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PA-01: A dose-finding trial with a novel ingenol derivative (LEO 43204) for field treatment of actinic keratosis on full face or 250 cm2 on the chest

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BACKGROUND: Seek to find the right dose for field treatment of AK on full face or 250 cm2 on the chest with a new ingenol derivative, LEO 43204, that has improved chemical and biologic properties compared with ingenol mebutate.
OBJECTIVE: Investigate the efficacy and safety of 3 doses of LEO 43204 gel in subjects with actinic keratosis (AK) in a Phase 1/2 trial.
METHODS: This was a randomised, double-blind, parallel group, vehicle-controlled 8-week trial investigating efficacy and safety of 0.006%, 0.012% and 0.018% LEO 43204 gel applied as field treatment once daily for 2 consecutive days to full face or approx. 250 cm2 on the chest in patients with 5-20 clinically typical AKs in the treatment area. The 0.018% dose was identified in the dose escalation part of the trial as the maximal tolerated dose based on local skin responses (LSRs). Six individual components of LSRs (erythema, flaking/scaling, crusting, swelling, pustulation/vesiculation and erosion/ulceration) were assessed on a scale from 0 to 4, yielding a max composite score of 24. Efficacy was assessed by AK count on days 29 and 57, while LSRs and adverse events were assessed on days 1, 3, 8, 15, 29 and 57. Patients completed a Treatment Satisfaction Questionnaire for Medication at day 57.
RESULTS: A total of 242 patients were randomised and received treatment. In each treatment group at least 95% of patients completed all treatments. The median age was 69 years; 69% were men, all were white, 96% had Fitzpatrick skin type I-III, and the median history of AK was 8 years. At baseline the median number of AKs in the treatment area was 11. For all 3 doses the reduction in AK count at week 8 compared to baseline was significantly greater than with vehicle (70% [0.006%], 73% [0.012%], 79% [0.018%] vs 42% [vehicle]; $P < .001$) with a dose response trend and most (94% to 96%) of this effect observed by week 4. For all active doses the composite LSR score peaked at day 3, rapidly declined and was almost back to baseline at 2 weeks. The peak composite LSR score for the three active treatments was higher than for vehicle and with a dose response trend (6.0, 8.0, 8.6 vs 1.4). All active treatments were well-tolerated with the most common adverse drug reactions being application site pain (including application site burning; 40%, 55%, 60% vs 9%) and application site pruritus (23%, 23%, 26% vs 2%). There were no treatment-related serious adverse events. Global treatment satisfaction was high for all active treatments and significantly higher than vehicle (75%, 73%, 72% vs 45%; $P < .001$).
LIMITATIONS: This data awaits confirmation in a larger number of patients.
CONCLUSION: All 3 active doses of LEO 43204 gel were effective as field treatment of AK on full face or a large area on the chest and statistically significantly superior to vehicle with dose-response trend. Further, all 3 active doses were considered well-tolerated based on the adverse event profile and LSRs and associated with high global treatment satisfaction.
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DISCLOSURES: Dr Bourcier reports he is a clinical trialist for Leo Canada. Dr Stein Gold reports grants and other from LEO, outside the submitted work. Drs Andreassen and Peterson are employees of LEO Pharma. Dr Goldenberg reports other (consultant/speaker) from LEO Pharma, other (consultant/speaker) from Valeant, during the conduct of the study.

PA-02: A novel blend of antioxidants minimizes UV-induced DNA damage markers in human skin

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BACKGROUND: Chronic sun exposure triggers accelerated aging or photoaging. Ultraviolet (UV) rays, UVA and UVB, have been implicated in DNA damage and immune suppression. UV-exposed skin shows an increased level of sunburn cells, cyclobutane pyrimidine dimers (CPD) and expression of mutant p53 proteins. Topically applied antioxidants may protect the skin against UV-induced damage by neutralizing Reactive Molecule Species. Effective protection with antioxidants depends on potency as well as its stability in skin or in the formulation. Topical antioxidants may also increase skin antioxidant capacity by accumulating in the skin or by inducing/restoring endogenous antioxidants levels.
OBJECTIVE: A novel topical product (TD+R SPF 34) containing a proprietary blend of antioxidants and sunscreen actives

was developed to provide patients with combined protection against UV-induced skin damage.
METHODS: Increased antioxidant capacity in the skin was assessed in a double-blind, randomized, single-center study by comparing TD+R SPF34 vs. an acidic solution containing the most commonly used antioxidants in topical cosmetic products: Vitamin C and Vitamin E (Aox1) and an SPF30 sunscreen. 20 subjects (24-58 years), Fitzpatrick Skin Types II-III completed the study. On days 1-10, staff applied the test products (2 mg/cm2) once-daily. On day 10, at least 2 h prior to UV-exposure, the test sites were wiped clean to minimize the effects of SPF actives. Under this protocol, we evaluated the build-up of antioxidants in the skin as UV-protectors. Subjects were exposed to a single dose of UV-light with spectral output in UV range comparable to natural solar spectrum. 24 h after UV-exposure, standardized digital photographs were taken and analyzed for erythema (a*). In addition, 4 mm punch biopsies from the 3MED sites were taken for histological analysis (n = 10).
RESULTS: Results showed that UV-induced erythema a* values for all TD+R SPF34-treated sites were significantly lower than corresponding untreated MED sites (all p<0.002, Tukey's HSD test) as well as consistently lower than the Aox1 + SPF 30-treated sites. Histological analysis for sunburn cells by H&E staining, CPD and mutant p53 proteins by immunohistochemistry supported these results, showing that TD+R SPF 34-treated sites had consistently lower damage vs. untreated/UV exposed sites.
LIMITATIONS: Limitations of this study are the smaller sample size. Additional larger studies are needed to confirm results.
CONCLUSION: These results indicate that skin UV-protection can be accomplished by topical antioxidants.
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DISCLOSURES: Authors are paid employees of the sponsor company, SkinMedica, Inc, an Allergan Company.

PA-03: Adapalene 0.3%/benzoyl peroxide 2.5% gel for the treatment of severe inflammatory acne: a randomized, double-blind, parallel-group, controlled study

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BACKGROUND: More effective therapies are needed in the specific treatment of severe inflammatory acne vulgaris.
OBJECTIVE: This multicenter, randomized, double-blind, parallel-group, controlled study compared the efficacy and safety of adapalene 0.3%/benzoyl peroxide 2.5% (0.3% A/BPO) topical gel vs vehicle in subjects with moderate-to-severe acne (overall population [OP]), and in a subpopulation of the OP (severe acne subjects only; severe population [SP]). The study also compared 0.3% A/BPO to adapalene 0.1%/benzoyl peroxide 2.5% (0.1% A/BPO) topical gel in the SP, but the study was not powered to compare the active groups.
METHODS: Subjects were randomized to receive 0.3% A/BPO, 0.1% A/BPO (benchmark) or vehicle (comparator) once daily for 12 weeks. Co-primary efficacy endpoints were success rate at week 12 (percentage of subjects rated "clear" or "almost clear," ≥3-grade IGA improvement), and change in inflammatory (IN) and noninflammatory (NIN) lesion counts from baseline to week 12. Secondary efficacy endpoints were percent changes in IN and NIN lesion counts. Safety endpoints were incidence of adverse events (AEs) and local tolerability signs/symptoms.
RESULTS: In the severe inflammatory acne population, a total of 252 subjects were randomized with 106, 112 and 34 subjects in the 0.3% A/BPO, 0.1% A/BPO and vehicle groups, respectively, reaching a high rate of study completion (88.5%). For success rate, 0.3% A/BPO was superior to vehicle, with a treatment difference of 20.1% (31.9% vs 11.8%; 95% CI: [6.0%, 34.2%], P = .029). At week 12, 0.3% A/BPO was superior to vehicle in changes in IN (-35.2 vs -15.5) and NIN lesion counts (-45.6 vs -17.3), as well as percent changes in IN (-74.4% vs -33.0%) and NIN lesion counts (-72.1% vs -30.8%; all, P < .001). Also, 0.3% A/BPO was safe and well tolerated by severe acne subjects in the study.
LIMITATIONS: The study was not powered to compare the active groups.
CONCLUSION: The availability of this new treatment option should allow clinicians to better customize severe inflammatory acne management.
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DISCLOSURES: Dr Weiss reports grants from Galderma Laboratories, during the conduct of the study; grants from Allergan, personal fees from Galderma, grants from Intrepid, grants from Sebacia, grants and personal fees from Valeant, outside the submitted work. L Stein Gold is an investigator/advisor for Galderma for the submitted work; an investigator/advisor for Allergan and Valeant, and an investigator for Novari outside the submitted work. E Tanghetti is involved in clinical studies for Galderma and a consultant for Allergan outside the submitted work. H Liu is an employee of Galderma and is a statistician of the study.MJ Rueda is an employee of Galderma.
FUNDING: This study was funded by Galderma R&D and poster support provided by Galderma Laboratories, LP.

PA-04: Apremilast, an oral phosphodiesterase 4 inhibitor, in patients with moderate-to-severe plaque psoriasis: pooled 16-week efficacy in patient subgroups (ESTEEM 1 and 2)

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BACKGROUND: ESTEEM 1 and 2 evaluated the efficacy and safety of apremilast (APR) in patients with moderate-to-severe plaque psoriasis.
OBJECTIVE: This analysis evaluated APR efficacy in specified subpopulations.
METHODS: In ESTEEM 1 and 2, patients with moderate-to-severe plaque psoriasis (PASI ≥12, BSA ≥10%, sPGA ≥3) were randomized (2:1) to APR 30 mg BID (APR30) or placebo (PBO). At Week 16, all PBO patients switched to APR30 through Week 32. This was followed by a randomized treatment withdrawal phase up to Week 52. Subgroup analyses were based on baseline demographics (eg, gender, race, age, body weight, body mass index), baseline disease characteristics (eg, disease duration, history of nail, scalp, and palmoplantar psoriasis), and prior psoriasis therapies. Using data pooled from ESTEEM 1 and 2, efficacy was evaluated at Week 16 by baseline PASI score (≤20, >20) and number/type of prior and failed psoriasis therapies (including phototherapy, conventional systemics, biologics, or TNF blockers).
RESULTS: The pooled analyses included 1,255 patients who entered the PBO-controlled phase (PBO, n = 419; APR30, n = 836). At Week 16, PASI-75 responses (primary end point) were significantly greater with APR30 (ESTEEM 1, 33.1%; ESTEEM 2, 28.8%) vs PBO (ESTEEM 1, 5.3%; ESTEEM 2, 5.8%; $P < .0001$). The primary end point analysis consistently demonstrated the treatment benefit of APR30, relative to PBO, across multiple demographic and disease characteristic subgroups, including baseline disease severity (moderate vs severe psoriasis) and whether or not patients had been treated previously with systemic (including biologics) psoriasis treatments. Although not significant, there were trends for higher PASI-75 responses in patients with PASI scores ≤20 at baseline and patients who had not received prior systemic therapies. Subpopulation analyses of sPGA 0 (clear) or 1 (almost clear) achievement and PASI-50 responses had similar findings.
LIMITATIONS: Study was limited to 52 weeks.
CONCLUSION: In pooled analyses of PASI-75, PASI-50, and sPGA responses at Week 16 in ESTEEM 1 and 2, APR30 was effective across subgroups regardless of baseline demographics or prior psoriasis therapy.
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PA-05: Assessing relapse in rosacea after cessation of treatment: ivermectin 1% cream vs metronidazole 0.75% cream

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BACKGROUND: The efficacy and safety of ivermectin has been established in two 12-week phase 3 pivotal trials and 2 long-term (40-week) safety study extensions of the phase 3 studies.
OBJECTIVE: The study was designed to demonstrate superiority of once-daily ivermectin 1% cream (IVM 1%) compared to twice-daily metronidazole 0.75% cream regarding percent reduction of inflammatory lesions in subjects with moderate-to-severe papulopustular rosacea, with the objectives of generating efficacy and safety data.
METHODS: The first part of the study (Part A) demonstrated that IVM 1% cream was significantly more efficacious than metronidazole 0.75% cream after 16 weeks of treatment. Subjects who were treatment successes from the first part of the study were eligible for the second part (Part B). Subjects discontinued treatment at the start of Part B until their investigator's global assessment (IGA) score was >2 at which point they resumed treatment. Efficacy endpoints for Part B included time to first relapse, relapse rate, and number of days free of treatment.
RESULTS: The median time to relapse significantly favored IVM 1% cream over metronidazole 0.75% cream (P = .0365) and fewer subjects relapsed with IVM 1% cream compared to metronidazole 0.75% cream. The total number of days free of treatment based on IGA also significantly favored IVM 1% cream (P = .026). IVM 1% cream was safe with 2 subjects reporting 3 related adverse events.
CONCLUSION: Overall this study demonstrated the superiority of IVM 1% cream over metronidazole 0.75% cream in reducing the likelihood of relapse of the inflammatory lesions of rosacea.
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FUNDING: This study was funded by Galderma R&D and poster support provided by Galderma Laboratories, LP.

PA-06: Assessment of the antipruritic efficacy of a topical herbal ointment: a pilot study

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BACKGROUND: Pruritus is a common symptom associated with a number of skin conditions. There are a limited number of effective topical treatments that provide rapid and durable relief. A large number of natural herbs have been described to provide anti-pruritic and anti-inflammatory properties.
OBJECTIVE: Assess the efficacy of a topical herbal ointment in providing rapid and durable relief for itch.
METHODS: Fourteen subjects with an average age of 32 years old were enrolled. Ther subjects had three different types of skin conditions. Three patients had recent insect bites (<3 days), 4 were diagnosed with psoriasis and 7 with eczema. Each subject was asked to rate their itching score from 1-10 (eg, 10 as most severe itch) at baseline, 5 minutes and 2 hours after application of the topical herbal ointment, which contained meadowfoam delta-lactone, indigofera tinctoria leaf extract, glycyrrhiza uralensis (licorice) root extract, scutellaria baicalensis root extract, coptis chinensis root extract, taraxacum officinale (dandelion) extract, mentha herba (peppermint) extract, phellodendron amurense bark extract, rubia cordifolia root extract.
RESULTS: The average itch sore was 6.7 at the baseline. Five minutes after application, all 14 patients experienced a decrease in itch sensation, with a mean itch socre of 2.6 on the self-reported itch scale. This represents an average of 61% reduction in itch score. Two hours after treatment, 12 patients reported to have the same or lower itch score as when they reported during the 5-minute assessment. All subjects tolerated the treatment, and there was no skin irritation.
LIMITATIONS: This is an observational study with no control vehicle or group, and it had a small number of subjects who had 3 separate skin conditions. It will be interesting to compare the efficacy of this topical herbal ointment to topical steroids.
CONCLUSION: These preliminary results showed this topical herbal ointment to have provided rapid and sustained relief for patients with pruritus associated with eczema, psoriasis and insect bites.
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DISCLOSURES: The authors have nothing to disclose.

PA-07: BOLT 18-month analysis: efficacy and safety with sonidegib in locally advanced basal cell carcinoma

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BACKGROUND: Durable clinical benefit and manageable tolerability were observed with the hedgehog pathway inhibitor (HPI) sonidegib in patients with locally advanced basal cell carcinoma (laBCC) in the phase 2 BOLT study (NCT01327053; Migden MR, Guminski A, Gutzmer R, et al. Treatment with two different doses of sonidegib in patients with locally advanced or metastatic basal cell carcinoma (BOLT): a multicentre, randomised, double-blind phase 2 trial. Lancet Oncol. 2015;16(6):716-728).
OBJECTIVE: Updated efficacy and safety profiles in patients with laBCC treated with sonidegib 200 mg are reported here using data collected for up to 18 months after randomization of the last patient.
METHODS: Tumor responses were assessed by central review—using magnetic resonance imaging (MRI) per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1, photo per World Health Organization guidelines, and histology in multiple biopsies—and a composite overall response (COR) for each patient was determined using criteria A (per protocol; more stringent) and B (similar to the criteria used in prior HPI studies in BCC). The key distinction between these criteria is the stringency required to achieve a COR of complete response (CR); criteria A required negative histology and a CR (or CR equivalent) by all image modalities used in this analysis, whereas criteria B allowed a COR of CR with negative histology and either a CR or partial response (PR) by MRI or photo. In this analysis, objective response rate (ORR; CR + PR) and duration of response were evaluated separately using each set of criteria. Safety was assessed in treated patients until 30 days after the last dose per common terminology criteria for adverse events v4.03.
RESULTS: Median duration of exposure was 11.1 months in patients with laBCC treated with sonidegib 200 mg (n = 66). ORR using criteria A and B was 56% and 61%, respectively. However, more patients achieved CR with criteria B than A—15 (23%) vs 3 (5%). PR was achieved in 34 (52%) patients with criteria A, and in 25 (38%) with criteria B. Responses were durable, with few responders progressing or dying per A (10/37 responders) or B (11/40). Adverse events (AEs) observed with sonidegib 200 mg in patients with laBCC were primarily grade 1/2, with the most common AEs (any grade/grade 3 or 4) including muscle spasm (56%/3%), alopecia (52%/not applicable [NA]), and dysgeusia (47%/NA).
CONCLUSION: In the BOLT 18-month analysis, sonidegib 200 mg had a manageable safety profile and provided sustained tumor responses in patients with laBCC. Most patients responded to treatment with sonidegib 200 mg using either wet of response criteria; 12 additional patients had a CR with the less stringent BCC-RECIST-like criteria. These data support the potential of sonidegib 200 mg as a new treatment option in laBCC.
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DISCLOSURES: Dr Dummer reports grants and personal fees from Novartis, during the conduct of the study; grants and personal fees from Novartis, grants and personal fees from Bristol-Myers Squibb , grants and personal fees from Roche, grants and personal fees from GlaxoSmthKline, grants and personal fees from Merck , personal fees from Amgen, outside the submitted work. Dr Migden reports personal fees from Novartis, during the conduct of the study; personal fees from Novartis, personal fees from Genentech, personal fees from Lilly, outside the submitted work. Dr Combemale reports personal fees from Novartis, during the conduct of the study. Dr Schwartz reports personal fees from Novartis, during the conduct of the study. Dr Gutzmer reports personal fees from Novartis, during the conduct of the study; grants and personal fees from Novartis, grants and personal fees from Pfizer, grants and personal fees from Roche, grants from Johnson & Johnson, personal fees from BMS, personal fees from GlaxoSmithKline, personal fees from MerckSerono, personal fees from MSD, personal fees from Almirall, personal fees from Amgen, personal fees from Galderma, personal fees from Janssen, personal fees from Leo Pharma, personal fees from Boehringer Ingelheim, outside the submitted work. Dr Lear reports grants and personal fees from Novartis, during the conduct of the study; grants and personal fees from Novartis, grants and personal fees from Bristol-Myers Squibb, grants and personal fees from Roche, grants and personal fees from GlaxoSmithKline, grants and personal fees from Merck, personal fees from Amgen, outside the submitted work. Dr Yi reports personal fees from Novartis, during the conduct of the study; personal fees from Novartis, outside the submitted work. Dr Sellami reports personal fees from Novartis, during the conduct of the study; personal fees from Novartis, outside the submitted work. Dr Guminski reports personal fees from Novartis, during the conduct of the study; personal fees from Novartis, personal fees from Bristol-Myers Squibb, outside the submitted work.

PA-08: Clinical effects of a novel blend of antioxidants on subjects with moderate-to-severe facial photodamage

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BACKGROUND: Antioxidants have been shown to protect against Reactive Molecule Species (RMS) when topically applied, and are commonly recommended for morning-use, since chronic sun exposure is a key environmental factor contributing to RMS generation, ultimately resulting in the appearance of photoaged or photodamaged skin. A novel topical product (TD+R SPF 34) containing a proprietary blend of antioxidants and sunscreen actives was developed to not only provide protection against the damaging effects of RMS but to also support the repair of existing photodamage.
OBJECTIVE: To assess the efficacy and tolerability of TD+R SPF 34, an open-label clinical usage study was conducted on subjects presenting with moderate-to-severe facial photodamage.

METHODS: Eighteen male and female subjects aged 33-65 years with Fitzpatrick Skin Types II-IV completed the twelve week study. Subjects applied TD+R SPF 34 twice-daily, once in the morning after cleansing and then once again at least two hours after the initial application as per current recommendation for sunscreen use. Subjects were also provided with a basic skincare regimen including a facial cleanser as well as a light moisturizer (evening use only). Investigator assessments for key photodamage parameters including the appearance of lines/wrinkles (periocular, forehead, cheek, perioral), tactile roughness, and skin tone unevenness were conducted at all visits (baseline, week 2, week 4, week 8 and week 12). Global improvement was assessed by the investigator at all follow-up visits. Standardized digital photography was conducted at all visits. Subjects also completed a self-assessment questionnaire on product efficacy and attributes at all follow-up visits.
RESULTS: At weeks 2, 4, 8 and 12, statistically significant improvements were observed for periocular, forehead, cheek and perioral lines/wrinkles, tactile roughness and skin tone unevenness (all $P < .03$). Results from standardized digital photographs and subject self-assessments support the improvements observed by the investigator with 100% of subjects agreeing that the test product "improved skin's overall health, firmness, fine lines and wrinkles, and skin tone evenness."
LIMITATIONS: Limitations of this study are the smaller sample size and the open-label design.
CONCLUSION: In conclusion, the results from this study suggest that the proprietary antioxidant blend within TD+R SPF 34 may help improve the appearance of existing photodamage with twice-daily use.
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DISCLOSURES: Authors are paid employees of the sponsor company, SkinMedica, Inc, an Allergan Company.

PA-09: Comparing ixekizumab with placebo and etanercept for moderate-to-severe plaque psoriasis: results from the 12-week induction period of UNCOVER-2

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BACKGROUND: IL-17A plays a key role in the immunopathogenesis of psoriasis.
OBJECTIVE: To evaluate the efficacy and safety of an anti-IL-17A monoclonal antibody, ixekizumab, for the treatment of psoriasis.
METHODS: In this double-blind trial, 1224 patients were randomized to receive subcutaneous placebo n = 168), etanercept (50 mg twice weekly; n = 358), or a single injection of 80 mg ixekizumab every 2 (IXE Q2W; n = 351) or 4 weeks (IXE Q4W; n = 347) following a 160-mg starting dose. The co-primary efficacy endpoints were proportions of patients who achieved 1) an sPGA 0/1, and 2) PASI-75 by Week 12. Treatment groups were compared using the Cochran-Mantel-Haenszel test. For response analyses, missing data were imputed using nonresponder imputation.
RESULTS: At Week 12, PASI-75 response rates were 89.7% in IXE Q2W, 77.5% in IXE Q4W, 2.4% in placebo, and 41.3% in etanercept groups, and sPGA 0/1 was achieved by 83.2% in the IXE Q2W, 72.9% in IXE Q4W, 2.4% in placebo, and 36.0% in etanercept groups ($P < .001$ each ixekizumab vs placebo or etanercept). Differences were seen as early as Week 1 for IXE Q2W and IXE Q4W compared to the etanercept group ($P < .05$). Complete resolution (PASI-100) was achieved 40.5% in IXE Q2W, 30.8% in IXE Q4W, 0.6% in placebo, and 5.3% in etanercept groups ($P < .001$ each ixekizumab vs placebo or etanercept). Treatment-emergent adverse events reported in ≥5% of ixekizumab-treated patients and at higher percentages than in placebo-treated patients included injection-site reaction and headache, most of which were mild to moderate in severity. The percentages of these events in ixekizumab-treated patients were similar to those in etanercept-treated patients. Serious adverse events were reported in 1.4% of IXE Q2W, 1.7% of IXE Q4W, 1.2% of placebo, and 1.7% of etanercept patients.
LIMITATIONS: A limitation is the relatively short duration of the trial.
CONCLUSION: Both ixekizumab dosing regimens were highly effective and superior to placebo and etanercept with onset of efficacy as early as Week 1 and a safety profile comparable to etanercept in this induction period. Over 75% of ixekizumab-treated patients achieved PASI-75, and over 30% achieved complete resolution of psoriasis.
REFERENCE: Griffiths CE, Reich K, Lebwohol M, et al; UNCOVER-2 and UNCOVER-3 Investigators. Comparison of ixekizumab with etanercept or placebo in moderate-to-severe psoriasis (UNCOVER-2 and UNCOVER-3): results from two phase 3 randomised trials. Lancet. 2015;386(9993):541-551.
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DISCLOSURES: Dr Griffiths receives grant/research support from: AbbVie, Janssen, Celgene, Eli Lilly and Company, MSD, Bristol-Myers Squibb, Novartis, Sandoz, LEO, Trident, Regeneron, Pfizer, is a consultant of: AbbVie, Actelion, Janssen, Amgen, Eli Lilly and Company, Celgene, Pfizer, Sandoz, UCB Pharma, GSK-Stiefel, LEO. Dr Reich is a consultant of: AbbVie,

Amgen, Biogen-Idec, Celgene, Centocor, Covagen, Eli Lilly and Company, Forward Pharma, GlaxoSmithKline, Janssen-Cilag, LEO Pharma, Medac, MSD, Novartis, Ocean Pharma, Pfizer, Regeneron, Takeda, UCB, Vertex, Xenoport, Speakers bureau of: AbbVie, Amgen, Biogen-Idec, Celgene, Centocor, Covagen, Eli Lilly and Company, Forward Pharma, GlaxoSmithKline, Janssen-Cilag, LEO Pharma, Medac, MSD, Novartis, Ocean Pharma, Pfizer, Regeneron, Takeda, UCB, Vertex, Xenoport. Dr Lebwohl receives grant/research support from: AbGenomics, Amgen, Anacor, Canfite Biopharma, Celgene, Clinuvel, Coronado Biosciences, Ferndale, Consultant of: Dermipsor. Dr van de Kerkhof Consultant of: Celgene, Centocor, Allmiral, Amgen, Pfizer, Phillips, Abbott, Eli Lilly and Company, Galderma, Novartis, Janssen Cilag, LEO Pharma, Sandoz, Mitsubishi. Dr Paul Grant/Research support from: Pierre Fabre, Consultant of: Pfizer, AbbVie, Amgen, Celgene, Janssen, Eli Lilly and Company, LEO, Novartis, GSK. Dr Menter Grant/Research support from: AbbVie, Allergan, Amgen, APoPharma, Boehringer Ingelheim, Cengene, Convoy Therapeutics, Eli Lilly and Company, Genentech, Janssen Biotech, Leo Pharma, Merck, Novartis, Pfizer, Symbio, Syntrix, Wyeth, XenoPort, Consultant of: AbbVie, Allergan, Amgen, Convoy Therapeutics, Eli Lilly and Company, Janssen Biotech, Novartis, Pfizer, Syntrix, Wyeth, Xenoport, Speakers bureau of: AbbVie, Amgen, Janssen Biotech, Leo Pharma, Wyeth. K Solotkin, Drs Cameron, Erickson, Zhang, Secrest, Ball, Braun, Osuntokun, and B. Nicholoff are employees and shareholders of Eli Lilly and Company. Dr Heffernan is a shareholder and consultant for Eli Lilly and Company. Dr Papp Grant/Research support from: Abbott, Amgen, Anacor, Astellas, Celgene, Celtic, Dow Pharma, Eli Lilly and Company, Galderma, Consultant of: Abbott, Akesis, 3M, Akros, Alza, Amgen, Astellas, Baxter, Boehringer Ingelheim, Celgene, Centocor, Cipher, Eli Lilly and Company, Forward Pharma, Funxional Therapeutics, Speakers bureau of: Abbott, 3M, Amgen, and Astellas.
FUNDING: Sponsored by Eli Lilly and Company.

PA-10: Comparing ixekizumab with placebo and etanercept for moderate-to-severe plaque psoriasis: results from the 12-week induction period of UNCOVER-3

Griffiths CE,[1] Reich K,[2] Lebwohl M,[3] van de Kerkhof P,[4] Paul C,[5] Menter A,[6] Solotkin K (presenter only),[7] Cameron G,[7] Erickson J,[7] Zhang L,[7] Secrest R,[7] Ball S,[7] Braun D,[7] Osuntokun O,[7] Heffernan M,[7] Nickoloff B,[7] Papp K,[8]

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BACKGROUND: IL-17A plays an important role in the immunopathogenesis of psoriasis.
OBJECTIVE: To assess the efficacy and safety of an anti-IL-17A monoclonal antibody, ixekizumab, for the treatment of psoriasis.
METHODS: In this double-blind trial, 1346 patients were randomized to receive subcutaneous placebo (n = 193), etanercept (50 mg twice weekly; n = 382), or a single injection of 80 mg ixekizumab every 2 (IXE Q2W; n = 385) or 4 weeks (IXE Q4W; n = 386) following a 160-mg starting dose. The co-primary efficacy endpoints were proportions of patients who achieved 1) an sPGA 0/1, and 2) PASI-75 at Week 12. Treatment groups were compared using the Cochran-Mantel-Haenszel test. For response analyses, missing data were imputed using nonresponder imputation.
RESULTS: At Week 12, PASI-75 response rates were 87.3% in IXE Q2W, 84.2% in IXE Q4W, 7.3% in the placebo, and 53.4% in etanercept groups, and sPGA 0/1 was achieved by 80.5% in IXE Q2W, 75.4% in IXE Q4W, 6.7% in placebo, and 41.6% in etanercept groups ($P < .001$ each ixekizumab vs placebo or etanercept). Differences were seen as early as Week 1 for IXE Q2W and IXE Q4W compared to the etanercept group ($P < .05$). Complete resolution (PASI-100) was achieved by 37.7% in IXE Q2W, 35.0% in IXE Q4W, 0 in placebo, and 7.3% in etanercept groups ($P < .001$ each ixekizumab vs placebo or etanercept). Treatment-emergent adverse events reported in ≥5% of all ixekizumab patients and at higher percentages than in placebo patients included injection-site reaction and nasopharyngitis. Most of these events were mild to moderate in severity. The percentages of these events in ixekizumab patients were similar to those in etanercept patients. Serious adverse events were reported in 2.3% of IXE Q2W, 1.6% of IXE Q4W, 2.6% of placebo, and 1.3% of etanercept patients.
LIMITATIONS: A limitation is the relatively short duration of the trial.
CONCLUSION: Both ixekizumab dosing regimens were highly effective and superior to placebo and etanercept with onset of efficacy as early as Week 1 and a safety profile comparable to etanercept in this induction period. Over 75% of ixekizumab-treated patients achieved PASI-75, and over 30% achieved complete resolution of psoriasis.
REFERENCE: Griffiths CE, Reich K, Lebwohol M, et al; UNCOVER-2 and UNCOVER-3 Investigators. Comparison of ixekizumab with etanercept or placebo in moderate-to-severe psoriasis (UNCOVER-2 and UNCOVER-3): results from two phase 3 randomised trials. Lancet. 2015;386(9993):541-551.
CORRESPONDING AUTHOR: Kathleen Solotkin; Lilly USA, LLC; Lilly Corporate Center, DC 5028; Indianapolis, IN 46285. Email: ksolotkin@lilly.com.
DISCLOSURES: Dr Griffiths receives grant/research support from: AbbVie, Janssen, Celgene, Eli Lilly and Company, MSD, Bristol-Myers Squibb, Novartis, Sandoz, LEO, Trident, Regeneron, Pfizer, is a consultant of: AbbVie, Actelion, Janssen, Amgen, Eli Lilly and Company, Celgene, Pfizer, Sandoz, UCB Pharma, GSK-Stiefel, LEO. Dr Reich is a consultant of: AbbVie, Amgen, Biogen-Idec, Celgene, Centocor, Covagen,

Eli Lilly and Company, Forward Pharma, GlaxoSmithKline, Janssen-Cilag, LEO Pharma, Medac, MSD, Novartis, Ocean Pharma, Pfizer, Regeneron, Takeda, UCB, Vertex, Xenoport, Speakers bureau of: AbbVie, Amgen, Biogen-Idec, Celgene, Centocor, Covagen, Eli Lilly and Company, Forward Pharma, GlaxoSmithKline, Janssen-Cilag, LEO Pharma, Medac, MSD, Novartis, Ocean Pharma, Pfizer, Regeneron, Takeda, UCB, Vertex, Xenoport. Dr Lebwohl receives grant/research support from: AbGenomics, Amgen, Anacor, Canfite Biopharma, Celgene, Clinuvel, Coronado Biosciences, Ferndale, Consultant of: Dermipsor. Dr van de Kerkhof Consultant of: Celgene, Centocor, Allmiral, Amgen, Pfizer, Phillips, Abbott, Eli Lilly and Company, Galderma, Novartis, Janssen Cilag, LEO Pharma, Sandoz, Mitsubishi. Dr Paul Grant/Research support from: Pierre Fabre, Consultant of: Pfizer, AbbVie, Amgen, Celgene, Janssen, Eli Lilly and Company, LEO, Novartis, GSK. Dr Menter Grant/Research support from: AbbVie, Allergan, Amgen, APoPharma, Boehringer Ingelheim, Cengene, Convoy Therapeutics, Eli Lilly and Company, Genentech, Janssen Biotech, Leo Pharma, Merck, Novartis, Pfizer, Symbio, Syntrix, Wyeth, XenoPort, Consultant of: AbbVie, Allergan, Amgen, Convoy Therapeutics, Eli Lilly and Company, Janssen Biotech, Novartis, Pfizer, Syntrix, Wyeth, Xenoport, Speakers bureau of: AbbVie, Amgen, Janssen Biotech, Leo Pharma, Wyeth. K Solotkin, Drs Cameron, Erickson, Zhang, Secrest, Ball, Braun, Osuntokun, and B. Nicholoff are employees and shareholders of Eli Lilly and Company. Dr Heffernan is a shareholder and consultant for Eli Lilly and Company. Dr Papp Grant/Research support from: Abbott, Amgen, Anacor, Astellas, Celgene, Celtic, Dow Pharma, Eli Lilly and Company, Galderma, Consultant of: Abbott, Akesis, 3M, Akros, Alza, Amgen, Astellas, Baxter, Boehringer Ingelheim, Celgene, Centocor, Cipher, Eli Lilly and Company, Forward Pharma, Funxional Therapeutics, Speakers bureau of: Abbott, 3M, Amgen, and Astellas.
FUNDING: Sponsored by Eli Lilly and Company.

PA-11: Comparative effectiveness of biologic therapy in the Psoriasis Longitudinal Assessment and Registry (PSOLAR) study

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BACKGROUND: PSOLAR is an observational study which evaluates safety and clinical outcomes in psoriasis patients. Physicians prescribe treatments including UST, ADA, ETN, and IFX per standard clinical practice.
OBJECTIVE: To compare the effectiveness of ustekinumab (UST) to adalimumab (ADA), etanercept (ETN) and infliximab (IFX) for the treatment of psoriasis at 6 months in a real-world setting.
METHODS: Physician's Global Assessment (PGA) scores and Body Surface Area (BSA) affected with psoriasis were assessed at the time of starting a new biologic on registry and at 6 months. Only patients who remained on therapy at 6 months were included; however, discontinuation before 6 months due to lack of effect was counted as treatment failure. Patients could be included in only one treatment group, and patients using concomitant systemic psoriasis therapies were excluded.
RESULTS: Overall, there were 2076 new users of biologics, including UST (n = 1041), ADA (n = 662), ETN (n = 257), IFX (n = 116). Baseline characteristics (eg, age, gender, race, BMI) were generally comparable among treatment groups, while baseline PGA scores and BSA affected with psoriasis were more variable. Results from adjusted logistic regression analyses (including adjustment for baseline severity) showed that patients on ADA were less likely to achieve a PGA of 0/1 at 6 months versus patients on UST (odds ratios: 0.69 [P = .0016]). Similarly, patients on ETN and IFX were less likely to achieve a PGA score of 0/1 at 6 months compared to patients on UST (odd ratios: 0.56 [P = .0005], and 0.40 [P < .0001], respectively). Change in percent BSA affected with psoriasis at 6 months versus baseline was significantly greater for UST compared to ADA (1.85%, P = .0019) and for UST compared to ETN (3.45%, P < .0001), and trended greater for UST compared to IFX (1.80%, P = .1048).
LIMITATIONS: Observational studies are subject to potential confounding from unmeasured variables, as well as selection and information bias. This study did not control for patients' baseline disease status with respect to timing of or response to their previous therapy, dosing regimen or adjustments in dosing.
CONCLUSION: Data comparing the effectiveness of available biologic treatments for psoriasis are limited. In this large observational study, UST revealed higher clinical effectiveness (PGA and BSA responses) than TNF inhibitors after 6 months of usage.
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DISCLOSURES: Dr Strober reports other from Janssen Scientific Affairs, LLC, during the conduct of the study; other from Abbvie, other from Amgen, other from Celgene, outside the submitted work. Drs Bissonnette, Kimball, Lebwohl, Naldi, and Shear are all investigators for Janssen Scientific Affairs, LLC.

PA-12: Consistent high efficacy adalimumab PASI-75 responders: a post hoc analysis of REVEAL

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BACKGROUND: Phase 2/3 clinical trials of adalimumab (ADA) in patients with moderate-to-severe psoriasis (Ps) have demonstrated that a high proportion of patients treated with ADA achieve a Psoriasis Area and Severity Index (PASI) 75 response. Among PASI-75 responders at Week 33 of the REVEAL trial, PASI-90/100 responses at Week 33 were 67% and 33%, respectively. (Gordon K, Papp K, Poulin Y, Gu Y, Rozzo S, Sasso EH. Long-term efficacy and safety of adalimumab in patients with moderate-to-severe psoriasis treated continuously over 3 years: results from an open-label extension study for patients from REVEAL. J Am Acad Dermatol. 2012;66(2):241-251.)
OBJECTIVE: This post hoc analysis was conducted to assess, among patients treated with ADA who achieved a PASI-75 response, whether this high-efficacy response was consistently maintained and affected other efficacy endpoints (eg, DLQI).
METHODS: REVEAL (NCT00237887) was a 52-week, double-blind, randomized, placebo (PBO)-controlled phase 3 study of ADA for moderate-to-severe plaque Ps. At Week 16, ADA-treated patients with ≥PASI-75 response continued onto period B. Patients from the ADA arm of Period B with a ≥PASI-75 response at Week 33, were rerandomized in Period C to continue ADA 40 mg eow or to receive PBO, and sustained responses were assessed at Week 52. Patients were considered to have a consistent high-efficacy response if their PASI score at every visit after Week 33 until Week 52 was never >2 points higher than their Week 33 PASI score.
RESULTS: A total of 250 patients achieved a PASI-75 response at Week 33 and were rerandomized to continue ADA treatment; 245 patients had a study visit after Week 33 and were evaluable for consistent high-efficacy response. A total of 76.3% of patients (187/245) were consistent high- efficacy responders through Week 52. PASI-75/90/100 response rates after 52 weeks of continuous ADA treatment were 84%/58%/33%, respectively. The mean change from baseline in PASI scores among high-efficacy responders at Week 52 was –16.7 and was significantly greater than in patients without a consistent high-efficacy response (–14.5; P=0.018). Mean Dermatology Life Quality Index scores at Week 52 were 0.8 among high-efficacy responders compared with 4.3 among those without a consistent high-efficacy response. Of the ADA-treated patients with post-week 33 PASI data, 10 (6.0%) of the PASI-90 responders and 1 (1.2%) of the PASI-100 responders at re-randomization lost their PASI-75 response by Week 52.
CONCLUSION: Evaluation of an enriched population of patients who had PASI-75 response at Weeks 16 and 33 after initiating ADA demonstrated that the majority of these patients had consistent high-efficacy response with continued ADA therapy beyond Week 33. Patients with consistent high-efficacy responses had better quality of life scores compared to those without consistent high-efficacy responses.
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DISCLOSURES: Dr Gordon: Paid work by commercial organizations either directly or indirectly through an intermediary: AbbVie, Amgen, Celgene, Eli Lilly, Jannsen, Novartis, Pfizer. M Karunaratne and D Williams receive a salary as employees of AbbVie and may also receive AbbVie stock, stock options and/or stock grants. M Okun is a former employee of AbbVie and is now affiliated with Fort HealthCare. He is a consultant for AbbVie.

PA-13: Crisaborole topical ointment, 2%, a novel anti-inflammatory phosphodiesterase 4 inhibitor, in children and adults with mild-to-moderate atopic dermatitis

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BACKGROUND: Atopic dermatitis (AD) is an inflammatory skin disease affecting children and adults. Up to 90% of the AD patient population has mild-to-moderate AD. Crisaborole Topical Ointment, 2%, is an investigational, novel, topical, nonsteroidal, anti-inflammatory phosphodiesterase 4 inhibitor being studied for the treatment of AD.
OBJECTIVE: To determine the efficacy and safety of Crisaborole Topical Ointment, 2%, in mild-to-moderate AD evaluated in 2 Phase 3 studies (NCT02118766 and NCT02118792).
METHODS: Two identical multicenter, double-blind, vehicle-controlled studies enrolled patients ≥2 years old with mild-to-moderate AD affecting ≥5% of body surface area (BSA). Patients were randomized 2:1 to receive twice-daily Crisaborole Topical Ointment, 2%, or vehicle for 28 days and were evaluated on Days 8, 15, 22, and 29. The primary endpoint defined success in the Investigator's Static Global Assessment (ISGA) at Day 29 from baseline as "almost clear/1" or "clear/0"

with ≥2-grade improvement. Secondary endpoints measured the percentage of patients achieving ISGA of "almost clear/1" or "clear/0" and time to success.

RESULTS: Key baseline characteristics were balanced across all groups/studies (crisaborole/vehicle [n:n], Study 1: 503:256 and Study 2: 513:250 patients; pooled data: mean age, ≈12 years; mean BSA, ≈18%; ISGA, ≈60% "moderate/3" and ≈40% "mild/2"). At Day 29, more patients achieved ISGA success with crisaborole than vehicle (Study 1: 32.8% vs 25.4%, $P = 0.038$; Study 2: 31.4% vs 18.0%, $P < 0.001$). Success in ISGA goals was achieved earlier with crisaborole-treated patients than vehicle-treated patients ($P < .001$). At Day 29, a greater percentage of crisaborole-treated patients achieved ISGA scores of "almost clear/1" or "clear/0" (Study 1: 51.7% vs 40.6%, $P = .005$; Study 2: 48.5% vs 29.7%, $P < .001$). Most treatment-related adverse events (AEs) were mild and included upper respiratory tract infection (pooled data, crisaborole vs vehicle: 3.0% vs 3.0%) and application site pain (4.4% vs 1.2%). For both crisaborole and vehicle, the discontinuation rate due to AEs was 1.2%.

LIMITATIONS: The visual criteria of the ISGA do not take into account BSA or the degree of pruritus.

CONCLUSION: In 2 large Phase 3 studies, Crisaborole Topical Ointment, 2%, exhibited favorable efficacy and safety. It may represent a novel, efficacious, and safe treatment for patients with mild-to-moderate AD as young as 2 years.

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DISCLOSURES: Dr Paller has served as consultant for Celsus Therapeutics, Chugai-Pharma, Galderma, GlaxoSmith-Kline-Stiefel, Novartis, Promius Pharma, and Regeneron; as consultant and investigator for Anacor; and as investigator for Astellas. Dr Tom has served as investigator for Anacor, Otsuka, Amgen, and Regeneron. Dr Lebwohl has served as investigator or subinvestigator for AbGenomics, Amgen, Anacor, Can-Fite, Celgene, Clinuvel, Coronado Biosciences, Eli Lilly, Janssen/Centocor, Kadmon, Leo Pharmaceuticals, Novartis, and Pfizer; and is course director for the annual Fall and Winter Clinical Dermatology Conferences, The Real World Dermatology for Residents Conference, and the Mount Sinai Winter Symposium, which receive support from numerous dermatology companies. Dr Blumenthal is an employee of Anacor. Dr Boguniewicz has served as investigator for Anacor. Dr Call has served as consultant for Anacor. Dr Eichenfield has served as consultant to Anacor. Drs Forsha and Rees have nothing to disclose. Dr Simpson has served on advisory boards for Pfizer and Valeant; as consultant for Anacor, ClearView Healthcare, Galderma, Genentech, Guidepoint Global, and Regeneron; as investigator for Amgen, Chugai, Galderma, Genentech, MedImmune, Merck, Otsuka, Pfizer, Regeneron, Tioga, and Valeant; and as speaker for Brown University. Dr Stein Gold has served on advisory boards for Allergan, Anacor, Galderma, Leo, Lilly, Novartis, Pfizer, Taro, and Valeant; as speaker for Allergan, Galderma, Leo, Novartis, Taro, and Valeant; and as medical/legal advisor for Roche. Dr Zaenglein has served on advisory boards for Sun; as consultant for Ranbaxy; and as investigator for Anacor, Astellas, and Ranbaxy. Dr Zane is an employee of and holds stock/stock options in Anacor. Dr Hebert has served on advisory boards and as investigator for Anacor.

PA-14: Crisaborole topical ointment, 2%, a novel phosphodiesterase 4 inhibitor reduces pruritus and signs of mild-to-moderate atopic dermatitis

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BACKGROUND: Atopic dermatitis (AD), an inflammatory skin disease, can present with intense inflamed, red, weepy lesions and pruritus. Crisaborole Topical Ointment, 2% (Anacor Pharmaceuticals, Palo Alto, CA), is a novel, topical, nonsteroidal, anti-inflammatory, phosphodiesterase 4 inhibitor being studied for the treatment of AD.

OBJECTIVE: To analyze the exploratory efficacy endpoints from 2 identical Phase 3 trials evaluating crisaborole's impact on pruritus and signs of AD (NCT02118766 and NCT02118792).

METHODS: Two double-blind, vehicle-controlled, multicenter Phase 3 studies of identical design enrolled patients ≥2 years old with mild-to-moderate AD. Patients were randomized 2:1 to receive Crisaborole Topical Ointment, 2%, or vehicle twice daily for 28 days. A 4-point scale (None [0] to Severe [3]) was used to evaluate exploratory efficacy endpoints. The severity of pruritus was evaluated twice daily and the time to success was determined by Kaplan-Meier analysis. Signs of AD (erythema, induration/papulation, exudation, excoriation, and lichenification) were examined weekly. Success for each symptom or sign was defined as achievement of None (0) or Mild (1) pruritus with ≥1-grade improvement from baseline.

RESULTS: Study 1 and Study 2 enrolled 503:256 and 513:250 (crisaborole:vehicle) patients, respectively. Baseline severity of symptoms and signs were generally balanced across treatment groups/studies. Success in pruritus was achieved earlier in patients treated with Crisaborole than in vehicle-treated patients (pooled data: median 1.37 vs 1.70 days; $P = .001$). By day 29 a greater proportion of crisaborole-treated patients achieved success for all clinical signs of AD than vehicle-treated patients (Study 1 crisaborole vs vehicle; Study 2 crisaborole vs vehicle) (erythema: 62.8% vs 46.1%, 54.9% vs 33.9%; induration/papulation: 57.7% vs 54.8%, 51.9% vs 40.2%; exudation: 41.0% vs 33.3%, 38.1% vs 27.2%; excoriation: 63.0% vs 51.8%, 57.2% vs 44.2%; lichenification: 51.7% vs 46.5%, 51.4% vs 35.3%).

LIMITATIONS: The study was not powered to detect the dif-

ference in exploratory endpoint measures (pruritus and signs of AD).

CONCLUSION: Early relief in pruritus and improvement in signs of AD in 2 large Phase 3 studies indicate that Crisaborole Topical Ointment, 2%, may represent a safe and efficacious treatment for patients as young as 2 years with mild-to-moderate AD.

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DISCLOSURES: Dr Hebert has served on advisory boards and as investigator for Anacor. Dr Eichenfield has served as consultant to Anacor. Dr Lebwohl has served as investigator or subinvestigator for AbGenomics, Amgen, Anacor, Can-Fite, Celgene, Clinuvel, Coronado Biosciences, Eli Lilly, Janssen/Centocor, Kadmon, Leo Pharmaceuticals, Novartis, and Pfizer; and is course director for the annual Fall and Winter Clinical Dermatology Conferences, The Real World Dermatology for Residents Conference, and the Mount Sinai Winter Symposium, which receive support from numerous dermatology companies. Dr Paller has served as consultant for Celsus Therapeutics, Chugai-Pharma, Galderma, GlaxoSmithKline-Stiefel, Novartis, Promius Pharma, and Regeneron; as consultant and investigator for Anacor; and as investigator for Astellas. Dr Simpson has served on advisory boards for Pfizer and Valeant; as consultant for Anacor, ClearView Healthcare, Galderma, Genentech, Guidepoint Global, and Regeneron; as investigator for Amgen, Chugai, Galderma, Genentech, MedImmune, Merck, Otsuka, Pfizer, Regeneron, Tioga, and Valeant; and as speaker for Brown University. Dr Tom has served as investigator for Anacor, Otsuka, Amgen, and Regeneron. Dr Hughes is an employee of Anacor. Dr Zane is an employee of and holds stock/stock options in Anacor.

PA-15: Current status of observations of malignancies in the Psoriasis Longitudinal Assessment and Registry (PSOLAR) study

Fiorentino D,[1] Lebwohl M,[2] Ho V,[3] Langley R,[4] Goyal K,[5] Fakharzadeh S,[5] Calabro S,[5] Langholff W,[5] on behalf of the PSOLAR Steering Committee

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BACKGROUND: PSOLAR is a multicenter, longitudinal, observational study evaluating long-term safety and clinical outcomes for pts eligible to receive treatment for psoriasis with biologics and/or conventional systemic agents.

OBJECTIVE: To report cumulative incidence and results of analysis of malignancies excluding nonmelanoma skin cancers (NMSC) in PSOLAR.

METHODS: The incidence of malignancies excluding NMSC (eg, basal/squamous cell carcinomas) overall and by treatment is reported. The rules for attribution of a malignancy to a therapy use a definition of exposure based on whether pts had ever been exposed to a given therapy at any time prior to the event. In cases of exposure to >1 therapy, the rule for attribution of malignancy to a treatment is ustekinumab(UST) 1st, infliximab (IFX)/golimumab (GLM) 2nd, other biologics 3rd (nearly all adalimumab(ADA) or etanercept(ETN), or nonbiologic therapy 4th, which is consistent with the prespecified analytic plan. Analysis using Cox hazard regression was used to identify predictors of malignancy and included medication exposure defined as UST vs no biologic and biologics other than UST (primarily ADA, IFX and ETN) vs no biologic.

RESULTS: PSOLAR is fully enrolled and, as of Aug 23, 2013, has 31 818 total pt-years of follow up with 12 095 pts. Cumulative rates of malignancy overall and across treatments were: overall 0.68 events/100 pt years of observation (PY) [95%CI: 0.59,0.77; 215/31818], UST 0.51/100 PY [95% CI: 0.37, 0.68; 45/8870 PY], IFX/GLM (almost exclusively IFX) 0.64/100 PY[95% CI:0.42,0.93; 27/4205,other biologics (almost exclusively ETN/ADA) 0.74/100 PY [95% CI: 0.60,0.91; 98/13167], and nonbiologic therapy 0.81/100 PY [95% CI:0.59,1.08;45/5576]. Multivariate analysis, based on any time exposure, revealed that increasing age ($P < .001$), and previous malignancy history ($P < .001$) were significant predictors of malignancy. Nonwhite ethnicity was associated with a lower risk of malignancy ($P = .012$). No statistically significant increased risk of malignancy with the use of any biologics was observed.

CONCLUSIONS: Overall cumulative rates of malignancies are comparable across treatments. Age and previous malignancy were found to be associated, however, no biologics or immunomodulators were found to be associated with an increased risk of malignancy.

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DISCLOSURES: Dr Fiorentino reports other from Janssen Scientific Affairs, LLC, during the conduct of the study; other from Janssen Scientific Affairs, LLC, outside the submitted work. Drs Lebwohl M, Ho V, and Langley R are investigators for Janssen Scientific Affairs, LLC

FUNDING: Janssen Scientific Affairs, LLC supported this study.

PA-16: Efficacy and safety of adalimumab versus methotrexate treatment in pediatric patients with severe chronic plaque psoriasis: results from the 16-week randomized, double-blind period of a phase 3 study

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BACKGROUND: This study (clinicaltrials.gov NCT01251614) evaluated safety and efficacy of TNF-alpha inhibitor adalimumab (ADA) vs methotrexate (MTX) treatment in pediatric patients with chronic plaque psoriasis.
OBJECTIVE: Results from the 16-week initial treatment period (Period A) are presented.
METHODS: This multisite international study included 4 periods. Period A: 16-week double-blind treatment; 1:1:1 randomization to initial 0.8mg/kg ADA up to 40mg, then every-other-week from Week1; initial 0.4mg/kg ADA up to 20mg, then every-other-week from Week1; or 0.1-0.4mg/kg MTX weekly up to 25mg/week. Period B: treatment withdrawal for treatment responders. Period C: ADA retreatment. Period D: 52-week treatment and follow-up. Eligibility included patient age-range 4-18 years, Physician's Global Assessment (PGA) ≥4 or; body-surface-area involved >20% or; Psoriasis Area Severity Index (PASI) >20; or PASI >10 plus at least 1 of the following: active psoriatic arthritis unresponsive to NSAIDS, clinically relevant facial, genital, or hand and/or foot involvement, or Children's Dermatology Life Quality Index >10. Primary efficacy endpoints, ≥PASI-75 response and PGA clear or minimal (0/1) at Week 16 (ADA-0.8mg/kg vs MTX), were evaluated for the intent-to-treat population; patients with missing data were imputed as nonresponders. Safety was evaluated for all patients who received at least 1 dose of study drug.
RESULTS: Of 114 enrolled (MTX, n = 37; ADA-0.4mg/kg, n = 39; ADA-0.8mg/kg, n = 38), 57% were female; 90% were white. Mean age was 13.0 years (SD, 3.76), range 5-18. Body mass index (BMI) distribution by age- and sex-adjusted percentiles was 4.4% (<5th, underweight), 59.6% (5th to <85th, normal weight), 14.9% (85th to <95th, overweight), 21.1% (≥95th, obese). A statistically significantly higher proportion of ADA-0.8mg/kg patients achieved PASI-75 response at Week 16 (22/38, 57.9%) vs MTX patients (12/37, 32.4%; [95% CI: -47.2, -3.7] P = .027). Approximately 20% more ADA-0.8mg/kg patients achieved PGA 0/1 response at Week 16 (23/38, 60.5%) vs MTX patients (15/37, 40.5%; [95% CI: -42.2, 2.2] P = .083). Treatment-emergent adverse events (TEAEs) were reported by 73.7% (84/114) in Period A: 75.7% (28/37) MTX; 76.9% (30/39) ADA-0.4mg/kg; 68.4% (26/38) ADA-0.8mg/kg. TEAEs of infection were reported by 54.1% (20/37) MTX; 56.4% (22/39) ADA-0.4mg/kg; 47.4% (18/38) ADA-0.8mg/kg; serious TEAEs were reported by only the ADA-0.4mg/kg patients, 7.7% (3/39) during Period A.
LIMITATIONS: As this was the first study using MTX in this population, no comparisons can be made.
CONCLUSION: After 16 weeks of treatment, adalimumab 0.8mg/kg every-other-week demonstrated significant and clinically meaningful efficacy outcomes over methotrexate in this population. Adalimumab treatment had a similar safety profile to methotrexate, and no new safety risks were identified.

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DISCLOSURES: Dr Papp received honoraria or grants from AbbVie, Amgen, Boehringer-Ingelheim, Celgene, Eli Lilly, Janssen, Kyowa, Leo Pharma, Merck (MSD), Novartis, Pfizer, for participation on ad boards, and for participation as a consultant and investigator. Dr Thaçi received honoraria from AbbVie, Amgen, Biogen-Idec, Celgen, Janssen, Leo, Novartis and Pfizer for participation on ad boards and as a speaker, and from AbbVie and Leo for consultancy; and received research grants from AbbVie, Leo and Pfizer. Dr Marcoux received honoraria or grants from AbbVie, Johnson & Johnson, Pierre Fabre and Galderma for participation on boards, as a consultant, an investigator, and as a speaker. Dr Weibel received honoraria from AbbVie for participation as an investigator of this study and from Pierre Fabre, Meda, and Pfizer for participation on ad boards, as a speaker and for consultancy. Drs Unnebrink and Williams receive a salary as employees of AbbVie and may also receive AbbVie stock, stock options and/or stock grants.
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PA-17: Efficacy and safety of ixekizumab, adalimumab, and placebo in patients naïve to biologic disease-modifying antirheumatic drugs with active psoriatic arthritis

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BACKGROUND: Psoriatic arthritis (PsA) is a chronic immune-mediated inflammatory disease associated with psoriasis which includes peripheral arthritis, enthesitis, dactylitis, and spondylitis manifestations. Ixekizumab, under investigation for PsA treatment, is an IgG4 monoclonal antibody that binds with high affinity and specificity to the proinflammatory cytokine IL 17A.
METHODS: In a Phase 3 trial, 417 biologic disease-modifying antirheumatic drug (bDMARD)-naïve patients with active PsA

were randomized to up to 24 weeks of placebo (n = 106); adalimumab 40 mg (n = 101) once every 2 weeks (Q2W; active control); or ixekizumab 80 mg Q2W (n = 103) or Q4W (n = 107) following 160 mg initial dose at Week 0. Endpoints included American College of Rheumatology 20 response (ACR20) at Week 24 (primary), ACR50, ACR70, a 75%/90%/100% improvement in Psoriasis Area and Severity Index (PASI-75/PASI-90/PASI-100), Disease Activity Score (28 joint count) based on C-reactive protein (DAS28-CRP), Leeds Dactylitis Index (LDI-B) and Enthesitis Index (LEI), Health Assessment Questionnaire – Disability Index (HAQ-DI), and Van der Heijde modified Total Sharp (mTSS) score at 12 and 24 weeks. Efficacy variables were evaluated using the intent-to-treat population. Continuous data were evaluated using mixed-effects model for repeated measures. Categorical data were compared using a logistic regression model with missing values imputed by nonresponder imputation, which treats inadequate responders as nonresponders.

RESULTS: A total of 382 patients completed 24 weeks of the study. A significantly greater percentage of patients treated with ixekizumab 80 mg Q2W or Q4W achieved ACR20, ACR50, ACR70 and PASI-75/90/100 responses than with placebo at 12 and 24 weeks ($P < .01$). Both ixekizumab groups experienced significantly greater reductions than placebo for measures of dactylitis (LDI-B) at 12 and 24 weeks but not for enthesitis (LEI). Disease activity (DAS28-CRP) and functional disability (HAQ-DI) improved and inhibition of radiographic progression of joint structural damage (mTSS) was demonstrated with both ixekizumab doses compared to placebo ($P < .025$). Efficacy results with adalimumab versus placebo were significant on most measures, thus validating the study design. At 24 weeks, the incidence of treatment-emergent adverse events (TEAE) was greater ($P < .05$) and the rate of serious adverse events was higher ($P > .27$) with ixekizumab and adalimumab compared to placebo. Discontinuation due to a TEAE was similar across groups. No deaths occurred.

LIMITATIONS: Enrollment was limited to bDMARD-naïve patients; therefore the results may not be generalizable to those who are bDMARD-experienced.

CONCLUSION: In bDMARD-naive patients with active PsA, ixekizumab showed significant, clinically meaningful improvements of disease activity and physical function, reduction in dactylitis, greater skin clearance of plaque psoriasis, and inhibition of structural progression. Ixekizumab was well tolerated with no unexpected safety findings.

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DISCLOSURES: Dr Mease: Research Grants: AbbVie, Amgen, Biogen Idec, Bristol Myers Squibb, Celgene, Crescendo, Genentech, Janssen, Lilly, Merck, Novartis, Pfizer, UCB Pharma; Consultant: AbbVie, Amgen, Biogen Idec, Bristol Myers Squibb, Celgene, Covagen, Crescendo, Genentech, Janssen, Lilly, Merck, Novartis, Pfizer, UCB Pharma; Speaker: AbbVie, Amgen, Biogen Idec, Bristol Myers Squibb, Celgene, Crescendo, Genentech, Janssen, Lilly, Pfizer, UCB Pharma. Dr van der Heijde: Consultant: AbbVie, Amgen, Astellas, AstraZeneca, BMS, Celgene, Daiichi, Eli-Lilly, Galapagos, Merck, Novartis, Pfizer, Roche, Sanofi-Aventis, UCB Pharma Director of Imaging Rheumatology. Dr Ritchlin: Research Grants: AbbVie, Amgen, UCB Pharma; Consultant: AbbVie Amgen, Boehringer Ingelheim Eli Lilly, Novartis, and Sanofi. Dr Cuchacovich: Employee of Eli Lilly and Company at the time of study conduct. K Solotkin, C Shuler, Dr Lin, Dr Vangerow, Dr Samanta, and Dr Lee are employees of Eli Lilly and Company. Dr Gladman: Research Grants: AbbVie, Amgen, Celgene, Janssen, Novartis, UCB Pharma; Consultant: Abbvie, Amgen, BMS, Celgene, Eli Lilly, Novartis, Pfizer, UCB.

ADDITIONAL CONTRIBUTIONS: Millie Hollandbeck, ClinGenuity, medical writing assistance. LaShanda Gordon, ClinGenuity, editorial assistance.

PA-18: Efficacy and safety of minoxidil 2% solution in combination with a botanical hair solution in women with female pattern hair loss/androgenic alopecia

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BACKGROUND: Female pattern hair loss (FPHL), also known as androgenic alopecia (AGA), affects over 21 million women in the United States with devastating impacts on self-esteem and sociability. Topical Minoxidil 2% and 5% formulations are the only FDA-approved treatments for FPHL, however, patient adherence to the recommended treatment duration for monoxidil monotherapy is low due to the length of time it typically takes to observe initial benefit.

OBJECTIVE: A novel botanical hair solution, which alone has been shown to improve the appearance of thinning hair, was developed to be used in combination with traditional minoxidil monotherapy. Evaluate the safety and efficacy of a twice-daily regimen of 2% Minoxidil solution used in combination with botanical Revitalizing Hair Solution (RHS).

METHODS: The safety and efficacy of a twice-daily regimen of 2% Minoxidil solution used in combination with botanical Revitalizing Hair Solution (RHS) for 12 weeks in 54 subjects was evaluated in a multicenter, single-arm, open label study. Assessments included investigator and subject ratings of improvement and subject satisfaction.

RESULTS: Subject self-ratings showed significant satisfaction with hair appearance and overall improvement at 4, 6 and 12 weeks, relative to baseline ($P < .005$). Subjects indicated a high degree of satisfaction with the regimen.

LIMITATIONS: Small number of subjects included in study.

CONCLUSION: The investigator and subject assessed efficacy and satisfaction with this novel regimen provides clinicians with an effective treatment for FPHL that also provides a high level of patient acceptance, which may help promote treatment adherence.

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DISCLOSURES: Dr McMichael reports personal fees from Galderma, during the conduct of the study; personal fees from Johnson and Johnson, grants and personal fees from Samumed, grants and personal fees from Allergan, grants from Incyte , grants and personal fees from Procter and Gamble, outside the submitted work. E van Grote and Dr Meckfessel are employees of Galderma Laboratories, LP.
FUNDING: Study and poster support funded by Galderma Laboratories, LP.

PA-19: Efficacy and safety of minoxidil 5% foam in combination with a botanical hair solution in men with androgenic alopecia

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BACKGROUND: Androgenic alopecia (AGA) is the most common type of hair loss in men, characterized by hairline recession and vertex balding. AGA affects approximately 50% of men negatively affecting self-esteem and sociability.
OBJECTIVE: Topical minoxidil formulations are approved up to 5% concentration for men, however low patient adherence to the recommended duration of monoxidil use is common due to a perceived lack of initial benefit.
METHODS: A novel botanical hair solution, which alone has been shown to improve the appearance of thinning hair, was developed as part of a regimen with traditional minoxidil monotherapy. The safety and efficacy of a twice-daily regimen of 5% minoxidil foam used in combination with the botanical hair solution (BHS) was evaluated in a 12 week, multicenter, single-arm, open label study in 56 subjects with mild-to-moderate AGA. Assessments included investigator and subject ratings of improvement and subject satisfaction.
RESULTS: Investigator ratings showed significant improvement in scalp hair coverage and overall treatment benefits at 4, 6 and 12 weeks, relative to baseline ($P < .001$). Subject self-ratings showed significant satisfaction with improved hair appearance and overall improvement at 6 and 12 weeks, relative to baseline ($P < .002$).
CONCLUSION: The regimen was well tolerated, and subjects indicated a high degree of satisfaction. Investigator and subject-assessed efficacy and satisfaction with this novel regimen provides clinicians with an effective treatment for AGA that also provides a high level of patient acceptance, which may help promote treatment adherence.
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DISCLOSURES: Dr Keaney reports personal fees and other from Allergan, personal fees from L'Oreal/Skinceuticals, personal fees from Syneron Candela, personal fees from Restoration Robotics, non-financial support from Galderma, outside the submitted work. Dr Pham reports other from Nestlé SHIELD Center, during the conduct of the study; other from Galderma Laboratories, LP. E van Grote and Dr Meckfessel are employees of Galderma Laboratories, LP.
FUNDING: Study and poster support funded by Galderma Laboratories, LP.

PA-20: Efficacy and safety of sonidegib in patients with nevoid basal cell carcinoma syndrome

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BACKGROUND: Nevoid basal cell carcinoma syndrome (NBCCS), a rare autosomal dominant disorder caused by mutations in the hedgehog (Hh) pathway regulator PTCH1, typically is associated with multiple basal cell carcinomas (BCCs)—particularly in the head and neck region—the treatment for which often necessitates numerous surgeries.
OBJECTIVE: Here we describe the efficacy and safety of sonidegib, a systemic Hh pathway inhibitor (HPI), in patients with NBCCS treated in two double-blind, randomized phase 2 trials (NCT01350115 [A]; NCT01327053 [B; BOLT 18-month analysis; median follow-up, 26.3 months]).
METHODS: In trial A, patients with NBCCS with ≥2 BCCs were randomized 6:1 to sonidegib 400 mg daily or placebo for 12 weeks, followed by surgical excision of the target BCC or tumor-free area at Week 16. The primary endpoint, rate of clinical clearance of the main target BCC (assessed until Week 16), was met if the complete clearance rate was ≥50%. Histological clearance of target BCCs and change in BCC tumor burden in up to 20 BCCs were also assessed. In trial B, patients with advanced BCC were randomized 1:2 to sonidegib 200 mg or 800 mg daily. The primary endpoint, objective response rate (ORR; complete response [CR] + partial response [PR]; met if ≥30% in either arm), was assessed by central review using modified Response Evaluation Criteria in Solid Tumors (mRECIST [locally advanced BCC]) and RECIST 1.1 (metastatic BCC) criteria. Safety was assessed as mild/moderate/severe for >7 months after the last dose in A and per common terminology criteria for

adverse events 4.03 until 30 days after the last dose in B.
RESULTS: The primary endpoint was not met in A; however, all sonidegib-treated patients (n = 7) had clinical clearance of target BCCs: 43% complete (100% improvement), 43% marked (76-99%), and 14% moderate (26%-75%). In contrast, target BCCs worsened or showed slight clearance (1%-25%) with placebo (n = 2). Histological clearance was observed in 4/7 patients receiving sonidegib and median tumor burden was reduced (change from baseline in total volume tumor measurement was -95 mm3 and change in longest dimension was -63.6 mm in the sonidegib 400-mg group at Week 16). In patients receiving sonidegib with high tumor burden at baseline (>50 BCCs; n = 4), BCC number reduced after day 43 and decreased further beyond the treatment period. In B, ORR in patients treated with sonidegib 200 mg (n = 3) or 800 mg (n = 13) was 33% (1 PR) and 62% (1 CR, 7 PRs), respectively. Overall, safety was consistent with previous reports of sonidegib and other HPIs, with muscle spasms, myalgia, nausea, alopecia, and dysgeusia being the commonly reported adverse events.
CONCLUSION: Given the clinical benefit and manageable safety profile observed in these studies, treatment with sonidegib may be a promising nonsurgical option for patients with NBCCS.
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DISCLOSURES: Dr Lear reports grants and personal fees from Novartis, during the conduct of the study; grants and personal fees from Novartis, grants and personal fees from Bristol-Myers Squibb, grants and personal fees from Roche, grants and personal fees from GlaxoSmithKline, grants and personal fees from Merck, personal fees from Amgen, outside the submitted work. Dr Migden reports personal fees from Novartis, during the conduct of the study; personal fees from Novartis, personal fees from Genentech, personal fees from Lilly, outside the submitted work. Dr Guminski reports personal fees from Novartis, during the conduct of the study; personal fees from Novartis, personal fees from Bristol-Myers Squibb, outside the submitted work. Dr Dirix has nothing to disclose. Dr Chang reports grants and personal fees from Novartis, during the conduct of the study; grants and personal fees from Novartis, outside the submitted work. Dr Sellami reports personal fees from Novartis, during the conduct of the study; personal fees from Novartis, outside the submitted work. Dr Gutzmer reports personal fees from Novartis, during the conduct of the study; grants and personal fees from Novartis, grants and personal fees from Pfizer, grants and personal fees from Roche, grants from Johnson & Johnson, personal fees from BMS, personal fees from GlaxoSmithKline, personal fees from MerckSerono, personal fees from MSD, personal fees from Almirall, personal fees from Amgen, personal fees from Galderma, personal fees from Janssen, personal fees from Leo Pharma, personal fees from Boehringer Ingelheim, outside the submitted work. Dr Stingl has nothing to disclose. Dr Dummer reports grants and personal fees from Novartis, during the conduct of the study; grants and personal fees from Novartis, grants and personal fees from Bristol-Myers Squibb , grants and personal fees from Roche, grants and personal fees from GlaxoSmthKline, grants and personal fees from Merck , personal fees from Amgen, outside the submitted work.

PA-21: Efficacy of sonidegib in patients with metastatic basal cell carcinoma

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BACKGROUND: In the BOLT phase 2 study (Migden MR, Guminski A, Gutzmer R, et al. Treatment with two different doses of sonidegib in patients with locally advanced or metastatic basal cell carcinoma (BOLT): a multicentre, randomised, double-blind phase 2 trial. Lancet Oncol. 2015;16(6):716-728), the hedgehog (Hh) pathway inhibitor sonidegib demonstrated durable clinical benefit in patients with metastatic basal cell carcinoma (mBCC).
OBJECTIVE: Updated efficacy data collected up to 18 months after randomization of the last patient are reported (cutoff, July 11, 2014; median follow-up, 26.6 months).
METHODS: Patients with mBCC were randomized to receive sonidegib 200 mg (n = 13) or 800 mg (n = 23) daily. Objective response rate (ORR; complete response [CR] + partial response [PR]), duration of response (DOR), and progression-free survival (PFS) were assessed by central and investigator review using Response Evaluation Criteria in Solid Tumors v1.1.
RESULTS: Median baseline tumor burden in patients with mBCC was 4.6 cm (range, 1.5-14.6 cm), and most patients had >1 lesion at baseline. The most common sites of metastases were lung (71%, 200 mg; 52%, 800 mg) and bone (14%, 200 mg; 22%, 800 mg). ORRs (200 mg/800 mg) were 7.7%/17.4% as assessed by central review and 23.1%/34.8% by investigator review. Tumor shrinkage per central review was observed in 92% and 84% of patients in the 200 mg and 800 mg arms, respectively. Importantly, disease control rates; CR + PR + stable disease [SD]) following 200 mg/800 mg treatment were high (92.3%/91.3% as assessed by central review and 84.6%/82.6% by investigator review), PFS was indicative of treatment benefit (median PFS was 13.1 months per both central and investigator review for 200 mg, and 11.1 months and 14.3 months, respectively, for 800 mg) and tumor responses were durable. Median DOR per investigator review was 17.7 and 10.2 months in the 200 mg and 800 mg arms, respectively. Data from the BOLT primary analysis (cutoff, June 28, 2013) showed that both doses of sonidegib provided near-complete pathway inhibition (>98% decrease from baseline in GLI1 [biomarker for Hh pathway activity] levels) in patients with mBCC. Additionally, maintenance or improvement in quality of life (QoL) was reported in patients with mBCC treated with sonidegib 200 mg and 800 mg. Effi-

cacy results in BOLT are further supported by the phase 1 study (Rodon J, Tawbi HA, Thomas AL, et al. A phase I, multicenter, open-label, first-in-human, dose-escalation study of the oral smoothened inhibitor Sonidegib (LDE225) in patients with advanced solid tumors. Clin Cancer Res. 2014;20(7):1900-1909); of 6 patients with mBCC treated with daily doses of sonidegib ranging from 100-1500 mg, 3 had PRs, 2 had SD, and 1 patient had an unknown response.

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DISCLOSURES: Dr Morton reports personal fees from Novartis, during the conduct of the study; personal fees from Novartis, personal fees from Almirall, personal fees from GlaxoSmithKline, personal fees from Leo Pharma, personal fees from Biofrontera, outside the submitted work. Dr Migden reports personal fees from Novartis, during the conduct of the study; personal fees from Novartis, personal fees from Genentech, personal fees from Lilly, outside the submitted work. Dr Yi reports personal fees from Novartis, during the conduct of the study; personal fees from Novartis, outside the submitted work. Dr Mone reports personal fees from Novartis, during the conduct of the study; personal fees from Novartis, outside the submitted work. Dr Sellami reports personal fees from Novartis, during the conduct of the study; personal fees from Novartis, outside the submitted work. Dr Dummer reports grants and personal fees from Novartis, during the conduct of the study; grants and personal fees from Novartis, grants and personal fees from Bristol-Myers Squibb , grants and personal fees from Roche, grants and personal fees from GlaxoSmthKline, grants and personal fees from Merck, personal fees from Amgen, ouside the submitted work.

PA-22: Efinaconazole topical solution, 10%: efficacy in onychomycosis patients when co-existing tinea pedis is treated with luliconazole cream, 1%.

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BACKGROUND: The co-existence of onychomycosis and tinea pedis is commonplace in dermatology and podiatry practice. It is believed that when co-existing tinea pedis is treated cure rates in onychomycosis patients might be greater than in those patients where co-existing tinea pedis is not treated.

OBJECTIVE: To evaluate efficacy of efinaconazole topical solution, 10% in onychomycosis patients when co-existing tinea pedis is treated with luliconazole cream, 1%.

METHODS: An analysis of 1655 patients, aged 18-70 years, randomized to receive efinaconazole topical solution, 10% or vehicle from two identical multicenter, double-blind, vehicle-controlled 48-week studies evaluating safety and efficacy. The primary end point was complete cure rate (0% clinical involvement of target toenail, and both negative potassium hydroxide examination and fungal culture) at week 52. Efficacy was assessed in a subpopulation of patients where co-existing tinea pedis at baseline was treated with once-daily luliconazole cream, 1%, or another physician-preferred antifungal.

RESULTS: Overall, complete cure rates for efinaconazole were 18.5% (observed case, pooled data) at week 52 (Gupta AK, Elewski BE, Sugarman JL, et al. The efficacy and safety of efinaconazole 10% solution for treatment of mild-to-moderate onychomycosis: a pooled analysis of two phase 3 randomized trials. J Drugs Dermatol. 2014;13(7):815-820). At baseline, 340 (20.5%) patients were reported as having co-existing tinea pedis. Efinaconazole topical solution, 10% was significantly more effective than vehicle when treating onychomycosis in these patients ($P < .001$, all primary and secondary endpoints, week 52). Complete cure rates of 35.3% (observed case, pooled data) were reported at week 52 in those efinaconazole patients where co-existing tinea pedis was treated with luliconazole cream, 1%, compared with 25.0% when another antifungal was used.

LIMITATIONS: A post hoc analysis and includes a small cohort of patients who were treated with luliconazole cream, 1%. All of these patients were from Japan, where luliconaole was commercially available at the time of the study.

CONCLUSION: Treatment of co-existing tinea pedis in onychomycosis patients with luliconazole cream, 1% appears to enhance the efficacy of once daily topical efinaconazole topical solution, 10%.

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DISCLOSURES: Dr Kircik is an advisor, investigator, consultant or speaker for PharmaDerm, Merz and Valeant. Dr Olin is an employee of Valeant. Dr Goldenberg has no relevant disclosures.

PA-23: Evaluating optimal medium-term dosing strategy for adalimumab in patients with moderate-to-severe hidradenitis suppurativa based on analysis of integrated results from the PIONEER I and II, phase 3, randomized, placebo-controlled trial

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BACKGROUND: This analysis reports integrated data from the PIONEER I & II phase-3 trials evaluating safety and efficacy of adalimumab for patients with moderate-to-severe hidradenitis suppurativa (HS).

OBJECTIVE: To evaluate optimal medium-term dosing strategy for adalimumab in patients with moderate–to-severe HS.
METHODS: Each study had 2 placebo-controlled, double-blind periods. 12-Week Period-A: 1:1 randomization to 40 mg adalimumab weekly (ew) or placebo (pbo) and 24-Week Period-B: at Week-12, 1:1:1 re-randomization of Period-A adalimumab patients to 40 mg adalimumab weekly (ew/ew), every-other-week (ew/eow), or placebo (ew/pbo), stratified by the primary endpoint of HS Clinical Response (HiSCR: ≥50% reduction in abscess and inflammatory nodule [AN] count with no increase in abscess or draining fistula counts) at Week-12, and by baseline Hurley Stage (II vs III). Early escapes were allowed, and those patients were treated as nonresponders.
RESULTS: The integrated HiSCR rate entering Period-B (Week-12) was 53.0% (ew/pbo), 51.5% (ew/eow), and 53.5% (ew/ew), and at Week-36, 28.0% (ew/pbo), 30.7% (ew/eow), and 43.4% (ew/ew). In Period-B, the serious adverse event rate was 2.0% (ew/pbo), 5.0% (ew/eow), and 3.0% (ew/ew).
CONCLUSION: Greater response rates with weekly dosing combined with similar safety across the 3 treatment arms suggest that adalimumab 40 mg weekly is the optimal medium-term dosing strategy in HS during the 36-week observation period.
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DISCLOSURES: Dr Kimball received honoraria as a consultant and grants as an investigator for Janssen, AbbVie, Amgen, and Novartis and has received fellowship funding from Janssen. Dr Jemec received honoraria from AbbVie, Pfizer and MSD for participation on advisory boards, and grants from Leo Pharma, Actelion, Janssen-Cilag for participation as an investigator. Dr Armstrong receives grants as investigator to AbbVie, Amgen, Janssen, Lilly, Celgene, and Pfizer, and as a consultant to AbbVie, Amgen, Janssen, Merck, Lilly, Celgene, and Pfizer. Dr Forman received grants from AbbVie, AstraZeneca, Janssen, Novartis, Promius, and Regeneron for research; honoraria from AbbVie for speaker services; and honoraria from Galderma for consultation services. Y Gu and Dr Williams receive a salary as employees of AbbVie and may also receive AbbVie stock, stock options and/or stock grants. Dr Okun is a former employee of AbbVie and is now affiliated with Fort HealthCare.
FUNDING: AbbVie Inc funded this study and participated in the study design; study research; collection, analysis and interpretation of data; and writing, reviewing and approving of this publication. All authors had access to the data, and participated in the development, review, and approval, and in the decision to submit this publication.

PA-24: Frequencies of dermatological procedures performed at an academic family medicine residency in New York City

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BACKGROUND: Between 8.4% and 36.5% of patients presenting to primary care practices present with at least least one dermatological health concern, and of those, for the majority it is their chief complaint. Surprisingly, despite the high volume of patients presenting with dermatological concerns at primary care sites, there has been notable lack of research on the prevalence of specific dermatological diagnoses or procedures in primary care in general, and particularly at academic health centers.
OBJECTIVE: This study seeks to provide further understanding of the frequencies of dermatological procedures performed as part of clinical care in a skin procedures clinic that involves educational precepting at an academic Family Medicine primary care site in New York City.
METHODS: Data were collected by analyzing CPT codes for procedures performed during Friday afternoon skin clinic at the Herman "Denny" Farrell, Jr. Community Health Center, which is the primary clinical site of the Family Medicine Residency at New York Presbyterian Hospital-Columbia University Medical Center. CPT codes from billing data from July 1, 2014 to June 30, 2015 were collected, then the frequencies of specific dermatologic procedures were calculated along with their corresponding ICD-9 diagnoses.
RESULTS: Over the study period analyzed, 97 dermatological procedure encounters were identified. Skin biopsy (28%), destruction of premalignant lesion (27%), and skin tag removal (26%) were nearly equal in frequency, followed by I&D of abscess or cyst (14%), intralesional injection (3%), and treatment of superficial wound (2%). The most common diagnoses were "other hypertrophic/atrophic condition of skin" (26%), warts (15%), seborrheic keratosis (14%), "other specific disorder of skin" (14%), and infectious cause (9%).
LIMITATIONS: These results only reflect a portion of dermatological procedures performed at the health center during a Friday skin clinic, but do not include all procedures performed for the year. Also, the frequency of of a given procedure likely varies from year to year at this site, and likely differs from other primary care sites. Finally, the results are limited by the limited number of CPT codes available, resulting in lower specificity for procedures.
CONCLUSION: A substantial number of dermatological procedures were performed by residents with attending supervision in the skin clinic over a one-year period. Dermatological conditions are common in primary care settings, and there is little research on the teaching of diagnoses and procedural training for family medicine residents. Future research is needed to better evaluate the teaching of skills to family medicine residents in diagnosing, treating, and perform procedures for dermatological conditions.
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DISCLOSURES: The authors have nothing to disclose.

PA-25: Immediate and long-term effects of a topical serum with five forms of hyaluronic acid on facial wrinkles and intrinsic skin moisture content

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BACKGROUND: The appearance of lines or wrinkles is one of the most prominent signs of skin aging that results from structural changes caused by intrinsic and environmentally-induced factors. The skin's hyaluronic acid (HA) content starts to decrease in as early as twenty years of age and is reduced to half by the age of fifty. Clinical manifestations of this reduction in HA levels include a diminished endogenous skin moisturizing capacity and the appearance of fine lines and wrinkles.
OBJECTIVE: In this study we evaluated the efficacy of a novel topical formulation (HA5) containing a blend of five forms of hyaluronic acid, polysaccharides and plant-derived stem cells extract to provide instant and long-term improvement in skin texture as well as skin moisturization.
METHODS: The immediate and long-term effects of HA5 formulation were evaluated in an open-label, single-center clinical study. 24 subjects (35-65 years old) with Fitzpatrick Skin Types II-IV completed the study. All subjects presented with mild to severe periocular lines/wrinkles. Subjects applied the HA5 twice daily (morning and evening) after cleansing. Investigator assessments for fine (periocular, perioral, forehead) lines/wrinkles, coarse (periocular, forehead) lines/wrinkles, overall skin appearance, and tactile roughness were conducted at baseline(within 15 minutes postapplication) and at weeks 1, 4 and 8. Standardized digital photography, three-dimensional images and corneometer measurements were taken at all visits. Subjects completed a self-assessment questionnaire at all follow-up time points.
RESULTS: Statistically significant reductions in mean scores for overall skin appearance, tactile roughness, fine (periocular, perioral, forehead) lines/wrinkles, coarse (periocular, forehead) lines/wrinkles were observed immediately after application of HA5 (all $P \leq .03$, student's paired t-test). Significant improvement in overall skin appearance, fine (periocular, forehead) lines/wrinkles, coarse (periocular, forehead) lines/wrinkles, and tactile roughness (all $P \leq .04$) were observed at weeks 1, 4 and 8. These observations were validated by the high ratings in self-perceived efficacy from the subject questionnaires, increases in corneometer values and standardized digital photography.
LIMITATIONS: Limitations of this study are the smaller sample size and the open-label design.
CONCLUSION: Overall, the results from this study suggested that HA5 formulation provided both immediate and long-term improvements in skin texture minimizing the appearance of fine and coarse lines/wrinkles and improving intrinsic skin moisture content.
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DISCLOSURES: The authors are paid employees of the sponsor company, SkinMedica, Inc, an Allergan Company.

PA-26: Improved rosacea-associated quality of life is reported by subjects in a long-term use study of once-daily brimonidine gel 0.33% that decreased basal erythema levels

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BACKGROUND: Rosacea has a variety of potential clinical manifestations that vary in presentation and magnitude among different patients but the central diagnostic feature is diffuse central-facial erythema, which persists to varying degrees and increases in intensity during a flare. Other cutaneous signs such as telangiectasia, papules, and pustules may also be present.
OBJECTIVE: Investigate safety and efficacy of 12 months of once-daily topical brimonidine gel 0.33% for facial erythema of rosacea treatment. Compare pre- and posttreatment subject social life questionnaire responses. Observe treatment effect on pre-application erythema and telangiectasia.
METHODS: Once daily application of topical brimonidine gel 0.33% was investigated in a 12 month open-label, 27 center US study of moderate-to-severe erythema of rosacea. There were no facial lesions of rosacea or concomitant medication restrictions. Pre-application erythema and telangiectasia severity were assessed at baseline, week 1, and months 1, 3, 9, and 12. Social life impact questionnaires were completed at baseline and every third month.
RESULTS: Two-hundred and seventy-nine subjects completed the study. Compared to baseline, one-grade pre-application erythema improvements were 69.6% (Patient's Self-Assessment) and 66.0% (Clinician's Erythema Assessment). At study end, 44.0% of subjects exhibited one-grade improvement in pre-application telangiectasia compared to baseline. Social life impact questionnaire responses indicated that treatment improved subject perception of social life impact of rosacea.
CONCLUSION: Pre-application erythema severity was lower after 12 months of study treatment in subjects with moderate-to-severe erythema of rosacea. Telangiectasia scores also improved and fewer patients reported negative social life impact compared to baseline.
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DISCLOSURES: Dr Weiss reports grants from Galderma Laboratories, during the conduct of the study; grants from Allergan, personal fees from Galderma, grants from Intrepid, grants from Sebacia, grants and personal fees from Valeant, outside the submitted work. Dr Schaefer reports other from Galderma R&D,

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PA-27: Long-term safety of crisaborole topical ointment, 2%, in children and adults with mild-to-moderate atopic dermatitis

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BACKGROUND: Atopic dermatitis (AD) is a chronic inflammatory skin disease that often requires long-term topical treatment. Unfortunately over the past 15 years topical therapies have not changed and are associated with potential safety concerns. Crisaborole Topical Ointment, 2% (Anacor Pharmaceuticals, Inc, Palo Alto, CA), a novel nonsteroidal, topical, anti-inflammatory phosphodiesterase 4 (PDE4) inhibitor, is currently being investigated for the treatment of mild-to-moderate AD.
OBJECTIVE: To investigate the long-term safety of Crisaborole Topical Ointment, 2%, in an open-label extension study in patients as young as 2 years of age with mild-to-moderate AD.
METHODS: After completing a 28-day Phase 3 pivotal study (NCT02118766, NCT02118792), patients who opted to continue treatment enrolled in a multicenter, long-term (48-week), open-label safety study. Every 4 weeks patients were assessed for AD severity using the Investigator's Static Global Assessment (ISGA) scale and were treated with 4-week cycles of crisaborole as needed. Investigators initiated each On-Treatment Period based on severity of AD (ISGA ≥2 [Mild]). Safety measures included assessment of local tolerability, adverse events (AEs), serious adverse events (SAEs), physical examinations, vital signs, and clinical laboratory results.
RESULTS: With a target of 500 patients, the study enrolled 517 patients (mean age: 11.7 years). During the open-label extension and the pivotal studies, at least 1 treatment-emergent AE (TEAE) was reported by 65% of patients; most of these were considered unrelated to treatment (93.1%) and mild (51.2%) or moderate (44.6%) in severity. Treatment-related AEs were observed in 10.2% of patients; the most frequently reported events were atopic dermatitis (3.1%), application site pain (burning/stinging, 2.3%), and application site infection (1.2%). None of 9 treatment-emergent SAEs (7 of which occurred in the extension study) were considered treatment-related. During the long-term study, 33 patients (6.4%) interrupted or discontinued treatment because of TEAEs, although only 9 patients (1.7%) discontinued the study because of TEAEs. Review of the clinical laboratory and vital sign results did not identify any safety signals. No cutaneous adverse reactions such as application site atrophy, hypopigmentation, or telangiectasia were reported. The safety profile of crisaborole was similar across age groups.
LIMITATIONS: This study did not include a vehicle-controlled analysis of long-term safety.
CONCLUSION: Long-term treatment of patients with mild-to-moderate AD aged 2 years or older with Crisaborole Topical Ointment, 2%, demonstrated a favorable safety profile.
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DISCLOSURES: L Eichenfield has served as consultant to Anacor. R Call has served as consultant for Anacor. D Forsha has nothing to disclose. J Fowler has received research grants from Anacor. A Hebert has served on advisory boards and as investigator for Anacor. M Spellman is an employee of Anacor. L Stein Gold has served on advisory boards for Allergan, Anacor, Galderma, Leo, Lilly, Novartis, Pfizer, Taro, and Valeant; as speaker for Allergan, Galderma, Leo, Novartis, Taro, and Valeant; and as medical/legal advisor for Roche. M Van Syoc is an employee of Anacor. L Zane is an employee of and holds stock/stock options in Anacor. E Tschen has served as investigator for Anacor.

PA-28: Maintenance of efficacy results from UNCOVER-1: a phase 3 trial of ixekizumab for moderate-to-severe plaque psoriasis

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BACKGROUND: IL-17A plays a key role in the pathogenesis of psoriasis.
OBJECTIVE: The objective of this study was to evaluate the safety and optimal dosing interval for ixekizumab, an anti-IL¬-17A monoclonal antibody, in the maintenance of response dur-

ing an additional 48 weeks of blinded treatment among patients who achieved an sPGA 0/1 following 12 weeks of induction therapy.

METHODS: In this trial, 1296 patients were randomized to receive subcutaneous placebo (n = 431), or a single injection of 80 mg ixekizumab every 2 (IXE Q2W; n = 433) or 4 weeks (IXE Q4W; n = 432) following a 160-mg starting dose at Week 0. At Week 12, ixekizumab-treated patients who achieved sPGA 0/1 were re-randomized to receive placebo (n = 226), 80 mg ixekizumab every 4 (IXE Q4W; n = 229) or 12 weeks (IXE Q12W; n = 227). Patients in any treatment arm who did not achieve sPGA 0/1 at Week 12 received IXE Q4W through Week 60. Comparisons were done using logistic regression analysis. For response analyses, missing data was imputed using nonresponder imputation method.

RESULTS: At Week 60, sPGA 0/1 was maintained in 72.9%, 37.4%, and 7.5% of patients in the IXE Q4W, Q12W, and placebo groups, respectively ($P < .001$ for each comparison vs placebo). Complete resolution of psoriasis (PASI-100) was achieved at Week 60 by 52.0%, 20.3%, and 2.7% of patients in the IXE Q4W, Q12W, and placebo groups, respectively ($P < .001$ for each comparison vs placebo). Exposure-adjusted, serious adverse event (SAE) rates (per 100 person-years) in the re-randomized population were 8.0, 5.8, and 6.8 in the IXE Q4W, Q12W, and placebo groups, respectively. By comparison, SAE rates at Week 12 were 6.0, 12.2, and 5.2, for IXE Q2W, Q4W, and placebo groups, respectively.

LIMITATIONS: A limitation of the trial was the lack of an active comparator group.

CONCLUSION: IXE Q4W was effective at maintaining sPGA 0/1 over 60 weeks, and over 50% of patients achieved complete resolution of their psoriasis by Week 60. These results provide further evidence for the long-term effectiveness of ixekizumab. The exposure-adjusted SAE rates in patients re-randomized to the Q4W dose were comparable in the maintenance period through Week 60 relative to the 12-week induction period.

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PA-29: Optimized acne treatment for adolescent student athletes

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BACKGROUND: Athletic participation can aggravate or increase the risk of developing acne, especially among adolescent athletes. Furthermore, certain treatment resistant acne subtypes are common among athletes. Prompt, effective treatment and good treatment adherence are vital to avoid the significant long term consequences of untreated acne.

OBJECTIVE: Unfortunately, many current acne treatments are associated with side effects that may be aggravated by athletic activity and that may reduce treatment adherence and considerably increase an athlete's risk of injury. Furthermore, adolescent athletes often have rigorously busy schedules that may interfere with adherence to treatment regimens. Thus, treatment strategies optimized for athletes must minimize side effects and be easy to use without interfering with sports participation.

METHODS: This review discusses the unique challenges and considerations of acne and acne therapy in adolescent athletes.

RESULTS: The pathophysiology and consequences of acne, sports specific acne subtypes, and sports related environmental and dietary triggers are presented. Acne treatment strategies and sports specific concerns associated with each treatment are presented in detail. Finally, we present a safe, tolerable, and efficacious acne treatment regimen for adolescent athletes comprised of cleansing, medicating, moisturizing, and photoprotection elements (referred to as the CoMMPlete regimen).

LIMITATIONS: More studies and larger populations of both male and female athletes are needed.

CONCLUSION: An 8 week study of student athletes 12 to 18 years of age with mild-to-moderate acne found that the CoMMPlete regimen (adapalene and benzoyl peroxide (A/BPO) gel, 0.1%/2.5%, Cetaphil® DermaControl™ Foam Wash and Cetaphil® DermaControl™ Moisturizer SPF 30) found that the regimen was safe, well tolerated, and helped optimize treatment outcomes in athletes.

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DISCLOSURES: Dr Adams received honoraria as a consultant and advisory board member for Galderma and Mission. Dr Lain reports personal fees from Galderma, during the conduct of the study; personal fees from Allergan, outside the submitted

work. Dr York reports other from Galderma Laboratories, LP, during the conduct of the study. MJ Rueda is an employee of Galderma Laboratories.

PA-30: Overview of a two-step skincare regimen designed to protect hands from external irritants

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BACKGROUND: Irritant contact dermatitis on the hands is a common condition in patients with occupational jobs. Frequent hand washing, contact with harsh chemicals, or alcohol-based disinfectants are frequent in this population. Management strategies are often inadequate and may lead to painful irritation resulting in loss of work and productivity.
OBJECTIVE: Show this regimen effectively minimizes irritation due to external insult.
METHODS: Various
RESULTS: Clinical studies conducted on this regimen show that it effectively minimizes irritation due to external insult. When the volar forearms of subjects were irritated twice-daily with 0.5% sodium lauryl sulfate, the regimen effectively minimized irritation and barrier disruption whereas sites treated with petrolatum or untreated did not. Additional studies of the protect cream alone demonstrate that it improves skin barrier function and reduces sweating under occlusive gloves and will not interfere with alcohol disinfection.
CONCLUSION: The results of these studies indicate that this skincare regimen is an effective tool for patients with occupational jobs who may be prone to irritant contact dermatitis. A summary of these clinical studies is presented in this poster.
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DISCLOSURES: Dr Palaniswamy and Dr Meckfessel are employees of Galderma Laboratories.
FUNDING: This study and poster were funded by Galderma Laboratories.

PA-31: Pilot study: protective effects against infrared radiation-induced heat from a proprietary blend of antioxidants with sunscreen

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BACKGROUND: Chronic sun exposure results in the appearance of photodamaged skin, characterized by the presence of wrinkles, pigmentation irregularities and loss of firmness. Historically, UVA and UVB wavelengths were the primary focus of preventing premature photodamage. However, recent research on other solar wavelengths such as infrared radiation (IR), have also shown contributory damaging effects on the skin. Exposure to direct sunlight causes skin temperature to rise to approximately 40°C, resulting from the conversion of IR to heat. The resulting IR-induced heat has been shown to cause disruption to the dermal extracellular matrix, inflammation, and other changes that contribute to accelerated skin aging.
OBJECTIVE: To provide protection beyond UVA and UVB wavelengths, a novel topical product (TD+R) containing a proprietary blend of antioxidants with sunscreen actives was developed. A pilot study was conducted to assess the protective effects of this product against skin temperature increases induced by IR exposure.
METHODS: Five subjects aged 52-60 years with Fitzpatrick Skin Types II-III were enrolled and completed the study. Two sites (untreated control and TD+R) were randomly assigned to designated locations on the back. TD+R was applied 15 minutes prior to IR exposure. Subjects were positioned 33cm away from the source of IR (Hydrosun® 750; Hydrosun GmbH, Mullheim, Germany). Sites received an emission wavelength range of 760nm to 1400nm and were exposed for 150 minutes. During this time period, skin temperature and infrared thermograph images were taken in 30 minute increments.
RESULTS: Mean skin temperature of test sites treated with TD+R was consistently lower than untreated at all follow-up time points (30, 60, 90, 120 and 150 minutes). At 90 minutes, TD+R treated sites had significantly lower skin temperatures than untreated sites ($P < .039$).
LIMITATIONS: Limitations of this study are the smaller sample size. Additional larger studies are needed to confirm results.
CONCLUSION: Results from this pilot study suggest that TD+R may help protect against IR-induced heat accumulation in the skin.
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DISCLOSURES: Authors are paid employees of the sponsor company, SkinMedica, Inc, an Allergan Company.

PA-32: Progression of hidradenitis suppurative: outcomes of placebo-treated patients in a phase 3, randomized, placebo-controlled trial (PIONEER II)

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BACKGROUND: Hidradenitis suppurativa (HS) is a chronic, painful skin disorder characterized by inflammatory skin lesions.
OBJECTIVE: This prespecified analysis evaluated progression of untreated HS among patients (pts) receiving placebo (PBO) continuously during a 36-week clinical trial.
METHODS: PIONEER II was a phase 3, multicenter, random-

ized, double-blind trial that enrolled adults with at least 1-year history of moderate-to-severe HS. Pts were randomized to adalimumab (ADA) 40 mg weekly or PBO for 12 weeks, and ADA pts were re-randomized to ADA weekly, ADA every other week, or PBO, while PBO pts received PBO, from weeks 12 up to 36. Use of a concomitant stable dose of doxycycline or minocycline was permitted. Primary efficacy endpoint was proportion of pts who achieved HS clinical response (HiSCR; ≥ 50% reduction in inflammatory lesion count (total abscesses and inflammatory nodules [AN] counts) with no increase in abscess/draining fistulas counts relative to baseline [BL]) at 12 weeks. Pts who achieved HiSCR at week 12 and experienced a loss of response (LOR; loss of 50% of improvement from BL to week 12) after week 12 and pts who failed to achieve HiSCR at week 12 and experienced worsening or absence of improvement (WOAI; AN count ≥ AN count at BL on 2 consecutive visits) after week 16 were discontinued from study and could enter an open-label extension study to receive ADA 40 mg weekly. This prespecified analysis reports the rates of LOR and WOAI.

RESULTS: Discontinuation rates for pts randomized to weekly ADA were 4.9% (8/163) at 12 weeks and 45.1% (23/51) at 36 weeks, and for PBO 7.36% (12/163) at Week 12 and 73.5% (111/151) at Week 36. Most frequently reported reason for discontinuation was LOR or WOAI. At week 12, 27.6% (45/163) of pts in PBO group achieved HiSCR. This rate decreased to 15.9% (24/151) at week 36. 32 pts randomized to PBO continued BL antibiotics in first 12 weeks, of which 7 (21.9%) achieved HiSCR. AN counts increased for a substantial proportion of PBO-treated pts during weeks 12 to 36; subsequently, rates of LOR and WOAI increased with each visit after week 12 to 12.6% and 43.0%, respectively, at week 36.

CONCLUSION: Pts who received PBO during this 36-week study experienced progression of HS, as indicated by increased AN counts and high rates of LOR and WOAI. Without early study discontinuation and receiving active treatment, further progression may have been reported.

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DISCLOSURES: Dr Kimball received honoraria as a consultant and grants as an investigator for Janssen, AbbVie, Amgen, and Novartis and has received fellowship funding from Janssen. Dr Jemec received honoraria from AbbVie, Pfizer and MSD for participation on advisory boards, and grants from Abbvie, Leo Pharma, Actelion, Janssen-Cilag, and Novartis for participation as an investigator, and received speaker honoraria from AbbVie, Galderma, Leo Pharma and MSD. He has furthermore received unrestricted research grants from AbbVie and Leo Pharma.
Y Gu and Dr Teixeira receive a salary as employees of AbbVie and may also receive AbbVie stock, stock options and/or stock grants. Dr Brooks is a former employee of AbbVie Inc and may own stock and/or stock options.

FUNDING: AbbVie Inc funded this study and participated in the study design; study research; data collection, analysis and interpretation of data; and writing, reviewing and approving this abstract for presentation. All authors had access to the data, and participated in the development, review, and approval of the abstract, and ultimately in the decision to submit this abstract.

PA-33: Randomized, double-blind, split-face study to compare the irritation potential of two topical acne formulations over a 21-day treatment period

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BACKGROUND: The use of fixed combinations in acne vulgaris (acne) is very common, however comparative clinical trial data are limited. Cutaneous tolerability can influence patient compliance, and concerns about skin irritation with topical acne treatments have lead to a number of comparative split-face studies. These studies confirm that fixed combinations of benzoyl peroxide (BP) with clindamycin (clin) may be better tolerated than those with BP and adapalene (adap).

METHODS: Recently, a new fixed combination product was introduced (clin-BP 3.75% gel) that was shown to be effective in reducing both inflammatory and noninflammatory lesions in moderate and severe acne. Here we assess its tolerability compared with adap-BP 2.5% gel in healthy volunteers with no apparent facial redness or dryness over 21-days, using a split-face methodology.

RESULTS: Cumulative irritation was higher with adap-BP 2.5% gel than clin-BP 3.75% gel with statistically significant differences in all parameters, starting as early as day 8 (dryness) and day 9 (erythema) through to study end (day 22). The composite irritation index AUC was significantly lower for clin-BP 3.75% gel ($P < .001$) and more patients perceived clin-BP 3.75% gel as producing less irritation. Transepidermal water loss was markedly less with clin-BP 3.75% gel, although the differences were not statistically significant.
LIMITATIONS It is not possible to assess the relative contributions of each of the monads.

CONCLUSION: Clin-BP 3.75% gel appears to be better tolerated than adap-BP 2.5% gel based on this split-face study.

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DISCLOSURES: Dr Kircik is an advisor, investigator, consultant or speaker for PharmaDerm, Merz and Valeant. Drs Pillai, Bhatt and Ms Martin are employees of Valeant Pharmaceuticals North America LLC.

PA-34: Regression analysis of local skin responses to predict clearance of actinic keratoses on the face in patients treated with ingenol mebutate gel

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BACKGROUND: Ingenol mebutate gel is a topical field-treatment for actinic keratosis (AK) that elicits application site reactions in most patients.
OBJECTIVE: This analysis explores the relationship between the severity of the local skin reactions (LSRs) and efficacy, as expressed by percentage reduction from baseline of AKs.
METHODS: The analysis included 218 subjects from two of the pivotal Phase 3 trials with ingenol mebutate gel, 0.015%, who were treated for AK on the face. Subjects had 4-8 AKs within a 25 cm2 area and were treated with ingenol mebutate gel, 0.015%, once daily for 3 days. Severity of LSRs was assessed on days 4, 8, 15, 29, and 57. Efficacy was assessed on day 57. Erythema, flaking/scaling, crusting, swelling, pustulation/vesiculation, and erosion/ulceration (LSRs) were assessed on a 5-point scale from 0 to 4 yielding a maximum composite score of 24. The analysis models the AK count at day 57 with the LSR score on day 4 for each subject as independent variable. A negative binomial regression was applied for modeling subjects' 8 week AK count with the number of baseline lesions as offset variable and anatomic location and study site as explanatory factors. This extension of the Poisson regression model for over-dispersed count outcomes is used to account for a correlation in clearance between AK lesions within a subject. The expected percent reduction in AK count across 57 days can be derived from this model. The modeling results were used to calculate 90% prediction interval for the AK reduction as a function of the composite LSR score.
RESULTS: Composite LSR scores assessed on day 4 were predictive of efficacy. For example, at a composite score of 10, the model predicts that the subject was 90% certain to experience at least 50% reduction in the lesion count. Higher LSRs predicted greater rates of response. At low scores, the LSR had no predictive value, ie, it neither predicted treatment success nor treatment failure.
LIMITATIONS: This analysis was only completed for patients who treated the face and not additional patients with AK on other body sites.
CONCLUSION: Composite LSR scores were predictive of efficacy at high scores and had little predictive power at low scores.
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DISCLOSURES: Dr On has nothing to disclose. Dr Knudsen reports being an employee of LEO Pharma. Dr Skov reports being an employee of LEO Pharma. Dr Lebwohl reports other from Amgen, other from Anacor, other from Aqua, other from Canfite Biopharma, other from Celgene, other from Clinuvel, other from Coronado Biosciences, other from Ferndale, other from Lily, other from Jassen Biotech, other from LEO Pharmaceuticals, other from Merz, other from Novartis, other from Pfizer, other from Sandoz, other from Valeant, outside the submitted work; (Other; research funds).

PA-35: Relationship between severity of the local skin response (LSR) and the rate of LSR resolution in patients treated with ingenol mebutate gel

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BACKGROUND: The time course of the local skin reponse has not been evaluated in relation to its severity.
OBJECTIVE: This analysis evaluated the relationship between the severity of reactions at their peak and speed of their resolution.
METHODS: For face and scalp locations, results from two pivotal phase 3 trials were included in the analysis. A total of 218 subjects were treated for AKs on the face, and 56 subjects were treated for AKs on the scalp. For trunk and extremity locations, results from two pivotal phase 3 studies were included in the analysis. A total of 209 subjects were treated for AKs on the trunk and extremities. All subjects had 4-8 AKs within a 25-cm2 area and were treated with ingenol mebutate gel, 0.015%, once daily for 3 consecutive days (face/scalp) or ingenol mebutate gel, 0.05%, once daily for 2 consecutive days (trunk/extremities). Local skin reactions (LSRs) were assessed on days 3 or 4 (1 day after the last application), 8 (week 1), 15 (week 2), 29 (week 4), and 57 (week 8). LSRs, which include erythema, flaking/scaling, crusting, swelling, pustulation/vesiculation, and erosion/ulceration, were assessed on a 5-point scale from 0 to 4 yielding a maximum composite score of 24. A simple regression model was used to predict the week 1, 2, 4, and 8 composite LSR scores from the composite LSR score at the day after the last administration.
RESULTS: The composite LSR score on the day after the last application is an important predictor of the resolution of LSRs. For example, among those treated on the face, a high initial composite LSR score of 21 at day 4 is predicted to decrease to 13.0 at 1 week, 3.9 at 2 weeks, 2.1 at 4 weeks, and 1.2 at 8 weeks. An intermediate initial LSR composite score of 10 is predicted to decline to 6.2, 1.8, 1.0, and 0.6, respectively, and a low initial LSR composite score of 5 is predicted to drop to 3.1, 0.9, 0.5, and 0.3, respectively. Similar patterns were seen in the scalp and the trunk and extremities populations. The percentage reduction in composite LSR scores from day 3 or 4 to weeks 1, 2, 4, and 8 was the same across all 3 groups (low, medium, and high composite LSR score at day 4) and specific for each of the 3 anatomic locations.
LIMITATIONS: Individual results may vary, as the model prediction limits are at 90%.
CONCLUSION: The absolute reduction in LSR score is proportional to the composite LSR score on the day after the last application. A brisk initial reaction is followed by rapid healing, so that all patients are expected to have minimal LSR scores at two weeks on the face and scalp and at 4 weeks on the trunk and extremities.
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DISCLOSURES: Dr On has nothing to disclose. Dr Knudsen reports being an employee of LEO Pharma. Dr Skov reports being an employee of LEO Pharma. Dr Lebwohl reports other from Amgen, other from Anacor, other from Aqua, other from Canfite Biopharma, other from Celgene, other from Clinuvel, other from Coronado Biosciences, other from Ferndale, other from Lily, other from Jassen Biotech, other from LEO Pharmaceuticals, other from Merz, other from Novartis, other from Pfizer, other from Sandoz, other from Valeant, outside the submitted work; (Other; research funds).

PA-36: Rosacea subjects' perception of doxycycline modified release treatment using the visual analog scale

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BACKGROUND: Rosacea remains one of the most common dermatological diseases. Many patients with rosacea report that it affects their social and professional interactions.
OBJECTIVE: While these perceptions have been well described, little emphasis has been given towards how to adequately assess them as patient reported outcomes (PROs) in clinical trials.
METHODS: This open label study evaluated one of the more common patient reporting assessments, the visual analog scale (VAS), in adult rosacea subjects receiving doxycycline modified release (MR) for 12 weeks.
RESULTS: The subject's perception of the severity of rosacea, measured by mean VAS score, decreased with doxycycline MR treatment during the 12 weeks. Also, most subjects had a patient's global assessment (PGA) and an investigators' global assessment (IGA) score of clear or near clear by week 12 with doxycycline MR treatment. Most subjects responded they were satisfied with doxycycline MR treatment for rosacea. The decrease in the RosaQoL© score also reflected this. Similarly, a video content analysis of subjects' transcripts showed a significant increase in the number of positive words recorded from the start of the study to week 12. Most adverse events (AEs) reported were mild or moderate in severity and the most common AEs reported were vomiting, diarrhea, and cough.
CONCLUSION: Overall, doxycycline MR was safe, well tolerated, and had a favorable profile for treatment of rosacea by subjects in this study.
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DISCLOSURES: Dr Herndon has nothing to disclose. Dr Winkelman was employeed by Galderma Laboratories, LP during the conduct of this study. Dr Rueda is an employee of Galderma Laboratories, LP.
FUNDING: This study and poster were funded by Galderma Laboratories, LP.

PA-37: Safety and efficacy of adalimumab in combination with different doses of methotrexate in patients with psoriatic arthritis: subanalysis of ADEPT

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BACKGROUND: The ADEPT study demonstrated that adalimumab (ADA) treatment reduced disease activity in patients (pts) with psoriatic arthritis (PsA; Mease PJ, Gladman DD, Ritchlin CT, et al; Adalimumab Effectiveness in Psoriatic Arthritis Trial Study Group. Adalimumab for the treatment of patients with moderately to severely active psoriatic arthritis: results of a double-blind, randomized, placebo-controlled trial. Arthritis Rheum. 2005;52(10):3279-3289).
OBJECTIVE: This post hoc analysis explored the safety and skin efficacy of ADA in combination with methotrexate (MTX) in pts with PsA in ADEPT.
METHODS: ADEPT (NCT00646386) was a 24-week randomized placebo (PBO)-controlled study of ADA 40 mg every other week in pts with moderate-to-severe PsA. Randomization was stratified by MTX use (yes/no) and extent of psoriasis (PsO; <3% or ≥3% of body surface area [BSA]). For this analysis, pts were grouped by baseline MTX (low-dose, ≤15 mg/wk; high-dose, >15 mg/wk). Efficacy endpoints were changes in PsO Area and Severity Index (PASI) response rates in pts with ≥3% affected BSA at baseline (nonresponder imputation). Adverse events (AEs) were monitored and reported as events per 100 pt-years (E/100PY).
RESULTS: Of the 162 pts randomized to PBO and 151 randomized to ADA, 70 (43%) and 70 (46%), respectively, were taking MTX and had ≥3% BSA involvement at baseline. Overall, PASI-50/75/90 response rates were significantly higher with ADA vs PBO ($P < .001$) at Weeks 12 and 24 regardless of MTX dose. PASI-50/75/90 response rates with ADA at Week 24 were 100/92/75% in the low-dose MTX subgroup (n = 12), 82/65/41% in the high-dose MTX subgroup (n = 17), and 63/46/32% in the ADA-only (n = 41) subgroup. AE rates were highest among pts taking high-dose MTX for both PBO (915 E/100PY) and ADA (1028 E/100PY) arms. Rates of serious and severe AEs were highest in the PBO arms of the no MTX and low-dose MTX subgroups, and lowest in the high-dose MTX PBO arm. Rates of discontinuation due to an AE were lowest in the high-dose MTX subgroup of the ADA arm.
CONCLUSION: In pts with PsA, treatment with ADA monotherapy or in combination with MTX regardless of dose provided greater response rates in PASI-related endpoints at Weeks 12

and 24 compared with PBO. AE rates were highest among pts receiving high-dose MTX alone or in combination with ADA.

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DISCLOSURES: Dr Gottlieb: Current Consulting/Advisory Board Agreements:Amgen Inc; Astellas, Akros, Centocor (Janssen), Inc; Celgene Corp, Bristol Myers Squibb Co, Beiersdorf, Inc, Abbott Labs (Abbvie), TEVA, Actelion, UCB, Novo Nordisk, Novartis, Dermipsor Ltd, Incyte, Pfizer, Canfite, Lilly, Coronado, Vertex, Karyopharm, CSL Behring Biotherapies for Life, Glaxo Smith Kline, Xenoport, Catabasis, Meiji Seika Pharma Co, Ltd, Takeda, Kineta; Research/Educational Grants (paid to Tufts Medical Center):Centocor (Janssen), Amgen, Abbott (Abbvie), Novartis, Celgene, Pfizer, Lilly, Coronado, Levia, Merck, Xenoport. Dr Teixeira, Dr Varothai, Dr Ganz, and Dr Valdecantos are all employees of AbbVie and may own stock/stock options.

PA-38: Safety of apremilast and etanercept compared with placebo in patients with moderate-to-severe psoriasis: results from the LIBERATE study

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BACKGROUND: The phase 3b LIBERATE double-blind, double-dummy study evaluated efficacy and safety of apremilast or etanercept vs placebo (PBO) in biologic-naive patients with moderate-to-severe plaque psoriasis.

OBJECTIVE: To describe the safety of apremilast up to Week 32 in the LIBERATE study.

METHODS: In this study patients were randomized (1:1:1) to PBO, apremilast 30 mg BID (APR30), or etanercept 50 mg QW (ETN50) through Wk16; thereafter, patients receiving PBO (PBO/APR30) or ETN50 (ETN50/APR30) switched to APR30 through Wk104. Patients in the APR30 group continued treatment (APR30/APR30) through Wk104. Adverse events (AEs) were assessed for Wks0-16 and Wks16-32.

RESULTS: 250 randomized patients received ≥1dose of study drug and were included in the safety analysis (PBO n = 84; APR30 n = 83; ETN50 n = 83). The most common AEs (≥5% of patients) were headache, nausea, diarrhea, upper respiratory tract infection (URTI), tension headache, and nasopharyngitis (Table). Across all subgroups: severe or serious AEs were reported in ≤3 patients and ≤3 patients discontinued due to AEs (Table). For Wks0-16, serious infections were pneumonia n = 1 APR30, n = 1 ETN50; no serious infections or malignancies were reported for Wks16-32. History of depression was reported at baseline in 9.5%, 16.9%, and 7.2% of patients, respectively, in the PBO, APR30, and ETN50 arms. Rates of depression and depressed mood with APR30 were low, occurring in patients with a prior history or with depression at baseline (Wks016, depression n = 1 APR30; Wks16-32, depression n = 1; depressed mood, n = 1 APR30/APR30). Suicidal ideation (n = 1 PBO/APR30) was reported for Wks16-32. At Wk16,

	Treatment Period					
	Wks 0-16			Wks 16-32		
Patients, n (%)	PBO n = 84	APR30 n = 83	ETN50 n = 83	PBO/APR30 n = 73	APR30/APR30 n = 74	ETN50/ APR30 n = 79
≥1 AE	50 (59.5)	58 (69.9)	44 (53.0)	37 (50.7)	36 (48.6)	38 (48.1)
≥1 serious AE	0	3 (3.6)	1 (1.2)	2 (2.7)	1 (1.4)	1 (1.3)
≥1 severe AE	2 (2.4)	3 (3.6)	2 (2.4)	1 (1.4)	2 (2.7)	1 (1.3)
AE leading to drug withdrawal	2 (2.4)	3 (3.6)	2 (2.4)	2 (2.7)	0	1 (1.3)
AEs ≥5%, any treatment group						
Headache	5 (6.0)	11 (13.3)	5 (6.0)	2 (2.7)	0	1 (1.3)
Nausea	2 (2.4)	9 (10.8)	4 (4.8)	3 (4.1)	2 (2.7)	5 (6.3)
Diarrhea	7 (8.3)	9 (10.8)	1 (1.2)	12 (16.4)	3 (4.1)	6 (7.6)
URTI	2 (2.4)	6 (7.2)	2 (2.4)	1 (1.4)	4 (5.4)	0
Tension headache	4 (4.8)	5 (6.0)	3 (3.6)	3 (4.1)	0	0
Nasopharyngitis	8 (9.5)	4 (4.8)	8 (9.6)	0	1 (1.4)	3 (3.8)

mean percent change from baseline in weight was +0.17%, -0.81%, and +1.44% with PBO, APR30, and ETN50, respectively. At Wk32, mean percent change from baseline in weight was -0.52%, -0.78%, and +0.09% with PBO/APR30, APR30/APR30, and ETN50/APR30, respectively.

LIMITATIONS: LIBERATE was not powered to detect differences in efficacy between active treatment arms.

CONCLUSION: The safety profile of APR30 was acceptable. No new safety or tolerability issues were observed between Wk16 and Wk32 in patients who switched from ETN50 to APR30 at Wk16.

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DISCLOSURES: Dr Gooderham reports personal fees from Celgene Corporation, during the conduct of the study; personal fees from AbbVie, personal fees from Actelion, personal fees from Allergan, personal fees from Amgen, personal fees from Astellas, personal fees from Celgene Corporation, personal fees from Dermira, personal fees from Dr Reddy's Laboratories, personal fees from Galderma Laboratories, personal fees from Janssen Pharmaceutical, personal fees from Kythera, personal fees from Kyowa Hakko Kirin Pharma, personal fees from LEO Pharma, personal fees from Lilly, personal fees from Merck, personal fees from Novartis, personal fees from Pfizer, personal fees from Regeneron, personal fees from Takeda, outside the submitted work. Dr Soung reports personal fees from Celgene Corporation, during the conduct of the study; personal fees from AbbVie, personal fees from Allergan, personal fees from Amgen, personal fees from Celgene Corporation, personal fees from Janssen Pharmaceutical, personal fees from Eli Lilly, personal fees from Genentech, personal fees from Genzum, personal fees from Pfizer, personal fees from Kadmon, personal fees from Merz, personal fees from Regeneron, outside the submitted work. Dr Green reports personal fees from Celgene Corporation, during the conduct of the study; personal fees from Celgene Corporation, outside the submitted work. Dr Augustin reports personal fees from Celgene Corporation, personal fees from Abbott, personal fees from Almirall, personal fees from Amgen, personal fees from Biogen Idec, personal fees from Centocor, personal fees from Eli Lilly, personal fees from Janssen-Cilag, personal fees from LEO Pharma, personal fees from Medac, personal fees from Merck, personal fees from Sharp and Dohme, personal fees from Novartis, personal fees from Pfizer, outside the submitted work. Dr Zhang reports personal fees from Celgene Corporation, outside the submitted work. Dr Shah reports personal fees from Celgene Corporation, outside the submitted work. Dr Goncalves reports personal fees from Celgene Corporation, outside the submitted work. Dr Reich reports personal fees from Celgene Corporation, during the conduct of the study; personal fees from AbbVie, personal fees from Amgen, personal fees from Biogen-Idec, personal fees from Celgene, personal fees from Centocor, personal fees from Covagen, personal fees from Forward Pharma, personal fees from GlaxoSmithKline, personal fees from Janssen-Cilag, personal fees from LEO Pharma, personal fees from Lilly, personal fees from Medac, personal fees from MSD, personal fees from Novartis, personal fees from Pfizer, personal fees from Takeda, personal fees from Vertex, outside the submitted work.

PA-39: Secukinumab administration by prefilled syringe maintains efficacy in moderate-to-severe plaque psoriasis over 100 weeks: results of the FEATURE trial

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BACKGROUND: Plaque psoriasis is a chronic disease; therefore, sustaining treatment benefits is important. Secukinumab, a human monoclonal antibody (mAb) that selectively targets interleukin (IL)-17A, has been demonstrated to be highly efficacious in the treatment of moderate-to-severe psoriasis, with a sustained effect and a favorable safety profile.

OBJECTIVE: The FEATURE study examined secukinumab efficacy and safety when self-administered using a prefilled syringe (PFS). Here, data from up to two years (100 weeks [Wks]) of treatment are reported.

METHODS: In this phase 3 trial, subjects were randomized 1:1:1 to secukinumab 300 mg, 150 mg, or placebo. Treatments were self-administered using a PFS at Wks 0, 1, 2, 3, and 4, then every 4 weeks until Wk 12 (placebo) or secukinumab until Wk 208. Placebo group nonresponders were re-randomized to secukinumab 300 mg or 150 mg after Wk 12. Co-primary endpoints were secukinumab Psoriasis Area and Severity Index (PASI) 75 and Investigator's Global Assessment 2011 modified version (IGA mod 2011 0/1) clear/almost clear response rates at Wk 12 compared to placebo. Secondary endpoints included PASI-90 and PASI-100. Here, Wk 100 interim efficacy analyses were performed using multiple imputation (MI) methods on data from 86 subjects who received 300 mg secukinumab and 88 subjects who received 150 mg secukinumab at any point during the study.

RESULTS: Wk 12 and 52 data were reported previously. Secukinumab was superior to placebo at Wk 12 with respect to PASI-75 response and IGA mod 2011 0/1 response, with substantial PASI-75, 90, and 100 responses maintained to Wk 52. At Wk 100, median treatment exposure at any dose was 624 (33–763) days for 274.3 subject-years overall experience. Wk 100 analysis in all subjects receiving secukinumab from Wk 0 or Wk 13 showed PASI-90 response for 59.7% of subjects with 300 mg and 41.3% with 150 mg secukinumab. At Wk 100, 40.8% and 22.2% of subjects had PASI-100 with secukinumab 300 mg and 150 mg, respectively. PASI-75 responses were seen in 79.6% of subjects with secukinumab 300 mg and in 58.4% receiving secukinumab 150 mg, and IGA mod 2011 0/1 scores were recorded for 55.2% and 41.1% of subjects receiving secukinumab 300 mg and 150 mg, respectively. No new or unexpected safety signals were observed to Wk 100.

CONCLUSION: Substantial and durable PASI-90 and PASI-100 responses at Wk 100 were achieved using long-term administration of secukinumab by PFS. The safety profile of secukinumab was consistent with previous studies, with no new or cumulative safety findings seen.

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PA-40: Secukinumab delivers greater improvement in health-related quality of life compared to ustekinumab in stujects with moderate-to-severe plaque psoriasis: 16-week data from the CLEAR study

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BACKGROUND: Secukinumab, a human anti–interleukin (IL)-17A monoclonal antibody (mAb), has been previously reported to be superior to etanercept in achieving strong responses with a favorable safety profile in moderate-to-severe plaque psoriasis.

OBJECTIVE: In the ongoing CLEAR study, which is a multicenter, double-blind, parallel-group, active comparator-controlled phase 3b study comparing efficacy/safety of secukinumab vs ustekinumab (an anti-IL-12/23 mAb) in adults with moderate-to-severe plaque psoriasis, superior efficacy was reported for secukinumab vs ustekinumab, with a superior Psoriasis Area and Severity Index (PASI) 90 response in the secukinumab arm at Week (Wk) 16. Here we report the 16-week Patient Reported Outcomes (PROs) from the CLEAR study.

METHODS: Subjects were randomized 1:1 to receive subcutaneous injection of secukinumab (300 mg) or ustekinumab (per label, for subjects ≤100 kg, 45 mg; >100 kg, 90 mg). In both treatment arms, randomization was stratified by body weight (≤100 and >100 kg). Secukinumab was administered at Baseline , Weeks (Wks) 1, 2, 3, and 4, and then every 4 weeks from Wk 8 to 48; ustekinumab at Baseline and Wk 4, then every 12 weeks from Wk 16 to 40. Exploratory objectives included assessing the effects of both treatments on health-related quality of life (HRQoL), including changes in the Dermatology Life Quality Index (DLQI; maximum range 0-30), patient assessment of psoriasis symptoms (pain, itching and scaling; using a numeric rating scale; 0-10), and, for subjects with psoriatic arthritis (PsA), the Health Assessment Questionnaire-disability index (HAQ-DI; maximum range of 0-3).

RESULTS: At each assessed time-point post Baseline (Wks 4, 8, 12, and 16), significantly more subjects achieved a DLQI score of 0 or 1 (ie, no impact of skin problems on HRQoL) with secukinumab vs ustekinumab (at Wk 16: 71.9% and 57.4%, respectively; $P < .0001$). The total DLQI change from Baseline (percentage and absolute change) was significantly greater with secukinumab vs ustekinumab at all time-points ($P \leq .002$). Improvements in psoriasis symptoms were greater for subjects on secukinumab at all time-points (Wks 1, 2, 3, 4, 8, 12, and 16). At Wk 16, subjects on secukinumab had mean decreases

of 81% in pain, 79.5% in itching, and 86.3% in scaling scores, and these differences were significantly greater vs ustekinumab ($P < .05$ for each). In subjects with PsA, the proportion achieving a decrease of at least 0.3 (minimum clinically important difference) in their HAQ-DI score was greater with secukinumab (34.9%) vs ustekinumab (26.5%).

CONCLUSION: The superior 16-week efficacy of secukinumab vs ustekinumab in subjects with moderate-to-severe plaque psoriasis also translates into greater improvements in patient HRQoL.

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PA-41: Secukinumab impact on psoriasis experiences: analysis of psoriasis symptom diary from ERASURE and FIXTURE

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BACKGROUND: Secukinumab, a fully human anti-interleukin 17A monoclonal antibody, was evaluated in ERASURE and FIX-

TURE, two phase 3 multicenter double blind vs placebo clinical studies for efficacy and safety in subjects with moderate-to-severe plaque psoriasis. Treatment effect was assessed using clinical measures such as the Psoriasis Area and Severity Index (PASI) and the 'new' Psoriasis Symptom Diary (PSD), which measures both the severity and bothersomeness of psoriasis-related symptoms.

OBJECTIVE: The objective of this study was to measure treatment effect as assessed by PASI and PSD.

METHODS: Patients aged ≥ 18 years were randomized 1:1:1 in ERASURE to receive subcutaneous treatment with secukinumab 300 mg, secukinumab 150 mg, or placebo; and 1:1:1:1 in FIXTURE which included etanercept 50 mg twice-weekly. Patients were asked to evaluate their psoriasis symptoms and experiences over the previous 24 hours. Weekly scores were derived as averages of daily 0-to-10 numerical ratings (higher scores indicative of greater severity/bothersomeness). Analyses focused on itching, pain and scaling. Absolute change from baseline to week 12 for the weekly average was analyzed using ANCOVA with covariates: geographical region, body weight stratum, and baseline value. Differences between treatment groups were determined using LS means and 95% CI. Among patients on secukinumab, differences in the bothersomeness of psoriasis-related symptoms between patients achieving clinical response (ie, PASI-90 or PASI-75) and those not achieving clinical response (not reaching PASI-75) at week 12 were also examined.

RESULTS: Approximately 40% of patients completed the voluntary PSD. For the pooled analysis, subjects treated with secukinumab had significantly greater reductions in the bothersomeness of psoriasis-related itching, pain, and scaling than those treated with placebo or etanercept (all $P < .01$). Patients treated with secukinumab (ERASURE, n = 187; FIXTURE, n = 266) who achieved PASI-90 clinical response had greater reductions in PSD itching and scaling bothersomeness than those who achieved PASI-75, and both achieved greater relief than patients who did not achieve clinical response (all $P < .05$).

LIMITATIONS: A limitation of this study was that the PSD was voluntary and completed by approximately 40% of subjects. Evaluations of the clinical and demographic characteristics of the sample provide evidence that subjects who completed the PSD are similar to the overall trial population.

CONCLUSION: Secukinumab offered significantly greater relief of the bothersomeness of psoriasis-related itching, pain, and scaling compared to placebo or etanercept. Greater skin clearance as assessed by PASI (PASI-90 vs PASI-75) was related to greater relief in the bothersomeness of patient-reported, psoriasis-related symptoms.

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PA-42: Secukinumab is psoriasis: relationship between clinical and PRO using clinical data from ERASURE and FIXTURE

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BACKGROUND: Secukinumab, a fully human anti-interleukin 17A monoclonal antibody, was evaluated in ERASURE and FIXTURE, two phase 3 multicenter double blind vs placebo clinical studies, for efficacy and safety in subjects with moderate-to-severe plaque psoriasis.

OBJECTIVE: Data from these trials provided an opportunity to evaluate the relationship between traditional clinical outcomes and patient-reported symptoms.

METHODS: Patients aged ≥18 years were randomized 1:1:1 in ERASURE to receive subcutaneous treatment with secukinum-

ab 300 mg, secukinumab 150 mg, or placebo; and 1:1:1:1 in FIXTURE which included etanercept 50 mg twice-weekly. The co-primary endpoints were the Psoriasis Area and Severity Index (PASI) and Investigator's Global Assessment Mod 2011 Rating Scale (IGA mod 2011). Symptom response was evaluated using the patient-completed Psoriasis Symptom Diary (PSD), which measures psoriasis-related disease characteristics which subjects have reported as important and relevant to their disease and treatment. Correlation coefficients were calculated at baseline, week 12, and change from baseline to week 12 between the PSD weekly itching, pain and scaling scores and the PASI and IGA mod 2011 scores. Logistic regression evaluated the relationship between itching, pain and scaling response (improvement of at least 2.2 points for itching and pain and 2.3 points for scaling), and percent change in PASI at week 12.

RESULTS: Approximately 40% of patients completed the voluntary PSD. For the pooled analysis (ERASURE, n = 187; FIXTURE, n = 266) of secukinumab data, correlation coefficients at baseline were positive but low in magnitude (0.11-0.21) and positive and stronger at week 12 (0.32-0.52). The change from baseline to week 12 correlation coefficients (0.18-0.30) were positive but lower in magnitude than week 12 values. Most coefficients were significant ($P < .001$).

The logistic models showed that the percent change in PASI score was a significant predictor of PSD response. The likelihood of a response for psoriasis-related itching, pain, and scaling at week 12 increased from 77.7%, 65.9% and 77.7% with a 75% PASI change between baseline and week 12 to 85.9%, 72.6%, and 86.1% with a 90% PASI change.

LIMITATIONS: A limitation of this study was that the PSD was voluntary and completed by approximately 40% of subjects. Evaluations of the clinical and demographic characteristics of the sample provide evidence that subjects who completed the PSD are similar to the overall trial population.

CONCLUSION: PASI-90 provides greater symptom response as measured by the PSD than PASI-75. It is important to evaluate both patient-reported outcomes and clinical endpoints to understand the full benefits of a psoriasis treatment.

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PA-43: Secukinumab is predominantly prescribed at the recommended 300 mg does to psoriasis patients in the United States

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BACKGROUND: Secukinumab is a novel, fully human monoclonal antibody indicated for the treatment of moderate-to-severe plaque psoriasis, and has been available to US patients since March of 2015. According to the US product label, the recommended dose is 300 mg. For some patients, a dose of 150 mg may be acceptable.

OBJECTIVE: To examine the profile of secukinumab patients and the dosage prescribed in the real world.

METHODS: Secukinumab Service Request Forms (SRFs) jointly filled by physicians and patients for initial secukinumab prescriptions from March 1, 2015 to May 31, 2015 were analyzed. All patients provided written informed consent. Information on the prescribed secukinumab dose and patient characteristics was analyzed descriptively.

RESULTS: The analysis included 5050 secukinumab SRFs completed by 1989 unique physicians. Patients were from all regions of the US: Northeast (14.5%), Midwest (20.2%), South (45.6%), and West (19.7%). The patient sample was roughly balanced by sex (females, 45.7%; males, 53.8%; missing data, 0.5%) and distributed across a wide range of age groups: 18-24 years (2.6%), 25-34 (10.6%), 35-44 (20.4%), 45-54 (25.1%), 55-64 (25.2%), 65+ (16.2%). 2494 patients (49.4%) had previously used a biologic (missing or unknown for rest of data), with 60% (1486) using 2 or more biologics. Overall, the initial secukinumab dose was 300 mg for 99.9% of the patients (5046) and 150 mg for only 4 patients (0.1%). A majority of the SRFs

requested the autoinjector pen as the injection device (4,543; 90.0%) rather than the prefilled syringe (507; 10.0%).
LIMITATIONS: Only patients captured in the secukinumab SRFs were analyzed.
CONCLUSION: Using a large number of secukinumab SRFs filled by US patients and their physicians distributed from all regions, this analysis found that secukinumab is predominantly prescribed at the recommended 300 mg dose. Therefore, secukinumab is being prescribed in accordance with the product label.
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PA-44: Secukinumab provides sustained improvements in the signs and symptoms of active psoriatic arthritis in TNFI-naïve patients and those previously exposed to TNFI therapy: 52-week results from a randomized, double-blind, placebo-controlled phase 3 trial with subcutaneous dosing

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BACKGROUND: There remains an unmet need for additional treatment options for patients with psoriatic arthritis (PsA) who have had an inadequate response to or intolerance of tumor necrosis factor inhibitor (TNFi) therapy. Secukinumab, a human anti-interleukin (IL)–17A monoclonal antibody (mAb), demonstrated significant efficacy in the randomized, double-blind, placebo-controlled phase 3 FUTURE 2 study (NCT01752634).
OBJECTIVE: Here, we present the 52-week efficacy and safety of secukinumab by TNFi history in patients enrolled in this study.
METHODS: Patients were randomized to receive subcutaneous (s.c.) secukinumab 300, 150, or 75 mg, or placebo at Baseline, weeks (Wks) 1, 2, 3, and 4, and then every 4 weeks from Wk 8. At Wk 16, placebo-treated patients were re-randomized to receive secukinumab 300 or 150 mg s.c. every 4 weeks from Wk 16 or 24, depending upon clinical response. Randomization was stratified by TNFi history: TNFi-naïve, or inadequate response/intolerance to not more than 3 TNFi agents (TNFi-exposed). The primary endpoint was American College of Rheumatology (ACR) 20 response at Wk 24. Secondary endpoints were Psoriasis Area and Severity Index (PASI) 75/90, Disease Activity Score 28 based on C-reactive protein (DAS28-CRP), Short Form-36 Physical Component Summary (SF-36 PCS), Health Assessment Questionnaire Disability Index (HAQ-DI), ACR 50, dactylitis, and enthesitis. ACR 70 was an exploratory endpoint. Analyses used nonresponder imputation (binary variables) and mixed-model repeated measures (continuous variables) through Wk 52. Analysis of primary and secondary endpoints, stratified by TNFi history, was prespecified.
RESULTS: Of the 397 patients enrolled in FUTURE 2, 65% were TNFi-naïve and 35% were TNFi-exposed. At Wk 24, ACR 20/50/70 and PASI-75/90 responses were higher with secukinumab vs placebo in both TNFi-naïve and TNFi-exposed patients. Improvements with secukinumab vs placebo at Wk 24 were also observed for other secondary endpoints in both TNFi-naïve and TNFi-exposed patients. Response rates were generally higher amongst TNFi-naïve patients vs TNFi-exposed patients. The greatest improvements in the TNFi-exposed group were generally observed with secukinumab 300 mg. Clinical responses to secukinumab were sustained or continued to improve through 52 weeks of therapy in both TNFi-naïve and TNFi-exposed patients.
CONCLUSION: Secukinumab provided sustained improvements in the signs and symptoms of PsA in both TNFi-naïve and TNFi-exposed patients.
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PA-45: Secukinumab re-treatment shows rapid regain or treatment responses: a pooled analysis of two phase 3 trials in psoriasis

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BACKGROUND: Secukinumab, a human anti–interleukin (IL)-17A monoclonal antibody (mAb), has been demonstrated to be rapidly efficacious in the treatment of moderate-to-severe psoriasis, with a sustained effect and a favorable safety profile.
OBJECTIVE: Here, we assessed the rates of regain of clinical responses following retreatment of subjects with moderate-to-severe psoriasis who had relapsed following per-protocol withdrawal of secukinumab during the extension of the ERASURE and FIXTURE studies. This abstract focuses on data up to 2 years (104 weeks).
METHODS: In this analysis, subjects who had Psoriasis Area and Severity Index (PASI) 75 responses at the end of the core studies (Week [Wk] 52) were randomized in the extension study 2:1, to continue on the same dose of secukinumab or receive placebo every 4 weeks. Subjects who relapsed in the two placebo arms (300 mg-placebo and 150 mg-placebo) were retreated with secukinumab upon relapse. Relapse was defined as a loss of >50% of the maximum PASI gain compared with Baseline in the core studies.
RESULTS: In total, 995 subjects entered this part of the extension study; the treatment groups were comparable with respect to Wk 52 Baseline characteristics. The percentage of subjects in the continuous-treatment groups who reached Wk 104 without relapse was 87.1% (secukinumab 300 mg, n = 363) and 72.8% (secukinumab 150 mg, n = 301). In the treatment-withdrawal groups, 16.0% (secukinumab 300 mg-placebo, n = 181) and 12.7% (secukinumab 150 mg-placebo, n = 150) reached Wk 104 without relapse. In subjects in the 300 mg withdrawal group who did relapse and were retreated, 94.8% of subjects re-captured PASI-75, 70.3% PASI-90, and 38.4% PASI-100 responses after 12 weeks of retreatment with secukinumab 300 mg. There were no new or unexpected safety findings in the extension study.
CONCLUSION: Secukinumab provided strong and sustained efficacy over 104 weeks, clearing psoriasis while maintaining a favorable safety profile. In subjects relapsing after being withdrawn from therapy, retreatment with secukinumab restored efficacy in the vast majority of subjects by 12 weeks post restart of treatment.
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PA-46: Treatment implications of a multidirectional approach to delivery of efinaconazole topical solution, 10% in onychomycosis patients

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BACKGROUND: Transungual nail penetrance has traditionally been considered to be the only route of delivery for topical antifungals in treating onychomycosis. Subungual penetrance may afford an additional or alternate route of drug delivery with important practical implications.
OBJECTIVE: To review transungual nail penetration and drug delivery studies with efinaconazole, and evaluate its potential to reach the site of toenail onychomycosis through application to the hyponychium or dorsal nail surface.
METHODS: Nail penetration and drug delivery data following daily application of efinaconazole to the nail surface in onychomycosis patients were reviewed. In addition, 23 participants with moderate-to-severe, onychomycosis were enrolled in a subungual delivery study. Two separate applications of efinaconazole vehicle solution containing fluorescein for visualization were applied at the hyponychium. Affected nails were later clipped to allow examination of the nail bed and further examination of the ventral surface of the nail. Spread of formulation was assessed under visible and UV light conditions by photographing target toenails after vehicle application and after nail clipping.
RESULTS: Efinaconazole concentrations in the nail were four orders of magnitude higher than dermatophyte MIC values following daily application to the nail surface of onychomycosis patients, and maintained two weeks' posttreatment. Transungual penetration of efinaconazole topical solution, 10% was not influenced by application of nail polish. However, polishes showed increased surface tackiness with repeated efinaconazole application directly to the nail plate. Application of efinaconazole vehicle subungually in our study resulted in spreading to the site of infection, with deposition of fluorescein wherever vehicle had reached. Nail clippings also indicated absorption into the ventral surface of the nail plate.
LIMITATIONS: Concentrations of efinaconazole in the nail with wash out periods are unknown.
CONCLUSIONS: Efinaconazole is present in the nail plate in high concentrations and studies suggests that the low surface tension vehicle developed for efinaconazole topical solution, 10% can reach the site of infection by application to the hyponychium, dorsal or ventral nail surface and nail folds. This multidirectional approach to drug delivery to the site of fungal infection may contribute to the magnitude of efficacy seen in clinical trials. These data suggest that applying efinaconazole topical solution, 10% subungually at the hyponychium would allow onychomycosis patients to use nail polish while treating their disease. In addition, the high concentrations of efinaconazole retained in the nail may afford an effective prophylaxis strategy to minimize recurrence.
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PA-47: Treatment of superficial basal cell carcinoma with ingenol mebutate gel, 0.05%

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BACKGROUND: Basal cell carcinoma (BCC) is the most common cancer in Caucasians. Excision with predetermined margins is one of the most widely used and effective treatment strategies for well-defined BCC. However, some BCCs are not suitable for surgery, and some patients prefer a nonsurgical treatment to reduce the risk of scarring. Ingenol mebutate gel, 0.05%, is approved for the treatment of actinic keratosis (AK) on the trunk and extremities, but its use in treating superficial BCC (sBCC) has been described in a randomized Phase 2a study. Our experience in using ingenol mebutate gel, 0.05%, for patients who refused surgical treatment for sBCC is described in this small case series.
OBJECTIVE: The purpose of this study was to describe the safety, tolerability, and efficacy of ingenol mebutate gel, 0.05%, treatment of sBCC in 6 patients who chose topical treatment instead of surgical excision.
METHODS: We conducted a retrospective chart review of 6 patients from our community dermatology practice for whom sBCC was treated with ingenol mebutate. The chart review extracted information on demography, patient dermatologic history, and prior treatment of AK or skin cancer. Analysis of the treatment outcome with ingenol mebutate included the size and location of the sBCC, description of administration, local skin reactions (LSRs), adverse events, and efficacy.
RESULTS: The 6 patients (3 men, 3 women; age range, 47 to 75 years) presented with lesions that were suspicious for BCC. Histopathologic analysis of a shave biopsy sample confirmed 7 sBCCs: a single sBCC in 5 patients and 2 well-separated lesions in 1 patient. All lesions occurred on the trunk and were located on the back (n = 3), chest (n = 2), or shoulder (n = 2).

Lesion size ranged from 0.6 cm to 3.5 cm, with 5 of 6 lesions being ≤1.5 cm in diameter. Patients were treated from May 2014 to June 2015, at 10 to 14 days after shave biopsy; biopsy sites were not required to be fully healed. Ingenol mebutate gel, 0.05%, was applied to cover the lesion, plus a 0.5-cm margin. Lesions were either occluded using a standard adhesive bandage (n = 4) or not occluded (n = 3). The 3.5-cm lesion was treated for 2 days, and all other lesions were treated for 7 days. One treatment kit of 2 tubes of medication was used by each patient. All patients experienced LSRs that began on day 1 or 2 of treatment, peaked on days 2 to 7, and largely resolved at 2 weeks. The most common LSRs were erythema, flaking/scaling, and crusting. Two patients reported mild itching and burning. LSRs were treated in 2 patients with moisturizers. All sBCCs were clinically resolved at short-term follow-up at 2 to 4 weeks. No patients experienced scarring at the treatment site. Mild erythema was present at 8 weeks in 2 patients. Repeat biopsy at 3 months in 3 patients confirmed histologic clearance. There were no clinically suspicious lesions in any patients at subsequent follow-up evaluations at 3-month intervals. The longest follow-up to date has been 14 months. All patients reported that the medicine was well tolerated.

LIMITATIONS: This is a small case series of 6 patients from a community dermatology setting. Confirmation of the safety and efficacy of ingenol mebutate for the treatment of sBCC requires evaluation in a larger number of patients.

CONCLUSION: Ingenol mebutate gel, 0.05%, was efficacious and well tolerated for the treatment of biopsy-confirmed sBCCs on the trunk in 6 patients.

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