (TEAEs) were evaluated throughout.

**RESULTS:** The most frequently reported TEAEs for HP/TAZ were contact dermatitis (7.4%), pruritus (3.0%), and application site pain (2.6%), compared with 0.0%, 2.9% and 0.7% respectively for vehicle. The majority of AEs were mild or moderate. There were only three serious AEs (SAEs) reported following HP/TAZ treatment (1.1%). None of the SAEs were treatment related (cellulitis staphylococcal, pneumonia/asthma and anemia). By Week 8, mean scores for itching, dryness and burning/stinging had reduced by 52.1% and 40.8% (Study 1 and 2 respectively), 46.2% and 47.3%, and 60.0% and 56.3% respectively. Side effects such as skin atrophy were infrequent, as were other skin reactions such as striae, telangiectasia, or folliculitis during the studies.

**CONCLUSIONS:** Safety data with HP/TAZ lotion were consistent with the known safety profile of halobetasol propionate and tazarotene, and did not reveal any new safety concerns with the combination product.

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#### **PA-43: Safety of guselkumab in patients with plaque psoriasis through 2 years: a pooled analysis from VOYAGE 1 and VOYAGE 2**

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**OBJECTIVE:** We evaluated the safety of guselkumab in patients with moderate to severe psoriasis from the VOYAGE 1 and 2 studies through 2 years.

**METHODS:** In the phase 3, randomized, double-blind, placebo/active comparator-controlled VOYAGE 1 (n=837) and VOYAGE 2 (n=992) trials, patients (≥18 years) had plaque psoriasis for ≥6 months, Investigator Global Assessment (IGA) scores ≥3, Psoriasis Area and Severity Index (PASI) scores ≥12, ≥10% body surface area involvement, and were candidates for systemic/phototherapy. Patients were randomized to guselkumab, placebo or adalimumab at baseline. Placebo patients crossed over to receive guselkumab at week 16 and adalimumab patients crossed over to receive guselkumab either at Week 52 (VOYAGE 1) or at Week 28 or beyond. (VOYAGE 2). Here we present safety data (event rates adjusted for follow-up, ie, per 100 pt-yrs) through 2 years for patients who were initially randomized to guselkumab and those who were randomized to placebo and crossed over to guselkumab at week 16.

**RESULTS:** Among these guselkumab-treated patients, the overall safety event rates were comparable through year 1 and cumulatively through year 2. Incidence rates reported per 100 pt-yrs for year 1 and year 2, respectively: AEs (259.42 and 210.41), AEs leading to discontinuation (2.36 and 1.82), SAEs (6.05 and 6.29), serious infections (1.03 and 1.06), malignancies, excluding NMSC (0.31 [0.06, 0.90] and 0.38 [0.17, 0.76]), NMSC (0.62 [0.23, 1.34] and 0.39 [0.17, 0.76]), and MACE (0.41 [0.11, 1.05] and 0.38 [0.17, 0.76]). The most commonly reported AEs were nasopharyngitis, upper respiratory tract infection and bronchitis. Additionally, safety data from ADA patients crossed over to guselkumab were consistent with overall guselkumab safety data, with no additional safety signals identified.

**CONCLUSION:** The safety profile of guselkumab through up to 2 years of continuous treatment was consistent with that observed through 1 year.

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**DISCLOSURES:** Yasmine Wasfi, Gigi Jiang, Yaung-Kaung Shen, Bruce Randazzo and Michael Song are all employees of Janssen Research & Development, LLC.

#### **PA-44: Secukinumab demonstrates significantly lower immunogenicity potential compared to ixekizumab in human in vitro assays**

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**BACKGROUND:** Secukinumab (SEC), a fully human monoclonal antibody (mAb) that selectively neutralizes interleukin-17A, has significant efficacy in the treatment of moderate to severe plaque psoriasis (PsO) and psoriatic arthritis (PsA), demonstrating a rapid onset of action and sustained responses, with a favorable safety profile and <1% immunogenicity in the phase 3 program. SEC has previously demonstrated lower potential for immunogenicity compared with other biotherapeutics used to treat PsO and PsA using in vitro assays.<sup>1</sup>

**OBJECTIVE:** To compare the T-cell precursor frequencies against 4 mAbs: SEC, ixekizumab (IXE), adalimumab (ADA), and ustekinumab (UST).

**METHODS:** Two sets of 16 healthy donors were analyzed (Study 1 and Study 2). Immunogenicity potential was evaluated using an in vitro T-cell amplification assay to measure the frequency of mAb-specific preexisting T cells from these donors. Monocyte-derived dendritic cells were generated from peripheral blood mononuclear cells and exposed in vitro to mAbs or positive control (keyhole limpet hemocyanin), and matured. CD4 T cells were stimulated by matured protein-loaded dendritic cells and cultured for 21 days. An enzyme-linked immunospot assay was used to assess antigen specificity of T-cell lines. The frequency of preexisting specific T cells was calculated from the proportion of culture wells that reacted to the protein. The data were analyzed using a Wilcoxon rank test.

**RESULTS:** In Study 1, 1/16 donors responded to secukinumab, generating 1 T-cell line (mean frequency 0.02 cells/million T cells; low immunogenicity potential). In contrast, 9/16 donors responded to IXE (35 T-cell lines; 0.54), 9/16 donors responded to ADA (15 T-cell lines; 0.21), and 6/15 donors responded to UST (14 T-cell lines; 0.19); all moderate immunogenicity potential. In Study 2, 1/15 donors generated T-cell lines specific for SEC (mean frequency 0.03 cells/million CD4 T cells; low immunogenicity potential); while 7 donors responded to IXE (frequency of 0.21–0.67 specific CD4 T cells/million CD4 T cells [mean 0.16]; moderate immunogenicity potential).

**LIMITATIONS:** None

**CONCLUSION:** SEC treatment resulted in a low number of donors responding with a low T-cell precursor frequency compared with other mAbs and, therefore, SEC has a significantly lower immunogenicity potential. This is in line with observed clinical immunogenicity rates.



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**DISCLOSURES:** S Spindeldreher, A Karle, P Jarvis, F Kolbinger: Employees of Novartis. B Maillère, E Correia, M Tenon: Research grants from Novartis.

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#### **PA-45: Secukinumab provides sustained improvement in major and moderate response of disease activity index for psoriatic arthritis (DAPSA): 2-year results from a Phase 3 study**

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**BACKGROUND:** DAPSA score is a validated tool to measure disease activity states and response criteria, focusing on peripheral joint involvement in patients (pts) with PsA.1 Secukinumab, a fully human anti-interleukin-17A mAb, significantly improved signs and symptoms versus placebo (PBO) at Week (Wk) 24, with sustained ACR responses through Wk 104 from the FUTURE 2 study. 2,3

**OBJECTIVE:** This post hoc analysis assessed DAPSA responses through Wk 104 from the FUTURE 2 study.

**METHODS:** The FUTURE 2 study design has been previously reported.3 DAPSA score was derived as the sum of 5 variables: tender and swollen joint counts (TJC 68 and SJC 66), pt global and pt pain assessed on a 10-cm visual analog scale, and CRP level (mg/dL). DAPSA responses are presented for secukinumab 300 and 150 mg (approved doses) in overall population and in pts stratified by prior anti-TNF therapy use (anti-TNF-naïve vs inadequate response/intolerance to these agents [anti-TNF-IR]) and time since first PsA diagnosis ( $\leq 2$  vs  $> 2$  years) using observed data.

**RESULTS:** Baseline demographics and clinical characteristics were similar across treatment groups.3 Totals of 96, 100, and 87 pts treated with secukinumab 300, 150 mg, and PBO, respectively, were available for the evaluation of DAPSA response at Wk 16. DAPSA response in overall population showed moderate/major response in 16%/14% and 22%/12% versus 2%/5%; minor response in 28% and 23% versus 15%; no response in 43% and 43% versus 78% for secukinumab 300 and 150 mg versus PBO, respectively. DAPSA response rates were higher and sustained at Wk 104 in secukinumab-treated pts. A higher proportion (35% and 23%) of pts showed major

response, with moderate response observed in 12% and 14% of pts treated with secukinumab 300 and 150 mg, respectively, at Wk 104. The proportion of pts achieving DAPSA response at Wks 16 and 104 by anti-TNF use and time since first PsA diagnosis will be reported. The proportion of pts in the overall population meeting DAPSA core-components thresholds and other components of PsA among pts with DAPSA moderate/major response at Wks 16 and 104 will also be reported.

**LIMITATIONS:** None

**CONCLUSION:** In the overall population, around 30% of secukinumab-treated pts at Wk 16 achieved DAPSA moderate/major response versus  $< 5\%$  in the PBO group, with numerical increases in the major response at Wk 104. Moderate/major response at Wk 16 was observed in pts regardless of prior anti-TNF use or time since first PsA diagnosis. The majority of the pts who achieved major response met all core components criteria, in contrast to the pts with moderate response.

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#### **PA-46: Secukinumab shows high and sustained efficacy in nail psoriasis: 2.5-year results from the TRANSFIGURE study**

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**BACKGROUND:** Nail psoriasis is associated with decreased finger mobility, functional impairment, pain and reduced quality of life (QoL) and is often difficult to treat. It correlates with more severe psoriatic disease and is an important predictor of psoriatic arthritis (PsA). Nails are affected in up to 50% of psoriasis patients, with a lifetime incidence as high as 90%. 1 Secukinumab, a fully human monoclonal antibody that selectively neutralizes interleukin-17A, has demonstrated significant efficacy in the treatment of moderate to severe psoriasis and PsA, demonstrating a rapid onset of action and sustained responses with a favorable safety profile. Here, we report the longterm follow-up efficacy and safety results from the TRANSFIGURE study, the first robust (2.5-year) data reported in subjects with nail psoriasis treated with secukinumab.

**OBJECTIVE:** To evaluate the efficacy and safety of secukinumab in patients with moderate to severe nail psoriasis over 2.5 years.

**METHODS:** TRANSFIGURE is a double-blind, randomized, placebo-controlled, parallelgroup, multicenter, phase 3b study, in which 198 subjects with moderate to severe nail psoriasis received subcutaneous secukinumab 150 and 300 mg. Moderate to severe nail psoriasis was defined as fingernail Nail Psoriasis Severity Index (NAPSI) score  $\geq 16$  and  $\geq 4$  fingernails involved.

**RESULTS:** As previously reported, at Week 16, the primary endpoint NAPSI and all secondary endpoints of this study were met, demonstrating superiority of secukinumab over placebo after 16 weeks placebo-controlled treatment.<sup>2</sup> An interim analysis at Week 80 demonstrated the continuation of improvement in nail psoriasis for all efficacy parameters. The effect was sustained through 2.5 years with a large mean NAPSI % improvement from Baseline of -73.3% and -63.6% with secukinumab 300 and 150 mg, respectively (as-observed analysis). Secukinumab demonstrated sustained reductions (improvements) in total mean Nail Assessment in Psoriasis and Psoriatic Arthritis (NAPPA) QoL scores from Baseline to 2.5 years of -52.4% and -18.1%, and 70.2% and 71.0% of subjects achieved a weighted NAPPA-Patient Benefit Index global score of  $\geq 2$  (at least moderate benefits) with secukinumab 300 and 150 mg, respectively (last observation carried forward). Subjects also showed considerable improvements in the European QoL 5-Dimension Health Status Questionnaire (EQ-5D) compared with Baseline, reporting decreased pain and discomfort. The safety profile was consistent with that observed in previous phase 3 trials of psoriasis and PsA.

**LIMITATIONS:** None

**CONCLUSION:** TRANSFIGURE is the first large, randomized, controlled trial to report long-term results in subjects with nail psoriasis. Secukinumab demonstrated strong sustainability of clinically meaningful efficacy, large QoL improvements, and a favorable safety profile up to 2.5 years in difficult-to-treat nail psoriasis.

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**DISCLOSURES:** K Reich: Adviser and/or paid speaker for and/or participated in clinical trials sponsored by AbbVie, Amgen, Biogen, Boehringer-Ingelheim Pharma, Celgene, Centocor, Covagen, Forward Pharma, GlaxoSmithKline, Janssen-Cilag, Leo, Lilly, Medac, Merck Sharp & Dohme Corp., Novartis, Ocean

Pharma, Pfizer, Regeneron, Takeda, UCB Pharma, Xenoport. P Arenberger: Grants from Novartis. U Mrowietz: Grants and/or participated in clinical trials for Abbott/AbbVie, Ammirall, Amgen, BASF, Biogen Idec, Celgene, Centocor, Eli Lilly, Forward Pharma, Galderma, Janssen, Leo Pharma, Medac, MSD, Miltenyi Biotech, Novartis, Pfizer, Teva, VBL, Xenoport; advisor and/or received speaker honoraria for Abbott/AbbVie, Ammirall, Amgen, BASF, Biogen Idec, Celgene, Centocor, Eli Lilly, Forward Pharma, Galderma, Janssen, Leo Pharma, Medac, MSD, Miltenyi Biotech, Novartis, Pfizer, Teva, VBL, Xenoport. S Jazayeri: Participated in clinical trials sponsored by Boehringer, Lilly, Novartis; speaker for Novartis. M Augustin: Grants and/or participated in clinical trials for AbbVie, Ammirall, Amgen, Biogen Idec, Boehringer-Ingelheim, Celgene, Centocor, Eli Lilly, Janssen-Cilag, Leo, Medac, MSD (formerly Essex, Schering-Plough), Mundipharma, Novartis, Pfizer (formerly Wyeth), Pohl Boskamp, Sandoz, Xenoport; advisor and/or received speaker honoraria from AbbVie, Ammirall, Amgen, Biogen Idec, Boehringer-Ingelheim, Celgene, Centocor, Eli Lilly, Janssen-Cilag, Leo, Medac, MSD (formerly Essex, Schering-Plough), Mundipharma, Novartis, Pfizer (formerly Wyeth), Pohl Boskamp, Sandoz, Xenoport. P Regnault, R You, J Frueh: Employees of Novartis.

**FUNDING:** This research was sponsored by Novartis Pharma AG, Basel, Switzerland.

#### **PA-47: Secukinumab shows high and sustained efficacy in subjects with moderate to severe palmoplantar Psoriasis: 2.5-year results from the GESTURE study**

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**BACKGROUND:** Palmoplantar psoriasis (ppPsO) occurs in up to 40% of plaque psoriasis subjects and is often resistant to treatment. It is associated with pain, functional limitations, and greater impairment of health-related quality of life compared with plaque psoriasis on other parts of the body.<sup>1</sup> Secukinumab, a fully human monoclonal antibody, which selectively neutralizes interleukin-17A, has demonstrated significant efficacy in the treatment of moderate to severe psoriasis and psoriatic arthritis, indicating rapid onset of action, sustained responses and a favorable safety profile. Here we report the long-term follow-up efficacy and safety results from the GESTURE study, the first robust (2.5-year) data reported in subjects with moderate to severe ppPsO treated with secukinumab.

**OBJECTIVE:** To evaluate the efficacy and safety of secukinumab in subjects with moderate to severe ppPsO over 2.5 years.

**METHODS:** GESTURE is a double-blind, randomized, placebo-controlled, parallelgroup, multicenter, phase 3b study in which 205 subjects with moderate to severe ppPsO received subcutaneous secukinumab 300 or 150 mg. Moderate to severe

ppPsO was defined as a palmoplantar Investigator's Global Assessment (pplGA) score of  $\geq 3$  (on a 5-point scale), and at least 1 additional plaque outside of the palms and soles to confirm the diagnosis of plaque psoriasis.

**RESULTS:** As previously reported, after 16 weeks of placebo-controlled treatment, the primary endpoint pplGA 0/1 and all secondary endpoints of this study were met, demonstrating superiority of secukinumab to placebo at Week 16.2 An interim analysis at Week 80 established the continuation of improvement of palmoplantar disease for all efficacy parameters. The effect was sustained through 2.5 years with 59.2% and 52.5% of subjects in the secukinumab 300 and 150 mg groups, respectively (by multiple imputation [MI]) achieving clear or almost clear palms and soles (pplGA 0/1). Consistent with this observation, the mean palmoplantar Psoriasis Area and Severity Index % change from Baseline reached -74.7% and -61.6% for secukinumab 300 and 150 mg, respectively, at 2.5 years (by MI). The Dermatology Life Quality Index 0/1 response was achieved in 45.5% versus 23.9% of subjects in the secukinumab 300 and 150 mg groups, respectively (by last observation carried forward [LOCF]). Pain and function of palms and soles was markedly improved with secukinumab, as reflected by the Palmoplantar Quality of Life Instrument overall scores, with 16.7% and 17.9% of subjects experiencing no difficulty in hand and feet functionality in secukinumab 300 mg and 150 mg groups, respectively (by LOCF). The safety profile was consistent with that seen in secukinumab phase 3 trials. The most common adverse events across all treatment arms were nasopharyngitis, upper respiratory tract infection, and headache.

**LIMITATIONS:** None

**CONCLUSION:** GESTURE, the largest and longest duration randomized controlled trial to date, revealed that secukinumab provides a novel treatment option for the difficult-to-treat and infrequently studied ppPsO population by providing a strong and sustained response through 2.5 years.

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**DISCLOSURES:** AB Gottlieb: Consultant/advisory board agreements for Janssen, Celgene, BristolMyers Squibb, Beiersdorf, AbbVie, UCB, Novartis, Incyte, Lilly, Reddy Labs, Valeant, Dermira, Allergan, Sun Pharmaceutical Industries; research/educational grants for Janssen, Incyte. J Sullivan: Educational grants from Novartis, AbbVie, Pfizer; consultancy fees from Novartis, AbbVie, Pfizer, Eli Lilly. A Kubanov: No conflict of interest to declare. R You, P Regnault, J Frueh: Employees of Novartis.

**FUNDING:** This research was sponsored by Novartis Pharma AG, Basel, Switzerland.

#### **PA-48: Secukinumab sustains individual clinical responses over time in patients with psoriatic arthritis: 2-year results from a Phase 3 trial**

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**BACKGROUND:** Achieving, sustaining, and improving clinical responses to biologics in psoriatic arthritis (PsA) are important parts of EULAR and GRAPPA recommendations aimed to optimize treatment goals.

**OBJECTIVE:** Here, we present patient (pt)-level secukinumab data and report the likelihood of improving, sustaining, or worsening an ACR response and disease status (28-joint disease activity score using CRP [DAS28-CRP]) from Week (Wk) 24 to 104 in pts with active PsA from the FUTURE 2 trial.

**METHODS:** Data from the FUTURE 2 trial through Wk 104 have been previously reported.<sup>4</sup> This post hoc shift analysis was performed on ACR responses (ACR nonresponders, ACR20, 50, or 70) between Wks 24 and 104 for subgroups of secukinumab-treated pts categorized by their highest ACR response criteria at the earlier timepoint, by evaluating whether this response was improved, sustained, or worsened at the later timepoint, using mutually exclusive ACR response categories and as-observed analyses. Similar shift analyses on DAS28-CRP-derived criteria were performed in 4 exclusive categories: high, moderate, and low disease activity (MDA and LDA), and remission (REM) only.<sup>5</sup>

**RESULTS:** In total, 86/100 (86%) and 76/100 (76%) pts in the secukinumab 300 and 150 mg groups, respectively, completed the 104-wk treatment. Of which, 73/70 and 81/75 pts in the secukinumab 300/150 mg groups were eligible for ACR and DAS28-CRP shift analyses, respectively, from Wks 24 to 104. Baseline demographics and clinical characteristics were balanced across treatment groups.<sup>3,4</sup> Most secukinumab-treated pts who achieved at least an ACR20, 50, or 70 response at Wk 24 improved or sustained their response at Wk 104. With secukinumab 300 mg, 84.3%, 66.7%, and 84.2% of ACR20, 50, and 70 responders at Week 24, respectively, improved or sustained their responses at Wk 104. With secukinumab 150 mg, 85.6%, 46.2%, and 75.0% of ACR20, 50, and 70 responders at Wk 24, respectively, improved or sustained their responses at Wk 104. Similarly, a majority of pts who were in the MDA, LDA, or REM status at Wk 24 sustained or improved their disease statuses related to DAS28-CRP score at Wk 104. In the secukinumab 300 mg group, 53% of pts with LDA improved to REM and a majority (76%) of pts with REM maintained their status from Wk 24 to 104, whereas, in the secukinumab 150 mg group, a majority of pts (75% and 72% with LDA and REM, respectively) improved or maintained their status by Wk 104.

**LIMITATIONS:** None

**CONCLUSION:** In this post hoc analysis, a majority of secukinumab-treated pts who achieved at least an ACR20 response or at least MDA at Wk 24 sustained or improved their ACR response or disease status at Wk 104. Numerically higher sustained ACR responses and LDA or REM rates were observed for secukinumab 300 mg, thereby extending the sustainability of ACR responses and lowering the disease activity that has been previously reported at group level.

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**PA-49: Serlopitant for the treatment of chronic pruritus: Results of a randomized, multicenter, double-blind, placebo-controlled Phase 2 clinical trial**

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**BACKGROUND:** Chronic pruritus is a common debilitating symptom of many conditions, and can result in significant morbidity and impaired quality of life. Many current therapies provide inadequate itch relief or can be associated with undesirable safety/tolerability issues. The neuropeptide substance P and its receptor, neurokinin 1 receptor (NK1R), play an important role in pruritus signaling. Serlopitant is a potent, highly selective, brain-permeable, oral NK1R antagonist currently under investigation for the treatment of chronic pruritus and other conditions. Here, we report the efficacy and safety results from a phase 2 clinical trial of serlopitant vs placebo for the treatment of chronic pruritus (ClinicalTrials.gov ID, NCT01951274).

**OBJECTIVES:** To determine the safety and efficacy of once-daily, oral serlopitant for the treatment of chronic pruritus.

**METHODS:** Key eligibility criteria were nonresponsive or inadequately responsive to treatment with topical steroids or antihistamines, pruritus lasting  $\geq 6$  weeks, and baseline Visual Analog Scale (VAS) pruritus score  $\geq 7$  cm. Patients were randomized 1:1:1:1 to receive serlopitant 0.25 mg, 1 mg, 5 mg, or placebo. After a loading dose of 3 tablets at baseline, patients took 1 tablet daily at bedtime for 6 weeks. The primary efficacy endpoint was the itch VAS score percent change from baseline. Secondary pruritus measures included the Numeric Rating Scale (NRS), Subject's Global Assessment of itch, subject

responses to the Dermatology Life Quality Index and Pittsburgh Sleep Symptom Questionnaire- Insomnia questionnaires, and Physician's Global Assessment. Adverse events (AEs) and clinical and laboratory assessments were evaluated during treatment and follow-up. Change from baseline itch VAS score was analyzed, with the difference in average change from baseline between the serlopitant and placebo groups tested using a t-test without control for multiplicity, with an alpha value of  $p < 0.05$ .

**RESULTS:** A total of 257 patients were randomized to serlopitant 0.25 mg (n=64), 1 mg (n=65), and 5 mg (n=64), or placebo (n=64); baseline characteristics were comparable between groups. Differences in change from baseline itch VAS score were statistically significantly greater with serlopitant 1 mg at weeks 3, 4, 5, and 6 and 5 mg at weeks 4, 5, and 6 ( $p < 0.05$ ), compared with placebo. At the week 6 efficacy evaluation, the mean (standard error) percent changes in VAS pruritus scores were -41.4 (4.0;  $p=0.022$ ) for serlopitant 1 mg and -42.5 (4.1;  $p=0.013$ ) for serlopitant 5 mg, vs -28.3 (4.1) for placebo. Statistically significant improvements in severity of itch from baseline were also demonstrated using the NRS with serlopitant 1 mg and 5 mg at weeks 4, 5, and 6 ( $p < 0.05$ ) compared with placebo. The most common treatment-emergent AEs (TEAEs) in the serlopitant groups were somnolence (1.6%, 4.6%, and 4.7% for serlopitant 0.25 mg, 1 mg, and 5 mg, respectively, and 1.6% for placebo) and diarrhea (0%, 6.2%, and 3.1% for serlopitant 0.25 mg, 1 mg, and 5 mg, respectively, and 1.6% for placebo). Most TEAEs were of mild or moderate intensity. There were no meaningful trends in laboratory abnormalities or changes in vital signs and no deaths.

**LIMITATIONS:** The 6-week treatment duration may not be long enough to assess the long-term safety of serlopitant.

**CONCLUSIONS:** Serlopitant 1 mg and 5 mg provided statistically significant reductions in pruritus intensity compared with placebo. Serlopitant was well tolerated; almost all TEAEs were of mild or moderate intensity, and no meaningful adverse safety trends were observed in this study.

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**DISCLOSURES:** Sonja Ständer: Received grants from Menlo Therapeutics (formerly Tigercat Pharma, Inc), Dermasence, Trevi, and Vanda; and served as an advisory board member for Menlo Therapeutics (formerly Tigercat Pharma, Inc), Almirall, Astellas, Beiersdorf, Celgene, Chugai Pharma, Creabilis, Daiichi Sankyo, Galderma, Kiniksa, Kniepp, Maruho, Merz, NeRRe Therapeutics, Novartis, Pierre Fabre, Sienna, and Ziarco. Gil Yosipovitch: Received grants from Menlo Therapeutics, Tioga, GlaxoSmithKline, the LEO Foundation, and Allergan; served as an advisory board member for Menlo Therapeutics (formerly Tigercat Pharma, Inc), Trevi, Sanofi Regeneron, Eli Lilly, Galderma, and Sienna; and served as a consultant for OPKO, Eli Lilly, Tioga, CARA, Sienna, Almiral, Sun Pharma, and Novartis. Matthew B. Kerby: Has received personal fees from Velocity Pharmaceutical Development and is an employee of and a shareholder in Menlo Therapeutics (formerly Tigercat Pharma, Inc). James W. Larrick: Is an employee of Velocity Pharmaceutical Development; is a shareholder in Menlo Therapeutics; and reports a patent issued to Menlo Therapeutics. Andrew J. Perlman: Is an employee of Velocity Pharmaceutical Development; is a shareholder in Menlo Therapeutics; and reports a

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#### **PA-50: Successful treatment of moderately severe onychomycosis with topical therapy: clinical experience with efinaconazole topical solution, 10%.**

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**BACKGROUND:** Onychomycosis is a common disease that remains difficult to treat. Topical therapy is normally reserved for mild disease, however clinical data with new topical agents in mild-to-moderate disease suggests they may now have a broader role. Data are limited in the treatment of patients with more severe disease with topical agents.

**OBJECTIVE:** To investigate the efficacy of efinaconazole topical solution, 10% in patients with moderately severe onychomycosis.

**METHODS:** Post hoc pooled analysis of two identical, multicenter, randomized, double-blind, vehicle-controlled studies in 1655 patients aged 18-70 years with a clinical and mycological diagnosis of mild-to-moderate dermatophyte toenail onychomycosis. Patients were treated with efinaconazole 10% solution or vehicle, once-daily for 48 Weeks, with 4-week posttreatment follow-up. For the post hoc analysis, patients were studied who had moderately severe disease at baseline (50% nail involvement). A clinically relevant improvement was defined as at least a 50% improvement in baseline nail involvement; treatment success as achieving 10% or less affected target toenail; and a clear nail as 0% affected target nail area at Week 52.

**RESULTS:** At baseline, almost a quarter of patients in the two studies (N=386, 23.4%) were considered moderately severe with 50% affected target toenail (N=285 efinaconazole and N=101 vehicle). By Week 52, 41.5% of these patients showed at least a 50% improvement in their target toenail; the majority (88.8%) being treated with efinaconazole. Indeed, almost half of the patients (49.8%) treated with efinaconazole had at least

a 50% improvement by study end. Not all patients with moderately severe onychomycosis improved during the study. In a proportion of patients (17.9%) disease had worsened by Week 52, and most of these patients (60.9%) had been treated with vehicle. At Week 52, 30.9% of patients treated with efinaconazole were treatment successes, and 14.4% had a clear nail; compared with 9.9% and 4.0% of patients treated with vehicle.

**CONCLUSIONS:** This post hoc analysis supports previous data showing good efficacy of efinaconazole in more severe onychomycosis. More than half the patients with moderately severe onychomycosis had clinically relevant improvement by Week 52, and almost a third were considered treatment successes.

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#### **PA-51: Sustained improvement in patient-reported outcomes with continued apremilast treatment over 104 weeks in patients with moderate to severe psoriasis**

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**BACKGROUND:** Apremilast, an oral phosphodiesterase 4 inhibitor, has demonstrated efficacy and safety in the LIBERATE phase 3b trial in patients with moderate to severe psoriasis.

**OBJECTIVE:** The effect of long-term apremilast treatment on patient-reported outcomes (PROs) was assessed at 104 weeks in the LIBERATE patient population.

**METHODS:** LIBERATE patients were randomized (1:1:1) to placebo (PBO), apremilast 30 mg twice daily (APR), or etanercept subcutaneous injection 50 mg once weekly (ETN). At Week 16, all patients receiving PBO or ETN were switched to APR (PBO/APR, ETN/APR) while APR patients continued APR (APR/APR); blinded APR treatment continued for all patients to Week 104. PRO assessments included the Dermatology Life Quality Index (DLQI), pruritus visual analog scale (VAS; 0–100 mm), 36-Item Short Form Health Survey version 2 Mental/Physical Component Summary scores (SF-36v2 MCS/PCS), and the Patient Health Questionnaire-8 (PHQ-8).

**RESULTS:** At Week 16, proportions of patients achieving minimal clinically important differences (MCID) in PRO responses were greater with APR vs. PBO. At Week 16, 59% (PBO), 75% (APR), and 80% (ETN) of patients achieved the DLQI MCID (i.e.,  $\geq 5$ -point decrease from baseline in DLQI score in patients with baseline DLQI score  $> 5$ ) vs. 70% (PBO/APR), 69% (APR/APR), and 68% (ETN/APR) at Week 104. The proportions of patients who achieved the MCID for pruritus VAS (i.e., improvement of  $\geq 20\%$  from baseline) at Week 16 were 60% (PBO), 87% (APR), and 89% (ETN) vs. 77% (PBO/APR) and 80% (APR/APR and ETN/APR) at Week 104. The MCID for SF-36v2 MCS/PCS (i.e., improvement  $\geq 2.5$  from baseline) was achieved by 51%/29% (PBO), 59%/41% (APR), and 53%/60% (ETN) of patients at Week 16 and by 54%/31% (PBO/APR), 45%/48% (APR/APR), and 45%/49% (ETN/APR) of patients at Week 104. The MCID for PHQ-8 (i.e., achievement of score  $\leq 4$ ) was achieved by 33% (PBO), 34% (APR), and 43% (ETN) of patients at Week 16 and by 40% (PBO/APR), 33% (APR/APR), and 49% (ETN/APR) of patients at Week 104. During Weeks 0 to 16, most adverse events (AEs) were mild or moderate and consistent with the known safety profiles of APR and ETN; the most common AEs ( $\geq 5\%$  of patients in any treatment group) were diarrhea, nausea, upper respiratory tract infection, nasopharyngitis, headache, and tension headache. No new safety concerns were observed through Week 104.

**CONCLUSIONS:** In patients with moderate to severe psoriasis, PRO improvements with APR were generally sustained with continued treatment up to 104 weeks. The AEs reported for APR in this long-term study were consistent with the known safety profile of APR; no new safety concerns were identified.

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## PA-52: The cost of biologics and newer oral treatments for plaque psoriasis

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**BACKGROUND:** Skin disease is one of the leading causes of disability and disease burden worldwide and affects more than 25% of individuals in the United States. Skin disease accounted for an estimated \$75 billion in direct health care costs and \$11 billion of indirect lost opportunity cost in 2013. The American Academy of Dermatology national burden of skin disease report estimated that \$15.6 billion were spent on prescription drugs and vaccines for skin disease in 2013, with specialty drugs, including biologic and newer oral agents for plaque psoriasis, accounting for 15% of that cost. However, accurate estimates of the costs of individual biologic treatments are hard to find. Most current estimates of biologic costs are based on average wholesale price (AWP) and wholesale acquisition cost (WAC). These benchmarks may not be accurate, as they are reported by manufacturers without significant standardized oversight. Therefore, they are not necessarily representative of the transactions between medication wholesalers or purchasers, and do not account for discounts, rebates, or other price reductions that are commonplace in such transactions. The Centers for Medicare & Medicaid Services (CMS) have put great effort into developing methods for more accurate evaluation of medication costs, using nationwide surveys of invoice prices for prescription medications from retail community pharmacies to develop a new metric – the National Average Drug Acquisition Cost (NADAC). This new pricing benchmark aims to increase the transparency of prescription medication costs, and is provided to state Medicaid agencies to set better standardized reimbursement policies.

**OBJECTIVES:** This study aims to use NADAC to generate a more representative estimate of the economic burdens associated with starting and maintaining currently approved biologic and small molecule medications for plaque psoriasis.

**METHODS:** Data from the Medicaid Pharmacy Pricing database from October 4, 2017 was analyzed for this study. Annual costs of medications were calculated based on standard approved dosing regimens for plaque psoriasis provided on their package inserts. When data was available for both autoinjector and syringe for methods of treatment, autoinjector data was used for analysis.

**RESULTS:** The first year cost of biologic or small molecule treatment for plaque psoriasis in Medicaid patients was \$52,552.91 for adalimumab, \$34,213.37 for apremilast, \$70,339.64 for etanercept, \$67,405.12 for secukinumab, \$45,507.84 for ustekinumab in patients less than or equal to 100 kg, and \$91,404.58 for ustekinumab in patients greater than 100 kg. The annual cost of maintenance biologic or small molecule treatment for



plaque psoriasis in Medicaid patients was \$55,755.49 for adalimumab, \$34,401.88 for apremilast, \$57,150.96 for etanercept, \$54,766.66 for secukinumab, \$39,440.13 for ustekinumab in patients less than or equal to 100 kg, and \$79,217.30 for ustekinumab in patients greater than 100 kg.

**LIMITATIONS:** Only biologic and small molecule medications found in the Medicaid Pharmacy Pricing database were included in this analysis. As starter pack pricing data was not available for all medications included in the analysis, estimates for the cost of administration of the loading dose (and consequently the first year of treatment) were based off of normal dosing costs for the medications provided in the database.

**CONCLUSIONS:** The first year cost of biologic or small molecule treatment in 2017 for plaque psoriasis in Medicaid patients ranged from \$34,213.37 to \$91,404.58. The annual cost of maintenance biologic or small molecule treatment in 2017 for plaque psoriasis in Medicaid patients ranged from \$34,401.88 to \$79,217.30. Costs for the first year of treatment were greater in all treatment modalities except for apremilast and adalimumab. The first year cost of etanercept was highest among biologic medications analyzed in this study for patients under 100 kg, with the first year of treatment costing more than \$13,000 more than maintenance treatment. Ustekinumab incurs the highest cost for patients weighing greater than 100 kg in the first year and during maintenance treatment, but is the second-most affordable option after apremilast in patients weighing less than or equal to 100 kg. Since biologic and small molecule medications are intended for lifetime treatment of chronic disease, increased transparency of medication acquisition costs can help dermatologists better identify medications that are best suited for their patients' long term care. Differences in biologic or small molecule medication costs, even at just one year of treatment, can amplify costs over a lifetime for patients, ultimately placing a significant economic burden on both payors and patients. Affordability, in addition to efficacy, should be evaluated as an important factor for long-term medication adherence in psoriasis patients.

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#### **PA-53: Treatment with fixed combination calcipotriol 50 µg/g and betamethasone dipropionate 0.5 mg/g aerosol foam provides rapid and significant itch relief in patients with psoriasis**

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**BACKGROUND:** The Phase III PSO-FAST study (NCT01866163) demonstrated that fixed combination calcipotriol 50 µg/g (Cal) and betamethasone dipropionate 0.5 mg/g (BD) aerosol foam provides significantly greater efficacy than vehicle in patients with psoriasis. Itch is a common and distressing aspect of psoriasis that negatively impacts on a patient's quality of life because it can cause discomfort, may aggravate the lesion, and often leads to sleep loss. There are currently few therapeutic options available that minimize itch. In this analysis, we assessed changes in itch during treatment with Cal/BD foam in patients who had clinically relevant itch at baseline.

**MATERIAL/METHODS:** Patients aged ≥18 years with mild-to-severe psoriasis of the body (trunk and/or limbs) were randomized 3:1 to Cal/BD foam or vehicle, once daily for 4 weeks. Patients assessed maximal itch intensity over the 24-hour period prior to days 3 and 5, and weeks 1, 2 and 4. Itch was evaluated based on a visual analogue scale (VAS; range 0–100, where 0 is no itch and 100 is the worst itch imaginable). Patients included in this analysis were those with a baseline itch VAS score >30, ie of at least moderate severity (Ständer et al. Acta Derm Venereol 2013;93:509–14). Cal/BD foam and vehicle were compared using analysis of variance, adjusting for baseline score and centre.

**RESULTS:** Mean (±SD) baseline VAS score was 66.1 ± 19.9 (n=225) in the Cal/BD foam group and 69.9 ± 18.1 (n=75) in the vehicle group. Patients receiving Cal/BD foam reported significant and rapid reduction in itch; itch relief was observed by day 3 and continued to improve during the 4-week study. The decreases in itch VAS score were significantly greater with Cal/BD aerosol foam than vehicle by day 3; these significant treatment differences were maintained at all subsequent time points throughout treatment.

**CONCLUSION:** This analysis of patients with psoriasis who had clinically relevant itch at baseline demonstrates that Cal/BD aerosol foam leads to rapid and significant relief of itch, which continues to improve throughout treatment.

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#### **PA-54: Two-year efficacy and safety of guselkumab for treatment of moderate-to-severe psoriasis: Phase 3 VOYAGE 1 trial**

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**BACKGROUND/OBJECTIVES:** Guselkumab (GUS) is an interleukin-23 inhibitor recently approved in the US for treatment of moderate-to-severe psoriasis. Efficacy and safety data for up to 100wks of GUS treatment are reported.

**MATERIALS/METHODS:** In the VOYAGE 1 Phase 3, randomized, double-blind, placebo/active comparator-controlled trial, 837 patients were randomized at baseline to placebo (PBO) at wks0/4/12 then GUS 100mg at wks16/20 and q8w (n=174); GUS at wks0/4/12, and q8w (n=329); or adalimumab (ADA) 80mg at wk 0, 40mg at wk1, and q2w through wk47 then GUS at wk52 and q8w (n=334). Efficacy was assessed using nonresponder imputation through wk48 and treatment failure rules from wks52-100.

**RESULTS:** Among patients randomized to GUS, or PBO→GUS at wk16, efficacy (PASI, Psoriasis Area and Severity Index; IGA, Investigator's Global Assessment) was maintained from wks52- 100 with continuous GUS treatment. Among GUS-

treated group, PASI90 and IGA 0/1 were 80.1%, and 82.7% at wk52 respectively, compared with 82.1% and 82.4%at wk100. Among the PBO→GUS-treated group, PASI90 and IGA0/1 were 78.9% and 88.2% respectively at wk52 compared with 82.3% and 84.8% at wk100. Among those randomized to ADA and →GUS at wk52, PASI90 and IGA 0/1 were 50.5%, and 60.4% at wk52 respectively, compared with 81.1%, and 84.0% at wk100). Similar findings were observed for patient-reported outcomes (PSSD, Psoriasis Symptoms and Signs Diary; DLQI, Dermatology Life Quality Index). Through wk100, there were no disproportionate increases in rates of Adverse Events (AEs) compared with rates through wk48. Serious AE rates were low and remained stable; no TB, opportunistic infections, or serious hypersensitivity reactions were reported.

**CONCLUSIONS:** Efficacy among GUS patients was maintained through 2 years of continuous treatment. Efficacy among ADA→GUS patients improved from wks52-100. GUS was welltolerated, with a similar safety profile as previously reported.

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