PA-01: PA-Adalimumab Efficacy in Hidradenitis Suppurativa Patients is Sustained at Least Three Years with Weekly Dosing: Results from a Phase 3 Open-Label Extension Study (PIONEER)

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BACKGROUND: To determine the long-term safety and efficacy of originator-adalimumab (ADA) in moderate to severe hidradenitis suppurativa (HS), an open-label extension (OLE) trial (NCT01635764) of the PIONEER I and II phase-3 trials of ADA treatment in patients (pts) with moderate to severe HS was conducted.
OBJECTIVE: Results to week 168 are reported.
MATERIALS/METHODS: Upon entry into the OLE, all pts received ADA 40 mg weekly (ADAew). Safety and efficacy were analyzed for pts who received continuous 40 mg ADAew in Periods A and B of PIONEER I or II and entered OLE (ADAew Population). The primary outcome measure was Hidradenitis Suppurativa Clinical Response (HiSCR), defined as ≥50% reduction in abscess and inflammatory nodule (AN) count with no increase in abscess count and no increase in draining fistula count relative to baseline (BL) . Last-observation-carried-forward was used to handle missing values.
RESULTS: At weeks 120 and 168, respectively, of the OLE for the 88 pts in the ADAew Population, HiSCR was achieved by 56.8% and 52.3%; mean % changes from baseline in AN count were -37.8 (±SD 84.36) and -32.8 (±SD 86.29); mean % changes from baseline in draining fistulas were –29.4 (±SD 102.85) and –28.1 (±SD 110.70); mean % change from baseline in pain (change in numeric rating scale [NRS] at worst at each visit, among pts with BL NRS at worst ≥3; N=63) was- –27.0 (±SD 56.83) and –25.6 (±SD 61.82). At week 72, mean change in DLQI was –6.5 (±7.90) (DLQI was also collected at the last visit, which occurred at different time points and are not reported here). Adverse events (AEs) were reported by 86.4% (76/88) in the ADAew Population; serious AEs by 13.6% (12/88); serious infections by 3.4% (3/88), which included pneumonia (n=2) and cellulitis of right leg (n=1).
CONCLUSIONS: Data from the PIONEER OLE confirm that HS pts receiving weekly ADA treatment maintained long-term response, demonstrated by HiSCR rate of 52.3% (ADAew Population) at week 168, and by a clinically meaningful decrease in DLQI at week 72 of –6.5. The safety profile of long-term weekly ADA therapy in this study was consistent to the known ADA safety profile and no new safety risks were identified.
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PA-02: Adalimumab for Nail Psoriasis: Efficacy and Safety from the Open-Label Extension of a Phase-3, Randomized, Placebo-Controlled Trial

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BACKGROUND: Treatments simultaneously effective in nail psoriasis (Ps) and moderate-to-severe Ps are needed because quality of life and pain are worse for patients with Ps and concomitant fingernail Ps compared with patients with Ps alone.
OBJECTIVES: We evaluated the safety and efficacy of adalimumab (ADA) for fingernail Ps treatment in the open-label-extension (OLE) period of a phase-3 trial of originator adalimumab in patients with moderate-to-severe Ps.
METHODS: Patients with chronic, moderate-to-severe plaque Ps and fingernail Ps were enrolled. In 26-week (wk) Period A, patients were randomized 1:1 to 40mg ADA every-other-wk (eow) after initial 80mg dose, or matching placebo (PBO). From wk 16, if Ps body surface area increased by ≥25% from baseline, patients could early escape to the 26-wk Period B (OLE). Patients completing Period A (early escape or wk 26) entered the OLE at wk 26. At OLE entry, patients receiving PBO in Period A received an initial blinded dose of 80mg ADA; patients receiving ADA in Period A received matching PBO. All received 40mg ADAeow from wks 27-51. Missing data were handled by non-responder imputation. OLE results are reported for all patients who received ≥1 study drug injection in the OLE; groups are defined by treatment received in Period A/OLE, ie, PBO/ADA and ADA/ADA.
RESULTS: Of the 217 randomized patients, 94/108 (87.0%) PBO/ADA and 94/109 (86.2%) ADA/ADA entered the OLE; 81/94 (86.2%) PBO/ADA and 87/94 (92.6%) ADA/ADA patients completed the OLE. At OLE entry and at week 52, respectively, the proportion of patients achieving ≥75% improvement from baseline in modified Nail Ps Severity Index (mNAPSI 75) for PBO/ADA was 5/94 (5.3%) and 47/94 (50.0%) and for ADA/ADA was 46/94 (48.9%) and 53/94 (56.4%). The proportion achieving Physician's Global Assessment of fingernail Ps (PGA-F) of 0 (clear) or 1 (minimal) with ≥2-grades improvement from baseline for PBO/ADA was 5/94 (5.3%) and 50/94 (53.2%) and for ADA/ADA was 47/94 (50.0%) and 50/94 (53.2%). Adverse events (AEs) in the OLE were reported by percentage of patients in the PBO/ADA and ADA/ADA groups as follows: any event, 46.8% and 50.0%; serious AEs, 3.2% and 3.2%; serious infections, 2.1% and 1.1%. There were no AEs leading to study-drug discontinuation, and no deaths.
CONCLUSIONS: For patients receiving ADA in Period A, treatment response was maintained from OLE entry through week 52; patients receiving PBO in Period A, who switched to ADA in the OLE, reached a similar response at week 52. No new safety risks were identified with ADAeow treatment for 52 weeks.
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DISCLOSURES: A Gottlieb reports receiving fees for serving on advisory boards and for consulting services from AbbVie, Actelion, Akros, Amgen, Astellas, Baxalta, Beiersdorf, Bristol-Myers Squibb, Canfite, Catabasis, Celgene, Centocor (Janssen), Coronado, CSL Behring Biotherapies for Life, Dermipsor, Eli Lilly, Genentech, GlaxoSmithKline, Incyte, Karyopharm, Kineta One, KPI Therapeutics, Meiji Seika Pharma, Mitsubishi, Novartis, Novo Nordisk, Pfizer, Takeda, Tanabe Pharma Development America, TEVA,UCB Pharma, Vertex, and XenoPort, and grant support paid to Tufts Medical Center from AbbVie, Amgen, Baxalta, Celgene, Centocor (Janssen), Eli Lilly, Novartis, Pfizer, Levia, Merck, XenoPort, and Dermira. BE Elewski received research funding for clinical research support, paid to her affiliation, from Abbvie, Amgen, Boehringer Ingelheim, Celgene, Incyte, Lilly, Merck, Novan, Novartis, Pfizer, Valeant, and Viamet. Received honoraria for consultant services from Anacor, Celgene, Lilly, Novartis, Pfizer, and Valeant. MM Okun received honoraria from AbbVie for advisory board participation and speaker services, and from AbbVie, Gilead Science, and Crescendo Biosciences for consultant services. Dr. Okun was an AbbVie employee during this study and is currently affiliated with Fort HealthCare, Fort Atkinson, WI, USA. J Bagel received honoraria or

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PA-03: Characteristics of patients with Moderate-to-Severe Psoriasis Treated with Secukinumab in US Clinical Practice - A Focus on Biologic-Naïve and Biologic-Experienced Patients

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BACKGROUND: The literature on biologic-naïve (bio-naïve) and biologic-experienced (bio-exp) patients (pts) with moderate (mod)-to-severe (sev) psoriasis (PsO) initiated on secukinumab (SEC) is limited in the real world.
OBJECTIVE: To describe the treatment (TX) history and characteristics of bio-naïve and bio-exp pts with mod-to-sev PsO receiving SEC.
METHODS: An online chart questionnaire was completed by US dermatologists from 5/19/17 to 6/07/17 to extract data on adult pts who received SEC. Pts' demographics, PsO and comorbidity profile, PsO TX history, and SEC use (including dermatologists' reasons for prescribing SEC) were described for bio-naïve and bio-exp pts. All statistical methods for this study were descriptive.
RESULTS: Medical charts from 202 mod-to-sev PsO pts (102 bio-naïve and 100 bio-exp) initiated on SEC were collected from 58 US dermatologists. Bio-naïve and bio-exp pts were similar in demographics: respectively, the mean ages were 44 and 46 years (y), 40% and 37% were female, 80% and 72% were White, and 90% and 89% were commercially insured. However, bio-naïve pts had a shorter disease history than bio-exp pts (≤2y: 34% vs. 6%; >10y: 21% vs. 29%; respectively). Both groups had equal proportions of pts with an affected body surface area (BSA) between 3%-10% (mod PsO; both 16%) or >10% (sev PsO; both 83%) at SEC initiation. Comorbidities were more prevalent in bio-exp than bio-naïve pts (hypertension [39% vs. 22%, respectively], obesity [32% vs. 21%], hyperlipidemia [23% vs. 14%], diabetes [21% vs. 10%], and depression [18% vs. 11%]). SEC was the first non-topical TX (systemic TX and phototherapy) for 82% of bio-naïve pts. The top 5 systemic (biologic and non-biologic) TX received by bio-exp pts before SEC were: adalimumab (74%), ustekinumab (39%), methotrexate (32%), etanercept (30%), and apremilast (9%). Among bio-exp pts, 35% received ≥2 biologics. The top 5 dermatologists' reasons for prescribing SEC were similar among bio-exp and bio-naïve pts: (1) expected efficacy (83% vs. 78%, respectively), (2) opportunity for clear/almost clear skin (68% vs. 71%), (3) pt's disease severity (49% vs. 33%), (4) expected sustained/long-lasting efficacy (17% vs. 36%), and (5) favorable long-lasting safety (20% vs. 32%).
CONCLUSION: Despite higher comorbidity burden and longer PsO history in bio-exp pts, bio-naive and bio-exp pts had similar disease severity at SEC initiation. Efficacy and safety were the top reasons for prescribing SEC in both groups.
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DISCLOSURE: SF has received honoraria and grant support from Novartis Pharmaceuticals Corporation as a consultant, and speaker. PH, LD, and JP are employees of Novartis Pharmaceuticals. YZ was an employee of Novartis Pharmaceuticals at the time of the study.

PA-04: Clinical Responses in Patients with Moderate-to-Severe Plaque Psoriasis Following Withdrawal and Retreatment with Risankizumab or Switching from Ustekinumab to Risankizumab

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BACKGROUND: Risankizumab is a humanized IgG1 monoclonal antibody that inhibits IL-23 by binding its p19 subunit. In a phase 2 trial, risankizumab demonstrated superiority over ustekinumab in patients with moderate-to-severe plaque psoriasis.
OBJECTIVE: Efficacy following drug withdrawal/retreatment with risankizumab or switching from ustekinumab to

risankizumab at week 24 of open label extension (OLE) are assessed here.

MATERIALS/METHODS: In the phase 2 ("parent") study, 166 patients with moderate-to-severe plaque psoriasis were randomized to receive subcutaneous injections of risankizumab (18mg single dose, 90 or 180mg at weeks 0, 4, and 16) or ustekinumab (45 or 90mg, based on body weight at weeks 0, 4, and 16). Patients (N=110) who completed 48 weeks in parent study or who failed to achieve 50% improvement in psoriasis area and severity index (PASI 50) response between weeks 24 and 48 were eligible to enter OLE. In the OLE, all patients received 90mg risankizumab at baseline and every 12 weeks, regardless of response level at the end of parent study. Data through week 24 of OLE from all entering patients were included in this analysis; non-responder imputation (NRI) was used for missing efficacy data.

RESULTS: PASI 90 response rates for patients treated with 18mg, 90mg, or 180mg risankizumab or ustekinumab at OLE entry were 0% (0/22), 53.6% (15/28), 51.5% (17/33), and 14.8% (4/27), respectively, reflecting residual benefit from study drug in parent study. At week 24 of OLE, PASI 90 response rates improved to 68.2% (15/22), 60.7% (17/28), 66.7% (22/33), and 74.1% (20/27) in patients initially treated with 18mg, 90mg, or 180mg risankizumab or ustekinumab, respectively. At OLE entry, PASI 100 response rates for patients treated with 18mg, 90mg, or 180mg risankizumab or ustekinumab were 0% (0/22), 39.3% (11/28), 30.3% (10/33), and 3.7% (1/27), respectively, and improved to 27.3% (6/22), 46.4% (13/28), 39.4% (12/33), and 48.1% (13/27), respectively, at week 24 of OLE. Proportion of patients treated with 18mg, 90mg, or 180mg risankizumab or ustekinumab achieving Static Physician's Global Assessment of 0 or 1 (sPGA 0/1) at OLE entry were 9.1% (2/22), 57.1% (16/28), 63.6% (21/33), and 25.9% (7/27), respectively, and improved to 72.7% (16/22), 67.9% (19/28), 69.7% (23/33), and 77.8% (21/27), respectively, at week 24 of OLE. Overall rate of adverse events (AEs) and serious AEs were 38.2% (42 patients) and 2.7% (3 patients), respectively.

CONCLUSIONS: Patients treated with ustekinumab in parent study achieved higher clinical response rates with risankizumab than ustekinumab, as measured by increases in PASI and sPGA response rates following treatment with risankizumab for 24 weeks. Retreatment with two doses (OLE baseline and week 12) of 90mg of risankizumab following risankizumab withdrawal also resulted in return of substantial clinical benefit.

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PA-05: Co-prescription of isotretinoin and tetracyclines for acne is rare: An analysis of the National Ambulatory Medical Care Survey

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BACKGROUND: Acne is a commonly addressed problem by dermatologists and primary care physicians. Depending on the severity of acne, systemic therapy is often required, which may include oral antibiotics or isotretinoin. Tetracycline antibiotics are considered a first line treatment for inflammatory acne and are commonly prescribed. Patients with an inadequate response to tetracyclines or severe cases of acne may require isotretinoin. The concurrent use of tetracyclines and isotretinoin is known to increase the risk of pseudotumor cerebri (PTC). PTC is characterized by headaches and visual disturbances, and may lead to blindness if the causative agent is not discontinued. Therefore, the concurrent use of these medications must be avoided.

OBJECTIVES: (1) To quantify the estimated frequency of co-prescription of isotretinoin and tetracyclines given their association with PTC when used concomitantly; (2) To assess the trends of the use of isotretinoin and tetracycline for acne as it relates to age, sex, race, insurance, and provider specialty.

METHODS: Data for the National Ambulatory Medical Care Survey (NAMCS) from 2003 to 2013 were aggregated to form an 11-year data set and the number of prescriptions for isotretinoin and/or tetracycline were estimated by specialty (SPECR). Visits were then analyzed for mention of isotretinoin and/or tetracycline prescriptions and were

only included if the reason for visit or diagnosis included acne. Logistic regression for complex surveys was used twice to estimate the odds of mentioning isotretinoin and tetracycline, individually, during a visit for acne as a function of multivariable survey year, age at time of visit, sex, race, and physician specialty. Visits were stratified and weighted to reflect their clustered sampling probability as described by National Center for Health Statistics (NCHS). Odds ratio of drug mention by highest prescribing specialties were determined.

RESULTS: Among visits for acne to dermatologists (N = 51,980,042) and non-dermatologists (N = 29,063,717), approximately 13.56% of dermatologists mentioned isotretinoin vs 1.62% of non-dermatologists, 29.15% mentioned tetracycline vs 22.87% of non-dermatologists, and .40% mentioned both isotretinoin and tetracycline vs .025% of non-dermatologists. The odds of mentioning isotretinoin during a visit for acne declined by approximately 2% for every 1 year increase in age (OR = .98, 95% CI: .96 – .99; $P < .001$) while the odds of mentioning a Scientific Abstract with Background, Objective, Methods, Results, Limitations, Conclusion, Corresponding Author and Disclosure tetracycline during a visit for acne declined by approximately 1% for every 1 year increase in age (OR = .99, 95% CI: .98 – .99; $P = .01$). Females were only .60 (95% CI: .44 – .83) times as likely as males to mention isotretinoin during their visit for acne ($P = .002$). Compared to patients with private insurance, those with Medicare were less likely to mention isotretinoin (OR= .06, 95% CI: .01 – .44; $P = .01$). Dermatologists were 9.44 (95% CI: 4.69 – 18.98) times more likely to mention isotretinoin ($P < .001$) and 1.42 (95% CI: 1.11 – 1.83) times more likely to mention a tetracycline at a visit than non-dermatologists ($P = .01$) for treatment of acne. Compared to dermatology, family practice providers were only .16 (95% CI: .07 to .36) times as likely to mention isotretinoin at any visit for acne ($P < .001$). The odds of isotretinoin mention on a first visit by family practice versus dermatology was not statistically different (OR=1.95; 95% CI: .47-8.02, $P = .36$). For tetracyclines, no statistically significant differences were noted in the odds of tetracycline mention between family practice and dermatology for first (OR=.79; 95% CI: .40-1.55, $P = .49$) or any visit (OR=.90; 95% CI: .67-1.20, $P = .47$). All of these ORs are reported after controlling for model variables.

LIMITATIONS: The NAMCS data collection process has an inherent sampling bias from using a small sample to provide national estimates for a given parameter. It is a cross-sectional study that uses a visit as a sampling unit, hence, outcomes cannot be determined. NAMCS data do not include acne type or severity precluding us from providing more concrete explanations for differences in prescribing patterns.

CONCLUSION: Co-prescription of isotretinoin and tetracyclines comprise a miniscule fraction of acne visits. The increased PTC risk associated with their concomitant use is well known among dermatologists, hence, patient exposure is likely very uncommon. Acne severity and level of comfort because of specialty-based training may be at play in the isotretinoin prescribing pattern differences between dermatologists and non-dermatologists.

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DISCLOSURE: The authors have indicated no significant interest with commercial supporters.

PA-06: Describing the clinical and patient reported outcomes of patients with scalp psoriasis enrolled in the Corrona Psoriasis Registry*

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OBJECTIVE: Psoriasis (PsO) involving the scalp is frequently observed among plaque PsO patients but challenging to treat, and is known to substantially impair the physical and psychological health of patients. However, it is unclear if scalp PsO is associated with different clinical/demographic characteristics compared to patients without scalp PsO. The objective of this study is to describe the clinical features and patient reported outcomes (PROs) of patients with scalp PsO in the Corrona PsO Registry.

METHODS: This included adult PsO patients enrolled in the Corrona registry between 4/2015 – 4/2017 who initiated an eligible systemic therapy at enrollment. Descriptive analyses of demographics, disease severity (BSA, PASI), PROs (overall itch, pain, Dermatology Life Quality Index (DLQI), Work Productivity and Activity Impairment (WPAI), itch and EQ-VAS on visual analogue scale 0-100) and treatment history were examined and compared between patients with scalp PsO and those without, using appropriate statistical tests (t-test/chi-square tests for continuous and categorical variables respectively).

RESULTS: Of 1,037 patients who initiated an eligible systemic therapy at enrollment, 381 patients (36.7%) had scalp PsO. Patients with scalp PsO were younger (mean: 47.3 vs. 51.0 years), and less likely male (44% vs 52%) compared to patients without scalp PsO (all $P < .05$). About 58% (vs 57%) of patients with scalp PsO were previously treated by a biologic treatment with 53% (vs 51%) treated with ≥2 prior biologics. Patients with scalp PsO had similar disease duration (16.0 vs 14.9 years) and had more nail or inverse PsO involvement compared to patients without scalp PsO. Patients with scalp PsO had more severe disease (mean BSA 17.4% vs. 14.5%, mean PASI 10.7 vs. 8.0, $P < .05$) with 40% of scalp PsO group (vs. 27%) having PASI>10 compared to patients without scalp PsO, $P < .05$.

Both groups had comparable overall daily activity impairment (mean percent: 25.6 vs 24.7) and DLQI (mean: 9.3 vs 9.0, corresponding to a moderate impact on patient's life), but the scalp PsO group reported poorer health status (mean EQ-VAS: 67.0 vs 70.6, $P < .05$) and higher itch scores compared to patients without scalp PsO (17.4 vs 14.5, $P < .05$).

CONCLUSION: Scalp PsO impacts a third of the enrolled patients in this large US registry, with significantly more severe disease, poorer health status and itch problems compared to patients with no scalp PsO.

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PA-07: Distribution of Improvements in Psoriasis Area and Severity Index from the Phase 2 Trial of Risankizumab in Moderate to Severe Plaque Psoriasis

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INTRODUCTION: Risankizumab is a humanized IgG1 monoclonal antibody that inhibits IL-23 by binding its p19 subunit. In a phase 2 trial, risankizumab demonstrated superiority over ustekinumab in patients with moderate to severe plaque psoriasis.

OBJECTIVE: The objective of this analysis was to examine the distribution of Psoriasis Area and Severity Index (PASI) responses at weeks 12 and 16 in patients from the phase 2 trial treated with risankizumab versus ustekinumab.

MATERIALS/METHODS: Patients (N=166) with moderate to severe plaque psoriasis were randomized to receive subcutaneous injections of risankizumab (18 mg single dose, 90 or 180 mg at weeks 0. 4, and 16) or ustekinumab (45 or 90 mg, based on body weight at weeks 0, 4, and 16). The primary endpoint was proportion of patients achieving PASI 90 response at week 12. The proportions of patients achieving different levels of PASI responses were assessed at weeks 12 and 16 in an intent- to-treat population. Patients with a missing assessment were counted as having no change from baseline. The distribution of changes from baseline in PASI scores across treatment groups were assessed using cumulative probability plots.

RESULTS: The proportions of patients achieving the primary end point of PASI 90 response at week 12 were 30.2%, 73.2%, and 78.6% for 18 mg, 90 mg, and 180 mg risankizumab groups, respectively, compared with 40% for ustekinumab-treated patients. At week 16, the proportions of patients achieving PASI 90 response increased to 48.8%, 78.0%, and 81.0% for 18 mg, 90 mg, and 180 mg risankizumab groups, respectively, compared with 42.5% for ustekinumab-treated patients. Median values for improvement in PASI scores at week 12 were 83.0%, 94.6%, and 99.5% in patients treated with 18 mg, 90 mg, and 180 mg of risankizumab, respectively, compared with 86.4% in ustekinumab-treated patients. At week 16, median values for improvement in PASI scores were 87.4%, 97.5%, and 100.0% in patients treated with 18 mg, 90 mg, and 180 mg of risankizumab, respectively, compared with 89.3% in ustekinumab-treated patients. In addition, patients treated with 90 mg or 180 mg of risankizumab achieved higher response rates across all levels of PASI improvement when compared with patients treated with 18 mg risankizumab (single dose) or ustekinumab.

CONCLUSIONS: The overall improvements in PASI scores at weeks 12 and 16 was higher in patients treated with 90 or 180 mg risankizumab compared with ustekinumab. Patients treated with 90 or 180 mg risankizumab showed a greater shift in PASI distribution towards higher PASI response rates compared with ustekinumab-treated patients.

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DISCLOSURES: B Strober has received honoraria or fees for serving on advisory boards and as a consultant for AbbVie, Amgen, AstraZeneca, Boehringer Ingelheim,

Celgene, Dermira, GlaxoSmithKline, Janssen, Leo, Eli Lilly, Maruho, Medac, Merck, Novartis, Pfizer, Regeneron, Sanofi-Aventis, Sun, Stiefel/GlaxoSmithKline, and UCB. He is a scientific director for the CORRONA Psoriasis Registry. KA Papp has received honoraria or fees for serving on advisory boards, as a speaker, as a consultant, grants as an investigator from AbbVie, Amgen, Astellas, AstraZeneca, Baxalta, Baxter, Boehringer Ingelheim, Bristol-Myers Squibb, Celgene, Dermira, Eli Lilly, Forward, Galderma, Genentech, GlaxoSmithKline, Janssen, Kyowa-Kirin, Leo, MedImmune, Merck, MSD, Novartis, Pfizer, Regeneron, Roche, Sanofi-Aventis, Stiefel/GlaxoSmithKline, Sun Pharmaceuticals, Takeda, and UCB. M Flack is a full-time employee of Boehringer Ingelheim. Y Gu, EHZ Thompson, and WC Valdecantos are full-time salaried employees of AbbVie and may own stock/options.

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PA-08: Dupilumab in Moderate-to-Severe Atopic Dermatitis: Clinical Response Distribution and Responder Dynamics Over Time

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BACKGROUND: Atopic dermatitis (AD) is a chronic inflammatory disorder with a fluctuating course and a dynamic response to treatment. Dupilumab is a fully human anti-interleukin (IL)-4 receptor-alpha monoclonal antibody that inhibits signaling of the type 2/Th2 cytokines IL-4 and IL-13, key drivers of AD. Dupilumab is approved by the US FDA for treatment of adult patients with moderate-to-severe AD whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable, and can be used with or without topical corticosteroids (TCS).

OBJECTIVE: To characterize the distribution of responder categories and their dynamics over time for Investigator's Global Assessment (IGA), Eczema Area and Severity Index (EASI), and peak pruritus Numerical Rating Scale (NRS) scores from baseline to Week 16 in patients with moderate-to-severe AD.

METHODS: LIBERTY AD SOLO 1 & 2 (NCT02277743; NCT02277769) are two identical, randomized, double-blind, placebo-controlled phase 3 trials. Adults with moderate-to-severe AD were randomized (1:1:1) to receive monotherapy with subcutaneous dupilumab 300 mg once weekly (qw), 300 mg every 2 weeks (q2w), or placebo for 16 weeks. Patients had IGA 3 (moderate) or 4 (severe) at baseline. Responder dynamics analysis of the dupilumab 300 mg q2w (FDA approved dose) and placebo groups was performed using pooled data from SOLO 1 & 2. In this post-hoc analysis, patients were classified by IGA score (0–1, 2, 3, or 4), percent improvement from baseline in EASI score (<50%, 50–<75%, 75–<90%, ≥90%), and change from baseline in peak pruritus NRS score (<3 or ≥3 points) at Weeks 2, 4, 6, 8, 12, and 16.

RESULTS: The distribution of dupilumab-treated patients within the IGA 0–1/2/3/4 categories shifted over time, with 0%/0%/51.2%/48.8% at baseline, 12.5%/31.4%/41.9%/14.3% at Week 4, and 38.1%/22.3%/29.4%/10.2% at Week 16. The distribution in the placebo group did not shift as much, with 0%/0%/51.0%/49.0% at baseline, 2.3%/14.7%/44.0%/39.1% at Week 4, and 10.6%/11.7%/39.3%/38.4% at Week 16. The distribution of dupilumab-treated patients within the predefined EASI categories ≥90, 75–<90, 50–<75, and <50 changed from 10.3%/17.5%/29.3%/42.9% at Week 4 to 32.8%/14.9%/19.3%/33.0% at Week 16. In the placebo group the distributions did not change as much, with 1.7%/5.2%/12.0%/81.1% at Week 4 and 7.4%/5.9%/10.0%/76.7% at Week 16. The proportion of dupilumab-treated patients with ≥3-point improvement from baseline in peak pruritus NRS was 35.7% at Week 4 and 48.8% at Week 16, while in the placebo group at the same time points it was 11.9% and 15.0%. Sometimes, transitions between categories showed a crisscrossing pattern, reflecting fluctuations over time in both disease course and treatment response. Treatment groups (q2w, placebo) had similar treatment-emergent adverse event rates (69%, 69%). Injection-site reactions and conjunctivitis were more frequent in dupilumab patients.

CONCLUSIONS: The distributions of responder categories over time indicate progressive, robust, clinically meaningful improvement in patients treated with dupilumab. In some cases, the exchange of patients between categories reflected a degree of disease and response instability. In contrast, considerably fewer patients receiving placebo achieved clinically meaningful levels of response, although they showed similar inter-category transition patterns over time. These results underline the complex dynamics of clinical responses in AD and suggest that a single time point analysis may not be adequate to fully characterize the effects of treatment.

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DISCLOSURES: Silverberg JI: Other (investigator): AbbVie, Celgene, Galderma, GlaxoSmithKline, Incyte, Kiniksa, Leo, Lilly, Realm, Regeneron Pharmaceuticals, Inc, Roche. Consultant: AbbVie, Anacor, Galderma, GlaxoSmithKline, Incyte, Kiniksa, Leo, Lilly, Menlo, Pfizer, Proctor & Gamble, Medimmune, Realm, Regeneron Pharmaceuticals, Inc,

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PA-09: Efficacy and safety of ingenol mebutate gel in field treatment of actinic keratosis on full face, balding scalp or approximately 250 cm2 on the chest: a Phase III randomized controlled trial

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BACKGROUND: Ingenol mebutate (IngMeb) is approved for the treatment of actinic keratosis (AK) in areas ≤25 cm2; however, some patients may require treatment of areas >25 cm2.
OBJECTIVE: This Phase III trial (NCT02361216) compared the efficacy and safety of IngMeb gel with vehicle as a field treatment in patients with AK, when applied once daily for three consecutive days on full face, balding scalp or approximately 250 cm2 on the chest.
METHODS: This was a randomized, parallel group, double-blind, vehicle-controlled, 8-week trial in patients with AK, evaluating IngMeb .027% gel or vehicle gel once daily for three consecutive days. Patients had 5–20 clinically typical, visible and discrete AKs within a selected treatment area of sun-damaged skin on either full face, balding scalp (>25–250 cm2) or a contiguous area of approximately 250 cm2 on the chest. Efficacy assessments were complete clearance (AKCLEAR 100), partial clearance
(AKCLEAR 75) and reduction in AK count from baseline (all measured at Week 8). Local skin responses (LSRs) and adverse events (AEs) were assessed on Days 1, and 4, and Weeks 1, 2, 4 and 8. Treatment Satisfaction Questionnaire for Medication (TSQM) and cosmetic outcome were assessed at Week 8.
RESULTS: 729 patients were randomised to receive either IngMeb (n=552) or vehicle (n=177). Median age of patients was 67.5 years; 73.4% were male; all were white and 95.6% had Fitzpatrick skin type I–III. Median AK count at baseline was 12. AKCLEAR 100 at 4Week 8 was 21.4% (IngMeb) versus 3.4% (vehicle; $P < .001$). AKCLEAR 75 at Week 8 was 59.4% (IngMeb) versus 8.9% (vehicle; $P < .001$). Reduction in AK count at Week 8 was 75.7% (IngMeb) versus 12.7% (vehicle; $P < .001$). Mean composite LSR score peaked at Day 4 with IngMeb (10.8; vehicle 1.6), declined rapidly and was minimal by Week 4. Lower efficacy of IngMeb on the scalp versus face/chest treatment areas was observed; this corresponded with reduced LSR scores in this area. Treatment-related AEs were experienced by 73.8% and 9.1% of patients in the IngMeb and vehicle groups, respectively. Serious AEs occurred in 1.5% versus 1.1% of patients receiving IngMeb or vehicle, respectively; none were treatment-related. Most common AEs were application site pain (63.8% versus 2.3%) and application site pruritus (36.8% versus 4.0%). TSQM global satisfaction score was significantly higher for IngMeb versus vehicle (41.0-point difference; $P < .001$). For cosmetic outcomes, 'much improved' or 'somewhat improved' for overall feel and appearance were reported in 92% and 94% patients, respectively, receiving IngMeb, versus 18% and 19% in vehicle group.
LIMITATIONS: Since LSRs were observed during the study, with early onset and rapid resolution, both investigators and patients could potentially identify those receiving active treatment.
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DISCLOSURE: Dr Hanke's institution has received funding from Leo Pharma for consultancy services, grants/grants pending and honoraria. Dr Albrecht is a principal investigator participating in the sponsored clinical research on behalf of Leo Pharma. Drs Kyhl, Larsson and Osterdal are employees of Leo Pharma. Dr Spelman received grants and personal fees from: Abbvie, Amgen, Ascend Biopharmaceuticals, Astellas Pharma, Australian Wool Innovation Ltd, Baxalta, Blaze Bioscience, Celgene, Celtaxys, Dermira, Eli Lilly, Galderma, Genentech, GlaxoSmithKline, Janssen, Kythera, Leo Pharma, Medimmune, Merck, Novartis, Otsuka, Phosphagenics, Regeneron, and Roche.
CONCLUSIONS: IngMeb .027% gel was superior to vehicle as a field treatment on full face, balding scalp or approximately 250 cm2 on the chest in patients with AK. The safety profile of IngMeb, for both LSRs and AEs, was as expected. IngMeb was also associated with higher levels of patient treatment satisfaction and cosmetic outcomes compared with vehicle.
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PA-10: Efficacy of a Halobetasol .01%/Tazarotene .045% Fixed Combination in the Treatment of Moderate-to-Severe Plaque Psoriasis: Results of 2 Phase III Randomized Controlled Trials

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BACKGROUND: Psoriasis is a chronic, immune-mediated disease that varies widely in its clinical expression. Treatment options focus on relieving symptoms, reducing inflammation, induration, and scaling, and controlling the extent of the disease. Topical corticosteroids are the mainstay of treatment, however long-term safety remains a concern, particularly with the more potent formulations. Combination therapy with a corticosteroid and tazarotene may improve psoriasis signs providing a superior safety profile, potentially reducing the occurrence of cutaneous adverse events of each individual component.
OBJECTIVE: To investigate the efficacy of a once-daily application of a fixed combination halobetasol propionate .01% and tazarotene .045% (HP/TAZ) lotion in comparison with its vehicle in subjects with moderate-to-severe plaque psoriasis.
METHODS: Two multicenter, randomized, double-blind, vehicle-controlled Phase 3 studies in moderate or severe psoriasis (N=418). Subjects randomized (2:1) to receive HP/TAZ or vehicle, once-daily for 8 weeks. Efficacy assessments included treatment success (defined as at least a 2-grade improvement from baseline in the IGA score and a score of 'clear' or 'almost clear'), impact on individual signs of psoriasis (erythema, plaque elevation, and scaling) at the target lesion, and reduction in Body Surface Area (BSA).
RESULTS: HP/TAZ lotion demonstrated statistically significant superiority over vehicle as early as 2 weeks. At Week 8, 35.8% (Study 1) and 45.3% (Study 2) of subjects had treatment success compared with 7.0% and 12.5% in the vehicle ($P < .001$) groups respectively. HP/TAZ lotion was superior to its vehicle in reducing the psoriasis signs of erythema, plaque elevation, and scaling at the target lesion. At Week 8, a 2-grade improvement was achieved by 44.2% and 49.6% of subjects for erythema, 59.3% and 59.7% for plaque elevation, and 59.4% and 62.9% for scaling (all $P < .001$). In addition, there was a 32.8% and 42.5% reduction in mean BSA.
CONCLUSIONS: HP/TAZ lotion was consistently more effective than its vehicle in achieving treatment success, reducing psoriasis signs of erythema, plaque elevation, and scaling at the target lesion, and reducing BSA.
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DISCLOSURES: Dr. Lebwohl is an employee of the Mount Sinai Medical Center, which receives research funds from AbbVie, Amgen, Celgene, Eli Lilly, Janssen, Leo, Merck, Novartis, Pfizer, Sandoz, Sun Pharma and Valeant. Dr. Stein Gold is an advisor, investigator, and/or consultant for Leo and Valeant. Dr. Sugarman is an investigator for Galderma, Ranbaxy, and Activis, a consultant for Galderma, and a Medical Safety Monitor for Seegpharma and Valeant. Dr. Pariser or his institution has received grant/research support from Abbott Laboratories, Amgen, Astellas Pharma US, Asubio Pharmaceuticals, Basilea Pharmaceutical, Celgene Corporation, Dow Pharmaceutical Sciences, Eli Lilly, Galderma Laboratories, Graceway Pharmaceuticals, Intendis, Johnson & Johnson, Novartis Pharmaceuticals, Novo Nordisk A/S, Ortho Dermatologics, Photocure ASA, Stiefel Laboratories, and Valeant Pharmaceuticals, and has received other financial support from LEO Pharma US and Pfizer. Steven Yawn, Tina Lin, Gina Martin, Lindsey Mathew and Radhakrishnan Pillai are employees of Valeant Pharmaceuticals.

PA-11: Efficacy of brodalumab in ustekinumab-naive and -experienced patients with moderate-to-severe plaque psoriasis

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BACKGROUND: Brodalumab is a fully human anti–interleukin-17 receptor A (IL-17RA) monoclonal antibody that has shown efficacy in patients with moderate-to-severe plaque psoriasis.
OBJECTIVE: To evaluate the efficacy of brodalumab in a post hoc analysis of a subset of patients with prior expo-

sure to ustekinumab, a human anti–IL-12/-23 monoclonal antibody approved for the treatment of moderate-to-severe plaque psoriasis, enrolled in a phase 3, multicenter, randomized, double-blind, placebo-controlled study (AMAGINE-1).
METHODS: During the induction phase, patients received brodalumab 210 mg weekly for the first 3 weeks and every 2 weeks (Q2W) thereafter for 12 weeks. After 12 weeks, patients who achieved a static physician's global assessment (sPGA) score of 0 or 1 continued to the withdrawal phase and were rerandomized to receive brodalumab 210 mg Q2W or placebo for up to 52 weeks. Beginning at week 16, all rerandomized patients who experienced return of disease (sPGA ≥3) qualified for retreatment with their induction dose of brodalumab 210 mg and were imputed as nonresponders at the time of qualification. Skin clearance was monitored by the psoriasis area and severity index (PASI) and the sPGA.
RESULTS: Of 167 patients who were randomized to brodalumab 210 mg in the induction phase and continued into the withdrawal phase, 19.2% had taken ustekinumab prior to the start of the trial (n=32). Among patients receiving continuous brodalumab 210 mg, rates of 100% reduction in PASI score (PASI 100) were 65.2% (n=43 of 66) and 76.5% (n=13 of 17) in ustekinumab-naive and -experienced patients, respectively (rates for placebo were 0 [n=0 of 69] and 0 [n=0 of 15], respectively). Similarly, rates of PASI 75 and PASI 90 were 84.8% (n=56 of 66) and 75.8% (n=50 of 66), respectively, in ustekinumab-naive patients and 94.1% (n=16 of 17) and 88.2% (n=15 of 17), respectively, in ustekinumab-experienced patients (rates for placebo were 0 [n=0 of 69] and 0 [n=0 of 69], respectively, in ustekinumab-naive patients and 0 [n=0 of 15] and 0 [n=0 of 15], respectively, in ustekinumab-experienced patients).
LIMITATIONS: Real-world efficacy outcomes may differ from the data presented here from a controlled clinical trial.
CONCLUSION: Brodalumab 210 mg was associated with improved skin clearance efficacy in both patients with and without prior ustekinumab exposure.
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PA-12: Efficacy of Guselkumab in Previously Treated Patients with Moderate-to-Severe Plaque Psoriasis: An Analysis from VOYAGE 1 and VOYAGE 2

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INTRODUCTION/OBJECTIVE: To determine the efficacy of guselkumab (GUS) in patients with a history of previous use of psoriasis (PsO) treatments.
METHODS: Using pooled data from VOYAGE 1 and VOYAGE 2, an analysis was conducted in patients with "no previous use" vs. those with "previous use" of PsO treatments [non-biologic systemics, biologics, nonbiologic systemics or biologics, anti-tumor necrosis factor (TNF) agents etanercept {ETN} and infliximab {IFX}] using the Investigator Global Assessment (IGA) 0/1 and Psoriasis Area and Severity Index (PASI) 90 efficacy measures through Week 24.
RESULTS: A total of 1829 patients with moderate-severe PsO were included in this analysis (422 placebo [PBO], 825 GUS, and 582 adalimumab [ADA]). Significantly higher (all $P < .001$) proportions of patients in the GUS vs. PBO group achieved IGA 0/1 and PASI 90 at Week 16, both among patients with previous use and among those with no previous use of the above treatments. Similarly, significantly higher proportions of patients in the GUS vs. ADA groups achieved IGA 0/1 and PASI 90 at Week 24 (all $P <.001$), both among patients with previous use and among those with no previous use of the above treatments. Overall, IGA 0/1 and PASI 90 results were similar between GUS-treated patients with and without previous use of each type of PsO treatment at Week 16 and Week 24; however, IGA 0/1 and PASI 90 results were lower among ADA-treated patients with previous use of biologics or anti-TNF agents than those without previous use of these agents (Table).
CONCLUSION: GUS was superior to both PBO at Week 16 and to ADA at Week 24 in patients regardless of previous use of PsO treatments through Week 24. Prior use of anti-TNF therapy was associated with notably decreased clinical responses to ADA, but not to GUS.
DISCLOSURES: Drs. Kenneth Gordon, Andrew Blauvelt, Peter Foley, Christopher E M Griffiths-investigators for Janssen Research & Development, LLC, Spring House, PA. Drs. Michael Song, Yasmine Wasfi, Bruce Randazzo,

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PA-13: Guselkumab Decreases Physical Demand, Time Management, Mental-Interpersonal, and Output Demand Scores from the Work Limitations Questionnaire in Patients with Moderate-to-Severe Psoriasis: Results from VOYAGE2

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INTRODUCTION/OBJECTIVE: VOYAGE 2 was a phase 3, double-blind, placebo- and active-comparator-controlled study that evaluated the efficacy and safety of guselkumab (GUS) in patients with moderate-to-severe psoriasis (PsO). We report results of the self-administered Work Limitations Questionnaire (WLQ) to determine the change from baseline of on-the-job disability.
METHODS: Patients were randomized to GUS 100mg at wks0/4/12/20; placebo at wks0/4/12 then GUS 100mg at wks16/20; or adalimumab (ADA) 80mg at wk0, and 40mg at wk1, and q2wk through Week 23. PASI 90 responders initially randomized to GUS were re-randomized at Wk28 to either continue GUS 100 mg q8w or receive placebo. The WLQ consists of four work limitation scales: Time Management, Physical, Mental-Interpersonal, and Output scores; higher scores indicate increasing on-the-job disability. Mean changes from baseline for each of the four work limitation scales are presented.
RESULTS: Mean decreases from baseline across the four work limitations scales were observed as early as Week 8. At week 16, patients receiving GUS experienced significantly greater score reductions across all four work limitation scales compared to placebo. At week 24, patients receiving GUS experienced significantly greater score reductions for the Physical, Mental-Interpersonal, and Output scores compared to ADA (Table). For patients re-randomized to continue GUS 100 mg q8w, the Week 24 level of reduction from baseline was maintained at Week 48 across all four work limitations scales.
CONCLUSION: GUS significantly improved patients' Time Management, Physical, Mental-Interpersonal, and Output Demand scores compared with placebo and Physical, Mental-Interpersonal, and Output Demand scores compared with ADA in psoriasis patients as measured by the WLQ.
DISCLOSURES: Drs. Kristian Reich, Peter Foley, Kenneth Gordon, April Armstrong all investigators for Janssen Research & Development, LLC, Spring House, PA. Drs. Michael Song, Yasmine Wasfi, Shu Li, Reginald Villacorta, Yaung-Kaung Shen, Chenglong Han, Sean McElligott-all employees of Janssen Research & Development, LLC, Spring House, PA.

PA-14: Guselkumab Demonstrates Greater Reductions in Anxiety and Depression Symptoms than Adalimumab in Psoriasis Patients

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INTRODUCTION/OBJECTIVE: Anxiety and depression are comorbidities frequently associated with psoriasis. Improvement in psoriasis has been shown to decrease anxiety and depression. Guselkumab, an anti-interleukin-23 monoclonal antibody has demonstrated efficacy and safety for the treatment of moderate-to-severe plaque psoriasis.
METHODS: VOYAGE 2 was a Phase 3, randomized, double-blind, placebo- and adalimumab-controlled study in which patients received placebo (placebo-crossover to guselkumab occurred at week 16), guselkumab, or adalimumab through week 24. The Hospital Anxiety and Depression Scale (HADS) consists of two subscales measuring anxiety (HADS-A) or depression (HADS-D), with scores ranging from 0-21 and higher scores indicating more severe symptoms. Scores ≥8 represent the instrument's definition of anxiety/depression. Severity of psoriasis was assessed using the Psoriasis Area and Severity Index (PASI).
RESULTS: Among 992 patients randomized at baseline, mean HADS-A and HADS-D scores were 6.8±4.2 and 5.3±4.2, respectively; 38.6% of patients reported HADS-A≥8 and 27.7% HADS-D≥8 at baseline. At week 16, a significantly greater proportion of guselkumab (51.4%) patients with baseline HADS-A≥8 reported HADS-A<8 compared with placebo (25.9%; $P < .001$), and 59.2% of guselkumab patients reported HADS-D<8 vs placebo (27.0%; $P < .001$) among patients with baseline HADS-D≥8. At week 24, a greater proportion of guselkumab patients no longer reported anxiety/depression vs adalimumab patients (HADS-A<8 [58.4% vs 42.9%; p=0.03]) or HADS-D<8 [59.8% vs 46.4%; p=0.08]). Overall improve-

ments in PASI score significantly correlated with change from baseline in anxiety (r=-0.27; $P < .001$) or depression (r=-0.25; $P < .001$) in patients with baseline HADS scores ≥8.
CONCLUSION: Anxiety/depression are important comorbidities in psoriasis. Guselkumab treatment reduced anxiety and depression in patients with moderate to severe plaque psoriasis. The improvements in anxiety/depression were correlated with improvement in psoriasis severity.
DISCLOSURES: Drs. Kenneth Gordon, MD, April W. Armstrong, MD, MPH, Peter Foley, MD and Kristian Reich, MD all investigators for Janssen Research & Development, LLC, Spring House, PA. Drs. Chenglong Han, Michael Song, Yasmine Wasfi, Yin You, Yaung-Kaung Shen –employees of Janssen Research & Development, LLC, Spring House, PA.

PA-15: Healthcare Utilization and Costs Associated With Biologic Treatment Patterns Among Patients With Psoriasis: Analyses From a US Claims Database

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BACKGROUND: Discontinuation or switching of biologic treatment among patients with psoriasis (PsO) imposes a great economic burden.
OBJECTIVES: To assess the healthcare utilization and costs associated with non-switchers, switchers and discontinuers of biologics among patients with moderate to severe PsO.
METHODS: Patients aged ≥ 18 years with ≥ 1 pharmacy claim for a biologic (adalimumab, etanercept, infliximab and ustekinumab) from January 1, 2012 to June 30, 2015 (index period) were identified in the Truven Health Analytics MarketScan Commercial and Medicare Supplemental Databases. At the time of biologic initiation (index date), eligible patients were continuously enrolled with medical and pharmacy claims ≥ 1 year before (baseline period) and ≥ 1 year after the index date (follow-up period). Patients had ≥ 1 PsO diagnosis and had no pharmacy claims for the index biologic during the baseline period. Patients were categorized into three mutually exclusive groups based on their biologic treatment pattern during the follow-up period: non-switchers (patients who remained on the index biologic), switchers (patients who switched to a new biologic therapy) and discontinuers (patients who had gaps in prescription claims [> 90 days for adalimumab, infliximab and etanercept; > 120 days for ustekinumab]). Healthcare utilization and costs (per patient per year, inflated to year 2016 costs) during the 1-year follow-up period were compared descriptively across the three groups.
RESULTS: Among the 8710 patients with PsO included in study, 5000 patients (57.4%) were categorized as non-switchers, 1001 (11.5%) as switchers and 2709 (31.1%) as discontinuers. Overall, 4289 patients (49.2%) initiated adalimumab (57.4% non-switchers, 11.5% switchers and 31.1% discontinuers), 2795 (32.1%) initiated etanercept (52.2% non-switchers, 12.8% switchers and 35.0% discontinuers), 161 (1.8%) initiated infliximab (56.8% non-switchers, 12.7% switchers and 30.5% discontinuers) and 1465 (16.8%) initiated ustekinumab (68.7% non-switchers, 5.1% switchers and 26.3% discontinuers). Emergency room visits and hospitalizations, respectively, were more common among switchers (20.3% and 5.8%) and discontinuers (25.6% and 9.4%) compared with non-switchers (16.4% and 4.9%). Compared with non-switchers, switchers had higher mean total healthcare cost ($60,734 vs $51,133), which was driven by both increased prescription ($49,943 vs $42,315) and medical costs ($10,791 vs $8,819). The mean total healthcare cost for discontinuers ($33,828) was much lower than the other treatment pattern groups, due to reduced prescription costs from early discontinuation of therapy ($21,978); however, discontinuers had the highest mean medical cost ($11,850).
LIMITATIONS: The findings are not generalizable to the general population because the data used are limited to those patients who have commercial and Medicare supplemental insurances. As these are descriptive results, further advanced analyses are required to adjust for differences in baseline characteristics and baseline healthcare utilization and costs.
CONCLUSIONS: Switching or discontinuing biologics resulted in higher healthcare utilization and increased medical costs than remaining on the same biologic.
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DISCLOSURES: S. Feldman has received consulting, speaking and/or research support from Novartis, AbbVie, Amgen, Celgene, Galderma, Janssen, Lilly, and Valeant. J.B. Palmer and H. Tian are employees of Novartis. X. Wang and Z. Wei are employees of KMK Consulting, Inc, and work as consultants for Novartis. L. Djatche is an employee of Jefferson College of Population Health, and is providing onsite services to Novartis.
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PA-16: Impact of Brodalumab Treatment on Patient's Quality of Life in Moderate-To-Severe Psoriasis Patients: 12 Week Results from AMAGINE Trials

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BACKGROUND: Quality of life (QoL) of patients with psoriasis is markedly impaired, and is an important factor in assessing severity of disease. Psoriasis can negatively impact many aspects of life; including work/school productivity, skin-related personal relationship difficulties, and leisure activity. Brodalumab, a fully human interleukin-17 receptor A (IL-17RA) monoclonal antibody, has demonstrated good efficacy and safety in the treatment of moderate-to-severe psoriasis with a rapid onset of action and sustained response.
OBJECTIVE: To assess the effect of brodalumab treatment on individual aspects of QoL in patients with moderate-to-severe psoriasis evaluating the Dermatology Life Quality Index (DLQI).
METHODS: Pooled data (N=3760) were obtained from three large phase 3 trials (AMAGINE-1, -2, and -3) in patients with moderate-to-severe plaque psoriasis randomized to subcutaneous placebo or brodalumab for 12 weeks. QoL was assessed based on changes in DLQI, comprising 10 questions covering six key elements. Each question was scored between 0 ('not at all') and 3 ('very much'); and elements affecting daily life: symptoms/feelings (DLQI questions 1 and 2), daily activities (questions 3 and 4); leisure (questions 5 and 6); work and school (question 7); and personal relationships (questions 8 and 9). and treatment (question 10) assessed separately. The aggregated response ranging from 0 to 30 measuring the impact of skin disease on the quality of life of an affected person with 0 implying no effect on patient's life.
RESULTS: Overall, 844 patients were randomized to placebo, and 1458 to brodalumab 210 mg Q2W. At baseline, mean DLQI was 14.4 ± 6.8 and 14.5 ± 7.2, respectively, indicating a large negative effect of psoriasis on patients' lives. Treatment with brodalumab rapidly and significantly improved DLQI compared to placebo. At Week 12, 86.9% of patients achieved at least a 5-point improvement in total DLQI score, and 38.1% DLQI=0 (compared with 28.0% and 2.3% respectively with placebo, both $P < .001$). Improvements with brodalumab treatment in key elements affecting QoL were also significant better than with placebo by Week 12; with 84% of patients reporting no impact on work/school activities, 77% no impact on personal relationships, and 73% and 68% no impact on leisure and daily activities (compared with 47.3%, 39.2%, 23.3% and 12.7% respectively with placebo, all $P < .001$).
CONCLUSION: In this pooled analysis, 12 weeks of treatment with brodalumab 210 mg Q2W improves QoL as assessed by changes in DLQI in patients with moderate-to-severe psoriasis. These findings support the high levels of skin clearance reported in each of the individual studies.
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DISCLOSURES: Dr. Yamauchi is a consultant, an investigator, and on the speaker's bureau for Amgen, Celgene, Janssen-Ortho, Leo and Novartis, a consultant/speaker for AbbVie, consultant/investigator for Dermira, Lilly, Pfizer, and Regeneron, speaker/investigator for Galderma, and investigator for Medimmune and Sandoz. Dr Weiss is an advisor/consultant for AbbVie, Dermira, Ortho-Dermatologics and Janssen, and a speaker for AbbVie and Ortho-Dermatologics. Dr Desai is a consultant for AbbVie, Menlo, Valeant, Pfizer, Allergan and Galderma, an investigator for Menlo, Symbio, Perrigo, and a speaker for Pfizer, Valeant and Galderma. Dr Rastogi, Pillai and Israel are employees of Valeant Pharmaceuticals.

PA-17: Impact of palmoplantar psoriasis on clinical and patient reported outcomes: Results from the Corrona Psoriasis Registry

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OBJECTIVE: Palmoplantar psoriasis (PPP) is associated with a profound negative impact on patients' quality of life and is difficult to treat. The objective of this study was to assess the impact of PPP on clinical and patient reported outcomes (PROs) among patients enrolled in the Corrona Psoriasis (PsO) Registry.
METHODS: Adult PsO patients enrolled between 4/2015 – 4/2017, who initiated an eligible systemic therapy at enrollment were included. Descriptive analyses of demographics, disease severity (BSA, PASI), PROs (overall itch, pain on VAS 0-100, Dermatology Life Quality Index (DLQI), Work Productivity and Activity Impairment, EQ-5D-3L) and treatment history were compared between patients with and without PPP using appropriate statistical tests (t-test/chi-square tests for continuous and categorical variables resp.).

RESULTS: Of 1,037 patients who met inclusion criteria, 127 (12.2%) had PPP. Patients with PPP had comparable mean disease duration (14.4 vs 15.4 yrs), but were older (mean: 54.6 vs. 48.9 yrs), more likely female (58% vs 50%), and less employed as full/part time (62% vs 69%), compared to patients with no PPP, respectively (all $P < .05$). Patients with PPP were less biologic experienced (54% vs 58%), and 48% (vs 52%) had history of ≥2 prior biologic use, compared to patients without PPP, respectively. Disease severity was similar in patients with/without PPP (mean BSA: 15.0 vs 15.6; mean PASI: 9.5 vs 9.0, respectively). Patients with PPP had more erythrodermic (21% vs 2%), scalp (46% vs 35%) and nail (32% vs 13%) morphologies, compared to patients without PPP (all $P < .05$). Patients with PPP had significantly worse overall daily activity impairment (mean percent: 36.1 vs 23.5), overall work impairment (mean: 30.2 vs 17.8) and quality of life scores (mean DLQI 11.1 vs 8.0), compared to those without PPP, respectively (all $P < .01$). A significantly higher proportion of PPP patients reported some/extreme problems on the self-care, usual activities, pain/discomfort and anxiety/depression subdomains of the EQ-5D-3L vs those without PPP (all $P < .05$).
CONCLUSION: These results from the Corrona PsO registry showed that, although they have similar disease severity, PPP patients have more difficult-to-treat variants of PsO, including erythrodermic, nail and scalp disease than patients without PPP. They also reported a significantly higher burden of the disease in terms of work and activity impairment and quality of life.
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PA-18: Impact of Previous Biologic Use on Efficacy and Safety of Brodalumab and Ustekinumab in Patients with Moderate-to-Severe Plaque Psoriasis: Integrated Analysis of AMAGINE-2 and AMAGINE-3

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BACKGROUND: Biologics are increasingly used for treating moderate-to-severe psoriasis. Efficacy may differ in patients with previous biologics exposure.
OBJECTIVE: To investigate the impact of previous biologic exposure on efficacy and safety of brodalumab and ustekinumab in moderate-to-severe plaque psoriasis.
METHODS: Two placebo- and ustekinumab-controlled phase 3 clinical trials. Initial 12-week induction phase where patients were treated with brodalumab (210mg Q2W or 140mg Q2W), ustekinumab or placebo. Efficacy endpoints included: Psoriasis Area and Severity Index (PASI 75) and Physician's Global Assessment (sPGA 0/1) versus placebo, PASI 100 versus ustekinumab, Dermatology Life Quality Index (DLQI) and Psoriasis Symptom Inventory (PSI). Adverse events were monitored throughout.
RESULTS: 493 patients (334 [27%] brodalumab 210 mg Q2W and 159 [26%] ustekinumab) received prior biologics exposure; 150 (12%) and 62 (10%) reporting previously failed biologic. Brodalumab efficacy in patients with or without previous biologics exposure was statistically equivalent; 40.9% and 39.5% of bio-naïve and -experienced patients achieved PASI 100 at Week 12, compared with 21.1% and 17.0% with ustekinumab (both $P < .001$). In patients where prior biologics had been successful or failed, 41.7% and 32.0% achieved PASI 100, compared with 21.1% and 11.3% with ustekinumab. Tolerability was similar between brodalumab and ustekinumab, and did not appear to be influenced by previous biologic treatment.
CONCLUSIONS: Efficacy of brodalumab 210 mg Q2W was equivalent regardless of prior biologic therapy. Almost twice as many patients achieved PASI 100 or complete clearance at Week 12 compared with ustekinumab;

differences most noticeable where previous biologics had failed. Both treatments were well tolerated.

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DISCLOSURES: Dr. Papp is a consultant, an investigator, and on the speakers' bureau for AbbVie, Amgen, Astellas, Bayer, Boehringer Ingelheim, Celgene, Eli Lilly, Forward, Galderma, Janssen, LEO, Merck, Novartis, Pfizer, Roche, and UCB. Dr. Gordon has grant support from Eli Lilly and grant support/personal fees from AbbVie, Amgen, Eli Lilly, Janssen, and Boehringer Ingelheim, and personal fees from Celgene, Novartis, and Pfizer. Dr. Langley reports grant support and personal fees from AbbVie, Amgen, Celgene, Centocor, Eli Lilly, Novartis, Pfizer and Valeant. Dr. Lebwohl is an employee of the Mount Sinai Medical Center, which receives research funds from Amgen, Anacor, Aqua, Canfite Biopharma, Celgene, Clinuvel, Coronado Biosciences, Eli Lilly, Ferndale, Janssen, Leo, Merck, Novartis, Pfizer, Sandoz, and Valeant. Dr. Gottlieb is a consultant/advisor for Amgen, Astellas, Akros, Centocor (Janssen), Celgene, Bristol Myers Squibb, Beiersdorf, Abbott Labs. (Abbvie), TEVA, Actelion, UCB, Novo Nordisk, Novartis, Dermipsor, Incyte, Pfizer, Canfite, Lilly, Coronado, Vertex, Karyopharm, CSL Behring Biotherapies for Life, Glaxo Smith Kline, Xenoport, Catabasis, Meiji Seika Pharma, Takeda, Mitsubishi, Tanabe Pharma Development America, Genentech, Baxalta, Kineta One, KPI Therapeutics, Crescendo Bioscience, Aclaris, Amicus, Reddy Labs, Valeant, Dermira, and Allergan; and has research/educational grants (paid to Tufts Medical Center) with Centocor (Janssen), Amgen, Abbott (Abbvie), Novartis, Celgene, Pfizer, Lilly, Levia, Merck, Xenoport, Dermira, and Baxalta. Dr. Rastogi, Pillai and Israel are employees of Valeant Pharmaceuticals.

PA-19: Inappropriate prescription of nystatin for dermatophyte infections in the United States, 2003-2014

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BACKGROUND: Superficial cutaneous fungal infections are among the most common dermatologic conditions encountered in clinical practice and rank as one of the highest in total direct costs among skin disease groups. Dermatophyte infections, designated as different forms of tinea based on the cutaneous site involved, respond well to a variety of systemic and topical antifungal therapy. Although it is effective for the treatment of cutaneous or mucocutaneous candidiasis, the topical polyene nystatin, however, is clinically ineffective in the treatment of dermatophyte infection.

OBJECTIVES: (1) Estimate the number of visits associated with a diagnosis of dermatophytosis; (2) Evaluate demographic and health-care related factors associated with dermatophytosis; (3) Characterize the frequency of nystatin use for dermatophytosis and identify the odds of an inappropriate prescription by physician specialty.

METHODS: Twelve years (2003 – 2014) of data from the National Ambulatory Medical Care Surveys (NAMCS) and National Hospital Ambulatory Medical Care Survey – Emergency Department (NHAMCS-ED) as well as nine years (2003 – 2011) of data from the NHAMCS-Outpatient Department (OPD) survey were aggregated for analysis. Visits were stratified and weighted to reflect their clustered sampling probability as described by National Center for Health Statistics (NHCS). After identifying visits with a diagnosis of "dermatophytosis", logistic regression for complex samples was used to estimate the odds of a dermatophyte infection as a function of multivariable patient characteristics, including race, age, sex, and insurance status. Visits where nystatin was used for dermatophytosis were identified, including information on provider specialty, while excluding visits where candidiasis was a diagnosis and drugs appropriate for the treatment dermatophytosis were mentioned.

RESULTS: Among 13.8 billion ambulatory visits, dermatophyte infections accounted for 48.4 million with 13% of these visits occurring in the hospital OPD or ED setting. Controlling for age, sex, and insurance status, patients identifying as Black were 1.69 (95% CI: 1.43 – 1.99) times more likely to have a positive tinea infection ($P < .001$). Similarly, controlling for race, age, and insurance status, males were 1.73 (95% CI: 1.52 – 1.96) times more likely to have a positive tinea infection ($P < .001$). Conversely, controlling for all other variables in the model, patients using a payment method other than Medicaid or Medicare were only 0.70 (95% CI: .54 – .90) times as likely to have a positive tinea infection when compared to those with private insurance ($P = .01$). There were 1,459,184 (95% CI: 836,640 – 2,081,728) visits during which nystatin was prescribed for a dermatophyte infection. Compared to dermatologists, non-dermatologists were 11.08 (95% CI: 1.42 – 86.32) times more likely to prescribe nystatin ($P = .02$) for dermatophytosis.

LIMITATIONS: Although prevalence estimates may be calculated using census data, the number of visits does not reflect the true disease prevalence.

CONCLUSION: Disparities in healthcare affect those who present with dermatophytosis. Non-dermatologists may benefit from additional provider education on the diagnosis and appropriate treatment of dermatophyte infections.

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PA-20: Incidence of Inflammatory Bowel Disease Events in Adalimumab (HUMIRA) Clinical Trials Across Indications

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BACKGROUND: Adalimumab (ADA) is approved for treatment of Crohn's disease (CD) and ulcerative colitis (UC); therefore, it is postulated that new onset or flare of inflammatory bowel disease (IBD) is a rare occurrence in ADA clinical trials for non-IBD indications.
OBJECTIVE: The purpose of this analysis was to determine the rates of IBD adverse events (AEs) in ADA clinical trials, particularly in spondyloarthritis (SpA) patients who are at higher risk of IBD as a feature of SpA.
METHODS: Rates of IBD AEs in 73 phase 2–4 interventional ADA clinical trials in rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (pJIA), pediatric enthesitis-related arthritis, uveitis, hidradenitis suppurativa (HS), adult/pediatric psoriasis (Ps), psoriatic arthritis (PsA), non-PsA peripheral SpA (pSpA), non-radiographic axial spondyloarthritis (nr-axSpA), and ankylosing spondylitis (AS) were analyzed (trials in UC, CD, and intestinal Behcet's disease [BD] were excluded). Search criteria for IBD events included the following standardized MedDRA queries preferred terms: IBD, UC, CD, IBD-not otherwise specified, and ulcerative proctitis. Incidence rates (IR) for events of IBD (combined new onset and flare) are reported as events per 100 patient-years (PY). 95% confidence intervals (CI) were based on exact Poisson confidence limits.
RESULTS: ADA was administered to 23735 patients, representing 36404.6 PY of exposure. Overall, the IR for IBD events in all interventional ADA trials included in this analysis was 0.1/100PY. Rates of IBD events varied across therapeutic indications from <0.1 to 0.8/100PY; no reports of IBD events in pediatric patients. IR for IBD events in RA, uveitis, HS, and Ps trials were <0.1, 0.2, 0.4, and <0.1/100 PY. In SpA, the overall rates of IBD were 0.5/100 PY, while the rates were 0, 0.8, 0.5, and 0.7/100 PY in PsA, non-PsA pSpA, nr-axSpA, and AS, respectively. 2216 patients with axSpA (AS: 2026, nr-axSpA: 190) were exposed to ADA; in AS, 14 IBD events (7 new onset and 7 flares) were reported in 12 patients (7 new onset and 5 flares), while in nr-axSpA, 2 IBD events were reported in 1 patient (2 flares).
CONCLUSIONS: Rates of IBD AEs in ADA clinical trials were generally low across all indications, with all events occurring in adult patients. In AS patients, who are at increased risk of manifesting IBD, the rates of IBD for patients treated with ADA (.7/100 PY [95% CI, .4–1.1]) were similar to published placebo rates pooled across multiple clinical trials (1.3/100 PY [95% CI, .2–4.8]).1 In patients at risk for IBD requiring biologic therapy, ADA is a reasonable therapeutic option based on the observed low IBD event rates in ADA clinical trials and its demonstrated efficacy in treating UC and CD patients.
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DISCLOSURES: JR Curtis has received research grants and/or consulting fees from Amgen, BMS, CORRONA, Crescendo, Janssen, Pfizer, and UCB. D Elewaut has received research grants, consulting fees, and/or speaker's fees from AbbVie. S Chen, M Hojnik, N Naveh, and JK Anderson are employees of AbbVie and may own stock/options.
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PA-21: Long-Term Efficacy of Adalimumab Across Subgroups of Patients with Moderate to Severe Plaque Psoriasis

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BACKGROUND: Patients with moderate-to-severe plaque psoriasis (Ps) who had sustained ≥PASI 75 responses during the first 33 weeks of adalimumab (ADA) therapy in the phase 3 REVEAL trial (NCT00237887) continued to have substantial improvements through >3 years of total ADA treatment.
OBJECTIVE: In these patients, we evaluated post hoc if baseline demographics and disease characteristics had an effect on long-term efficacy of ADA.
METHODS: REVEAL was a 52-week trial of ADA for chronic plaque Ps followed by an open-label extension (OLE) study for a total of >3 years of uninterrupted treatment with ADA. Patients on ADA achieving ≥PASI75 response at weeks 16 and 33 were re-randomized to 40 mg ADA or PBO every other week. Patients who completed REVEAL at week 52 were eligible to enter the OLE. Long-Term Responders (patients treated with ADA from baseline who achieved ≥PASI75 responses at weeks 16 and 33 and re-randomized to continue receiving ADA therapy from week 33 of REVEAL) were evaluated at the end of REVEAL (week 52) and subsequently at every visit during OLE until week 160. The impact of baseline demographics and disease characteristics (age, sex, race, duration of Ps, history of PsA, or prior systemic therapy, weight, and BMI) on long-term efficacy (PASI 75/90) of ADA were evaluated for

Long-Term Responders at week 160. Missing values were imputed using last observation carried forward.
RESULTS: 250 patients achieved ≥PASI 75 responses at week 33 and continued to receive ADA through the OLE. Baseline demographics and disease characteristics of Long-Term Responders were consistent with moderate to severe Ps and comparable to the overall REVEAL population. At week 160, PASI 75, PASI 90, and PASI 100 rates, respectively, for patients with PsA (n=72) were 77.8%, 47.2%, and 23.6%; for patients without PsA (n=178), 76.4%, 51.7%, and 33.7%. Similarly, there was no impact of age, sex, race, duration of Ps, or prior systemic therapy on ADA efficacy at week 160. A marginal trend was observed for higher response rates in less overweight patients.
CONCLUSIONS: Overall, patients who achieved ≥PASI 75 responses at week 33 maintained their responses through >3 years of ADA treatment, regardless of baseline demographics and disease characteristics.
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DISCLOSURES: PS Yamauchi has received grants and research support, consulting fees, or honoraria from AbbVie, Amgen, Baxter, Celgene, Lilly ICOS LLC (now Eli Lilly), Galderma USA, Janssen-Ortho, Leo Pharma, Novartis and Pfizer. JF Maa and W Valdecantos are salaried employees of AbbVie and may receive stock or stock options.
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PA-22: Long-term efficacy of brodalumab for the treatment of moderate-to-severe psoriasis: data from a pivotal phase 3 trial

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BACKGROUND: Brodalumab is a fully human anti–interleukin-17 receptor A monoclonal antibody that antagonizes the action of specific inflammatory cytokines involved in psoriasis. Pivotal phase 3 clinical trials demonstrated the efficacy and safety of brodalumab through 52 weeks of treatment in patients with moderate-to-severe psoriasis.
OBJECTIVE: To evaluate the efficacy of brodalumab in psoriasis from week 52 through week 120. Data were derived from the long-term, open-label extension study of a 52-week, randomized, double-blind, placebo- and active comparator–controlled clinical trial (AMAGINE-2).
METHODS: Patients received brodalumab 210 mg or 140 mg every 2 weeks (Q2W), ustekinumab, or placebo during a 12-week induction phase, followed by a maintenance phase through week 52. During the maintenance phase, patients receiving brodalumab were rerandomized to a different dose and interval of brodalumab (210 mg or 140 mg Q2W, Q4W, or Q8W), patients receiving placebo were switched to brodalumab 210 mg Q2W, and patients receiving ustekinumab continued on ustekinumab. At week 52, patients who received brodalumab during the maintenance phase continued receiving their maintenance dose of brodalumab, and patients who were taking ustekinumab switched to brodalumab 210 mg Q2W. Data are presented for patients who received brodalumab 210 mg Q2W (the FDA-approved dose) through week 120 of the long-term extension phase.
RESULTS: A total of 1392 patients received brodalumab 210 mg Q2W in the long-term extension phase. At week 52, rates of these patients for psoriasis area and severity index 75% improvement (PASI 75), PASI 90, and PASI 100 were 90.6% (95 CI%, 88.9%-92.2%; n/N, 1162/1282), 77.6% (75.2%-79.9%; 995/1282), and 53.3% (50.5%-56.0%; 683/1282), respectively. Similarly, at week 120, corresponding responder rates were 88.4% (95% CI, 86.0%-90.6%; n/N, 689/779), 76.8% (73.6%-79.7%; 598/779), and 56.2% (52.7%-59.7%; 438/779), respectively. Success rates, based on static physician's global assessment score of 0 or 1, were 79.2% (95 CI%, 76.8%-81.4%; n/N, 1015/1282) and 76.6% (73.5%-79.6%; 597/779) at weeks 52 and 120, respectively.
LIMITATIONS: Real-world efficacy outcomes may differ from the "as-observed" data presented here from a controlled clinical trial.
CONCLUSION: Treatment with brodalumab resulted in substantial psoriatic lesion clearing for more than 2 years in most patients with moderate-to-severe psoriasis.
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DISCLOSURES: Medical writing support was provided by MedThink SciCom and was funded by Valeant Pharmaceuticals North America LLC. This study was sponsored by Amgen Inc. Robert J. Israel is an employee of Valeant Pharmaceuticals North America LLC and may hold stock and/or stock options in the company. Radhakrishnan K. Pillai is an employee of Dow Pharmaceutical Sciences (a division of Valeant Pharmaceuticals North America LLC) and may hold stock and/or stock options in the company.

PA-23: Long-term Safety and Effectiveness of Adalimumab for Moderate to Severe Psoriasis: Results from the Eight-Year Interim Analysis of the ESPRIT registry

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BACKGROUND: ESPRIT is a 10-year international prospective observational registry evaluating the long-term safety and effectiveness of originator adalimumab (ADA) in adult patients with moderate to severe chronic plaque psoriasis.
OBJECTIVE: Herein, we report the interim over the initial 8 years of the registry.
METHODS: ESPRIT enrolled patients from Europe and North America who were continuing ADA treatment from a current prescription or previous study participation, or initiating ADA ≤4 weeks of entering the registry (New Prescription Population [New-Rx]). The All-Treated Population (All-Rx) received at least 1 ADA dose in this registry. Patients were evaluated at 3 and 6 months (mos) post enrollment, and thereafter every 6 mos for up to 10 yrs. This 8-yr interim analysis included data collected retroactively since the initial ADA dose (including data from previous ADA studies for rollover patients) and cumulatively from 26 September 2008 through 30 November 2016. Incidence rates (IR) for all treatment-emergent adverse events (All-TEAEs) occurring from the initial dose through 70 days after the last ADA dose and excluding AEs during treatment interruptions are reported as events per 100 pt years of total ADA exposure (E/100PY), including pre-registry exposure. Physician's Global Assessment (PGA) was used to evaluate effectiveness in as-observed population.
RESULTS: In ESPRIT, 6045 patients (All-Rx, 58% male; mean age: 47 years; mean weight: 90 kg) were enrolled and dosed representing 25.268.1 PY of overall total ADA exposure, including 2554 (42.2%) New-Rx patients (54% male; mean age: 46 years; mean weight: 90 kg). Median duration of total ADA exposure was 1430 days (range 14–5161) and 658 days (range 14–2947) for All-Rx and New-Rx, respectively. After 8 years, registry discontinuation rate was 39.4% and 46.3% for All-Rx and New-Rx, respectively; the most frequent reason for discontinuing was being lost to follow up (18.2% and 23.9%, respectively). In All-Rx and New-Rx patients, discontinuation rate due to lack of efficacy was 1.6% and 2.5% respectively, while discontinuation rate due to AEs were .6% and .9%, respectively. The IR (E/100PY) for All-TEAEs (All-Rx) was: overall 22.0; serious AEs 4.5; malignancies 1.1, non-melanoma skin cancer .7; serious infections (SI) 1.0, active TB <.1; congestive heart failure <0.1; lupus-like reactions and systemic lupus <.1; and demyelinating disorder <.1. IR for All-TEAEs (All-Rx) leading to death was .2 E/100PY. Standardized mortality ratio (All-Rx) was .34 (95% CI, .25-.46), indicating that the observed number of deaths was below expected in an age-, sex- and country-matched population. All-Rx patients achieving PGA 'clear' or 'minimal' at 12, 24, 36, 48, 60, 72, 84, and 96 months in the registry were 2635/4624 (57.0%), 2376/4048 (58.7%), 2090/3537 (59.1%), 1994/3185 (62.6%), 1496/2415 (61.9%), 1114/1745 (63.8%), 428/653 (65.5%), and 9/20 (45.0%), respectively.
CONCLUSIONS: No new safety signals were observed with ADA treatment during this 8-year interim analysis and safety was consistent with the known safety profile of ADA. IR of SI and malignancies remained stable with up to >8 years of overall exposure to ADA. The number of TE deaths in the registry was below the expected rate compared with the general population. As-observed effectiveness of ADA remained stable through 96 months.
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DISCLOSURES: D. Thaçi has received honoraria from AbbVie, Amgen, Biogen-Idec, Celgene, GSK, Dignity, Janssen, Leo, Maruho, Mitsubishi, Lilly, Novartis, Pfizer, Regeneron/Sanofi and UCB for participation on ad boards, as a speaker and for consultancy; and received research grants from AbbVie, Biogen-Idec, Leo and Pfizer. A. Menter has grants and honoraria from AbbVie, Amgen, Janssen Biotech, Inc, and LEO Pharma for service on an advisory board, as consultant, investigator, and speaker; received grants and honoraria from Allergan for service on an advisory board, investigator and as a consultant; received grants and honoraria from Boehringer Ingelheim for service on an advisory board and as an investigator; received grants and honoraria from Novartis, Xenoport, and Pfizer for service as a consultant and investigator; received grants from Anacor, Celgene, Dermira, Regeneron, and Symbio / Maruho for service as an investigator; honoraria from OrthoDermatologics and Promius for service on an advisory board, consultant, and speaker; honoraria from Eli Lilly for service on an advisory board, as a consultant and investigator; and received honoraria from Afecta, Avillion, Galderma, Menlo and Vitae for service as a consultant. JJ Wu has received research funding from AbbVie, Amgen, AstraZeneca, Boehringer Ingelheim, Coherus Biosciences, Dermira, Eli Lilly, Janssen, Merck, Novartis, Pfizer, Regeneron, Sandoz, and Sun Pharmaceutical Industries; he is a consultant for AbbVie, Amgen, Celgene, Dermira, Eli Lilly, Pfizer, Regeneron, Sun Pharmaceutical Industries, and Valeant Pharmaceuticals. D. Arikan, H. Kupper, M. Bereswill,

and W.C. Valdecantos are full-time employees of AbbVie and may own stock/options.
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PA-24: Patient Preference for Calcipotriene 0.005%/Betamethasone Dipropionate 0.064% Foam or Topical Suspension vs. Latest Topical Treatment in the PSO-INSIGHTFUL Study

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BACKGROUND: Topicals are a mainstay in psoriasis vulgaris treatment and are used in combination therapy even in patients receiving systemic or biologic therapy. Patient preference for vehicle formulation can impact adherence and, consequently, real-life effectiveness.
OBJECTIVE: PSO-INSIGHTFUL was designed to assess patient-reported factors that influence preference following once-daily topical treatment with Cal/BD foam and topical suspension.
METHODS: A prospective, multicenter, Phase IIIb, open-label, randomized, two-arm crossover study was conducted in Germany and Canada on patients with stable plaque psoriasis involving 2-30% BSA and PASI of ≥2. After a 4-week washout from previous treatments, patients were randomized 1:1 to once-daily Cal/BD foam for one week, after which they switched or crossed over. Questionnaires (including Topical Product Usability Questionnaire, TPUQ; Comparison to Latest Topical Treatment, CLTT) were completed by patients at baseline and timepoints during the study to assess usability and preference differences.
RESULTS: Overall, mean TPUQ domain scores were significantly higher for both Cal/BD foam and topical suspension compared with latest topical treatment. Highest preferences were for "overall satisfaction" and almost every application and formulation domain evaluated. Both the foam and topical suspension had high application domain scores for use on large areas, quick application time, and ease of incorporation into daily routine. There were fewer preferences for Cal/BD foam compared to suspension. Significant differences in favor of Cal/BD foam over suspension were in domains of "immediate feeling of relief" and "felt soothing" while the suspension was preferred for "use on small areas", "ease of application to lesion only", and "accurately dispense wanted amount."
CONCLUSION: Overall, patients in the PSO-INSIGHTFUL study preferred both Cal/BD foam and topical suspension over their latest topical treatment. Cal/BD foam was not preferred over the suspension, but both were preferred over latest topical treatment. Some significant differences in favor Cal/BD foam when compared to suspension may be attributable to the vehicle. These data provide insight into aspects of topical product usability and vehicle selection, but additional research is necessary for greater understanding of formulation impact on adherence.
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DISCLOSURES: Jennifer Soung, MD has served as an investigator for Janssen, Eli Lilly, Amgen, Pfizer, Allergan, Cutanea, Actavis, Valeant, Actelion, Cassiopeia, GSK, an advisor for Celgene, a speaker for Celgene, Amgen, Abbvie, and a speaker for the National Psoriasis Foundation. Lisa Tiu, PharmD and Karen Veverka, PhD are employees of LEO Pharma Inc. Chih-Ho Hong, MD is a consultant, lecturer, advisory board member and has conducted clinical trials for LEO Pharma Inc.

PA-25: Persistence and Adherence of Secukinumab and Subcutaneously Administered Anti-TNF treatments among Biologic-Naïve and Biologic-Experienced Patients with Plaque Psoriasis: Analyses from a US Claims Database

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BACKGROUND: Many patients with plaque psoriasis (PsO) are prescribed multiple biologic treatments to identify a therapy that properly controls their condition. Real-world evidence of persistence and adherence to secukinumab and anti-TNF biologics is limited among biologic-naïve and biologic-experienced patients with moderate to severe plaque PsO.
OBJECTIVE: To describe the persistence with and adherence to biologics among biologic-naïve and biologic-experienced patients with PsO who initiated secukinumab, adalimumab, or etanercept in the real-world setting.
METHODS: Adults (age ≥18 years) with ≥1 pharmacy claim for secukinumab, adalimumab, or etanercept on or after 01/21/2015 were identified from the Truven Health Analytics MarketScan Commercial and Medicare Supplemental Databases (first qualifying claim = index date). Eligible pa-

tients were required to be continuously enrolled with medical and pharmacy benefits ≥12 months prior to (baseline period) and after biologic initiation (index date). Patients had ≥ 1 PsO diagnosis (ICD-9-CM 696.1x or ICD-10-CM L40.0 or L40.9) and no pharmacy claims for the index biologic during the baseline period. Patients were categorized as biologic naïve vs experienced by the presence or absence of biologic use during the baseline period, respectively. Adherence to (measured by the proportion of days covered) and persistence with (defined as the number of days from index until a gap of ≥ 90 days without index biologic (discontinuation), or the end of follow-up if no discontinuation was observed) the index biologic, as well as discontinuation of the index biologic were evaluated over the 12-month follow-up period.

RESULTS: Of 4,769 eligible PsO patients, 1,154 (24%) initiated secukinumab (23% biologic naïve, 77% biologic experienced), 2,631 (55%) initiated adalimumab (92% biologic naïve, 8% biologic experienced), and 984 (21%) initiated etanercept (90% biologic naïve, 10% biologic experienced). Secukinumab had the lowest discontinuation rate, followed by adalimumab and etanercept during the 12-month follow-up period, respectively (biologic-naïve: 35.1%, 42.3%, 46.7%; biologic-experienced: 32.1%, 41.0%, 54.3%). Secukinumab had higher mean days persistent than adalimumab and etanercept, respectively (biologic-naïve, 281, 266, 254; biologic-experienced: 289, 271, 233). Secukinumab, had a slightly higher mean proportion of days covered than adalimumab and etanercept (biologic-naïve: .68, .65, .60; biologic- experienced: .70, .64, .59).

CONCLUSIONS: Patients treated with secukinumab had the lowest discontinuation rate and highest persistence over 12 months compared with subcutaneously administered anti-TNFs, regardless of prior biologic use. Further studies may be needed to capture reasons for discontinuation as it may be driven by non-clinical factors such as access.

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PA-26: Reduction in Risk of Disease Flare with Adalimumab Weekly Dosing for 36 weeks in Patients with Hidradenitis Suppurativa from the PIONEER Trials

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BACKGROUND: Originator adalimumab 40 mg weekly dosing (ADAew) improves clinical response in patients with moderate-to-severe hidradenitis suppurativa (HS) (N Engl J Med. 2016; 375: 422-34); however, its effect on preventing HS flares has not been fully reported.

OBJECTIVES: We evaluated disease progression in patients with moderate-to-severe HS for ≥1 year and treated with ADAew for up to 36 weeks.

MATERIALS & METHODS: Data were pooled from the phase-3 Pioneer I & II trials for patients randomized to 40 mg ADAew or placebo (pbo) in Period A and for ADAew patients in Period A who were re-randomized to ADAew (ADAew/ew), ADAeow (ADAew/eow), or pbo (ADAew/pbo) in Period B, by week-12 HiSCR status (Hidradenitis Suppurativa Clinical Response, defined as ≥50% reduction in total abscess and inflammatory nodule [AN] count with no increase in abscess count or in draining fistula count). Disease flare was defined as a ≥25% increase and ≥2 absolute increases from BL in the total AN count. Mean change in lesion counts from BL and high-sensitivity C-reactive protein (hsCRP) were also summarized. Missing data were handled by last observation carried forward for lesion counts and hsCRP. Negative numerical changes indicate improvement. For mean % changes from baseline results are reported as: (mean [standard error (SE)], N).

RESULTS: 633 patients were included in the Period A analysis (ADAew=316; pbo=317). The rate of disease flare was lower for patients receiving ADAew vs pbo (12.3% vs 35.3%, P≤.001). Mean change (improvement) in AN count from baseline to week 12 was greater for ADAew vs pbo (–6.0 [.5], 316 vs –2.7 [.5], 313; P≤.001). Mean % change (improvement) from baseline to week 12 in draining fistulas was greater for ADAew vs pbo (–.7 [.3], 316 vs .2 [.3], 313; P≤.01). Mean change (improvement) in hsCRP at week 12 was greater for ADAew vs placebo (–4.6 [.9], 291 vs .9 [1.0], 303; P≤.001). 300 patients were included in the Period B analysis. Results are reported for patients who achieved HiSCR at week 12: ADAew/ew,52, ADAew/eow,52, ADAew/pbo,53. Rate of disease flare was lowest for ADAew/ew (0%) vs ADAew/eow (5.8%) or ADAew/pbo (7.5%) (P≤.05; ADAew/ew vs ADAew/pbo). Mean % changes from baseline in AN counts (ADAew/ew,–6.4 [.8], 51; ADAew/eow,–6.8 [.8], 52; ADAew/pbo,–5.5 [.8], 53) or draining fistula count (ADAew/ew,–1.6 [.3], 51; ADAew/eow,–1.1 [.3], 52; ADAew/pbo,–1.5 [.3], 53) were not significant at week 36. Mean change (improvement) from baseline in hsCRP at week 36 showed a dose-response trend (ADAew/ew=–2.3 [1.8], 47; ADAew/eow=–.8 [1.8], 48; ADAew/pbo=.3 [1.9], 45). Rates of any AE in Period B were similar between ADA groups (ADAew/eow,57.4% [N=101]; ADAew/ew,59.6% [N=99]) vs pbo (ADAew/pbo,65.0% [N=100]). ADA groups had lower rates of HS worsening (ADAew/eow,17.8%; ADAew/ew,5.1%) vs pbo (20.0%).

CONCLUSIONS: Risk of HS flare was significantly reduced

compared to pbo after 12 weeks of ADAew treatment, and was further reduced after continued ADAew treatment to 36 weeks, regardless of HiSCR achievement at week 12. Reduction in risk of HS flare was supported by reductions in lesion counts and in systemic inflammation (hsCRP). There were no new safety signals in this population.

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PA-27: REGN2810, a fully human anti-PD-1 monoclonal antibody, for patients with unresectable locally advanced or metastatic cutaneous squamous cell carcinoma (CSCC): initial safety and efficacy from Expansion Cohorts (ECs) of phase 1 study

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PURPOSE: There is no established standard of care for unresectable locally advanced or metastatic CSCC. UV-induced DNA damage causes hypermutation in most CSCCs. Therefore, these tumors may be responsive to PD-1 checkpoint blockade. In the dose escalation portion of the phase 1 study of REGN2810, a durable (19 + months) radiologic complete response was observed in a patient (pt) with metastatic CSCC (ASCO 2015, #3024).

PROCEDURE/STUDY: ECs enrolled pts with distantly metastatic (EC 7) and locally advanced (EC 8) CSCC. All patients received 3 mg/kg REGN2810 by intravenous infusion over 30 minutes every 2 weeks for up to 48 weeks. Research biopsies were performed at baseline and Day 29 (and at progression, if possible). Tumor measurements were performed every 8 weeks according to RECIST 1.1 to determine overall response rate (ORR). Data cutoff date was 31 Jan 2017.

RESULTS: 26 pts were enrolled (10 in EC 7 and 16 in EC 8): median age, 72.5 y (range, 56-88y); median PS 1 (range, 0 – 1); 21M:5F; median number of prior systemic therapy regimens, 1 (range, 0 – 2). Median exposure to REGN2810 was 7 doses (range, 1-22). The most common treatment-related adverse event of any grade was fatigue (19.2%). Each of the following ≥ Grade 3 related AEs occurred once: AST elevation, ALT elevation, arthralgia, and rash. ORR (PR + CR, including unconfirmed) and disease control rate (ORR+SD) were 52% (12/23; 4uPR, 5 PR, 2CR, 1 uCR) and 70% (16/23, including 4SD), respectively. Three patients are not yet evaluable. Median PFS and OS have not been reached, and only one patient has experienced PD during REGN2810 treatment after initial response. Correlative studies are in process, including PD-L1 status and whole exome tumor DNA sequencing.

CONCLUSION: REGN2810 is well tolerated and produces antitumor activity in patients with advanced CSCC. A pivotal trial of REGN2810 for patients with advanced CSCC is enrolling patients (NCT02760498).

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PA-28: Safety and Efficacy of A-101, a 40% Hydrogen Peroxide Topical Solution, in Adults with Seborrheic Keratosis: Results from the Randomized, Double-Blind, Vehicle-Controlled, Parallel-Group Phase 3 Study

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BACKGROUND: Seborrheic keratosis (SK) is one of the most common benign skin lesions, affecting over 80 million US citizens, yet there is no Food & Drug Administration (FDA)–approved treatment available.
OBJECTIVE: The purpose of this study was to evaluate the safety and efficacy of a proprietary 40% hydrogen peroxide topical solution (A-101) versus its matching vehicle for the treatment of seborrheic keratosis.
DESIGN: Subjects with 4 eligible SK lesions, identified by the study investigator, were randomized 1:1 to A-101 or a matching A-101 vehicle. Treatment was performed by a non-physician sub-investigator in order to maintain blinding on Day 1. During Visit 4 (Day 22), previously treated SK lesions with a Physician's Lesion Assessment score > 0 were re-treated by the study sub-investigator (PLA scale: 0 = clear, 1 = near clear, 2 = thickness ≤ 1 mm, and 3 = thickness > 1 mm). At Day 106, the investigator assessed the lesions using the validated PLA. Eligible target lesions were stable, typical SKs, measuring 5-15 mm in both length and width and ≤ 2 mm thickness, and were located on the trunk, extremities, and face. Subjects were required to present with ≥ 1 lesion on the trunk or extremities and ≥ 1 lesion on the face.
RESULTS/SUMMARY: 450 subjects were enrolled. At Day 106, significantly more subjects receiving A-101 (Intent-To-Treat, ITT population) achieved a PLA score = 0 on all 4 of 4 lesions (4% vs 0%, $P < .002$) and 3 of 4 lesions (13.5% vs 0%, $P < .0001$) versus vehicle in the primary and secondary endpoints, respectively. In the a priori exploratory analyses (Per-Protocol Population, n = 218), significantly higher mean per-subject percentage of lesions achieving clear/near clear (PLA ≤ 1) was observed in the A-101 arm (47.5% vs 10.2% in the vehicle group; $P < .0001$). Additionally, significantly higher mean per-subject percentage of facial lesions achieving clear/near clear (PLA ≤ 1) was observed in the A-101 arm (64.4% vs 15.0% in the vehicle group at Day 106; $P < .0001$) in the ITT population. Adverse events were comparable between groups. Local skin reactions were predominantly mild and had generally resolved by Day 106. At all visits, atrophy, erosion, hypopigmentation, scarring, or ulceration were reported for ≤ 4% of lesions.
CONCLUSION: A-101, a 40% hydrogen peroxide topical solution, is a safe, effective, and well-tolerated treatment for SK. If approved, it would offer the first US FDA-approved topical treatment for SK.
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DISCLOSURES: Z Draelos and S Smith report grants from Aclaris, during the conduct of the study. S Kempers and D Wilson have nothing to disclose. P Powala, E Estes, and S Shanler are employees of Aclaris Therapeutics. M Bradshaw is a consultant for Aclaris and provided statistical consulting and owns Aclaris stock and options.

PA-29: Safety and Tolerability of a Halobetasol 0.01%/Tazarotene 0.045% Fixed Combination in the Treatment of Moderate-to-Severe Plaque Psoriasis: Results of 2 Phase III Randomized Controlled Trials

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BACKGROUND: Psoriasis is a chronic, immune-mediated disease that varies widely in its clinical expression. Treatment options focus on relieving symptoms, reducing inflammation, induration, and scaling, and controlling the extent of the disease. Topical corticosteroids are the mainstay of treatment, however long-term safety remains a concern, particularly with the more potent formulations. Combination therapy with a corticosteroid and tazarotene may improve psoriasis signs at a lower corticosteroid concentration providing a superior safety profile.
OBJECTIVE: To investigate the safety and tolerability of a once-daily application of a fixed combination halobetasol propionate 0.01% and tazarotene 0.045% (HP/TAZ) lotion in comparison with its vehicle in subjects with moderate-to-severe plaque psoriasis.

METHODS: Two multicenter, randomized, double-blind, vehicle-controlled Phase 3 studies in moderate or severe psoriasis (N=418). Subjects randomized (2:1) to receive HP/TAZ or vehicle, once-daily for 8 weeks. Safety and treatment emergent adverse events (TEAEs) were evaluated throughout.
RESULTS: The most frequently reported TEAEs for HP/TAZ were contact dermatitis (7.4%), pruritus (3.0%), and application site pain (2.6%), compared with .0%, 2.9% and .7% respectively for vehicle. The majority of AEs were mild or moderate. There were only three serious AEs (SAEs) reported following HP/TAZ treatment (1.1%). None of the SAEs were treatment related (cellulitis staphylococcal, pneumonia/asthma and anemia). By Week 8, mean scores for itching, dryness and burning/stinging had reduced by 52.1% and 40.8% (Study 1 and 2 respectively), 46.2% and 47.3%, and 60.0% and 56.3% respectively. Side effects such as skin atrophy were infrequent, as were other skin reactions such as striae, telangiectasia, or folliculitis during the studies.
CONCLUSIONS: Safety data with HP/TAZ lotion were consistent with the known safety profile of halobetasol propionate and tazarotene, and did not reveal any new safety concerns with the combination product.
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DISCLOSURES: Dr Lebwohl is an employee of the Mount Sinai Medical Center, which receives research funds from AbbVie, Amgen, Celgene, Eli Lilly, Janssen, Leo, Merck, Novartis, Pfizer, Sandoz, Sun Pharma and Valeant. Dr Stein Gold is an advisor, investigator, and/or consultant for Leo and Valeant. Dr Sugarman is an investigator for Galderma, Ranbaxy, and Activis, a consultant for Galderma, and a Medical Safety Monitor for Seegpharma and Valeant. Dr Pariser or his institution has received grant/research support from Abbott Laboratories, Amgen, Astellas Pharma US, Asubio Pharmaceuticals, Basilea Pharmaceutical, Celgene Corporation, Dow Pharmaceutical Sciences, Eli Lilly, Galderma Laboratories, Graceway Pharmaceuticals, Intendis, Johnson & Johnson, Novartis Pharmaceuticals, Novo Nordisk A/S, Ortho Dermatologics, Photocure ASA, Stiefel Laboratories, and Valeant Pharmaceuticals, and has received other financial support from LEO Pharma US and Pfizer. Steven Yawn, Tina Lin, Binu Alexander, Susan Harris, and Robert Israel are employees of Valeant Pharmaceuticals.

PA-30: Secukinumab Demonstrates High Sustained Efficacy and a Favorable Safety Profile Through 5 Years of Treatment in Moderate-to-Severe Psoriasis

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BACKGROUND: Psoriasis is a chronic, immune-mediated, skin disease usually requiring long-term management. Secukinumab, a fully human monoclonal antibody that neutralizes interleukin (IL)-17A, has been shown to have significant efficacy in the treatment of moderate-to-severe psoriasis and psoriatic arthritis, demonstrating sustained and long-lasting high levels of efficacy with a favorable safety profile. This is the first phase 3 study of an IL-17A inhibitor presenting long-term sustainability and safety up to 5 years of continuous treatment at the approved dose.
OBJECTIVES: To assess the sustained efficacy and safety of secukinumab in moderate-to-severe psoriasis patients treated for up to 5 years.
METHODS: In the core SCULPTURE study, patients that were Psoriasis Area and Severity Index (PASI) 75 responders at Week 12 continued receiving subcutaneous secukinumab 300 mg every 4 weeks until Year 1 (n=168 at Week 52). Patients subsequently entered the extension phase and continued the same double-blinded treatment regimen to Year 3, and thereafter unblinded to Year 5 (n=126 at Week 260), which was the end of the study. Here we report final PASI 75/90/100 and absolute PASI ≤1/≤2/≤3 responses, Dermatology Life Quality Index (DLQI) 0/1 response, and safety/tolerability to Year 5. Efficacy data are reported as observed and safety events are analyzed per year.
RESULTS: Mean baseline PASI and body surface area (BSA) involvement were 23.5 ± 8.8 and 33.1% ± 18.9%, respectively. PASI 75/90/100 responses at Year 1 (88.9%, 68.5% and 43.8%, respectively) were well sustained to Year 5 (88.5%, 66.4%, and 41%). The average improvement in mean PASI was approximately 90% compared with Baseline through 5 years. Absolute PASI ≤1/≤2/≤3 responses were sustained from Year 1 (58.6%, 67.9%, and 74.1%, respectively) to Year 5 (53.3%, 66.4%, and 75.4%). Two thirds of patients reported no impact of skin disease on their lives over 5 years of treatment; DLQI 0/1 responses were 72.7% at Year 1 and 65.5% at Year 5. The safety profile of secukinumab remained favorable, with no cumulative or unexpected safety concerns identified. The most common adverse events included nasopharyngitis, upper respiratory tract infection, and headache, consistent with those reported in the core study and previous phase 3 studies. The most frequent reasons for discontinuation in the extension study (n, %) were: subject/guardian decision (13, 7.7%), adverse event (10, 6%), and lack of efficacy (7, 4.2%).

CONCLUSION: Secukinumab 300 mg treatment sustained high levels of skin clearance, and improved quality of life through 5 years in patients with moderate-to-severe psoriasis. Favorable safety established in a large phase 3 program was maintained to 5 years.
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DISCLOSURES: R Bissonnette: Honoraria or acted as a consultant, investigator, or speaker for AbbVie, Amgen, Apopharma, Astellas, Boehringer-Ingelheim, Celgene, Dermira, Lilly, Galderma, GlaxoSmithKline-Stiefel, Incyte, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Tribute. T Luger: Honoraria as an advisory board member from AbbVie, Amgen, CERIES, Celgene, Clinuvel, Lilly, Galderma, Janssen-Cilag, La Roche Posay, MEDA Pharma, Mundipharma, Pfizer, Sandoz, Symrise; grants as an investigator from Biogen Idec, Janssen-Cilag, MEDA Pharma, Pfizer, Wolff; honoraria as a speaker/consultant from Novartis, AbbVie, Astellas, Galderma, La Roche Posay, MEDA Pharma, Janssen-Cilag; honoraria as a clinical trial investigator from Janssen-Cilag, Lilly, Novartis, Pfizer. D Thaçi: Honoraria as an investigator from AbbVie, Almirall, Amgen, Astellas, Biogen-Idec, Boehringer-Ingelheim, Celgene, Dignity, Lilly, Forward-Pharma, GlaxoSmithKline, LEO Pharma, Janssen-Cilag, Maruho, MSD, Mitsubishi Pharma, Novartis, Pfizer, Roche, Sandoz; honoraria as a consultant from AbbVie, Biogen-Idec, Celgene, Dignity, Galapagos, Maruho, Mitsubishi, Novartis, Pfizer, Xenoport; honoraria as a scientific advisory board member from AbbVie, Amgen, Biogen-Idec, Celgene, GlaxoSmithKline, Janssen, Lilly, Mundipharma, Novartis, Pfizer, Sandoz. D Toth: Honoraria as an advisory board member, investigator, and/or speaker from AbbVie, Amgen, Celgene, Lilly, Galderma, Genentech, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Regeneron. A Lacombe, S Xia, R Mazur, M Patekar, P Charef, and M Milutinovic: Employees of Novartis. C Leonardi: Honoraria as a consultant for AbbVie, Amgen, Dermira, Janssen, Lilly, LEO, Sandoz, UCB, Pfizer; as an investigator for Actavis, AbbVie, Amgen, Celgene, Coherus, Dermira, Lilly, Galderma, Janssen, Merck, Pfizer, Sandoz, Stiefel, LEO, Novartis, Wyeth; speakers' bureau for AbbVie and Celgene.

PA-31: Secukinumab Provides Complete or Almost Complete Psoriasis Clearance in Moderate-to-Severe Plaque Psoriasis: Pooled Analysis of 4 Phase 3 Trials

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BACKGROUND: Investigator's Global Assessment modified 2011 (IGA mod 2011) is a more robust measure of psoriasis clearance than traditional IGA and Physician's Global Assessment scales. Secukinumab, a fully human monoclonal antibody that selectively neutralizes interleukin-17A, has significant efficacy in moderate-to-severe psoriasis and psoriatic arthritis, demonstrating a rapid onset of action and sustained responses with a favorable safety profile.
OBJECTIVES: This post hoc analysis evaluates IGA mod 2011 0 (clear) and IGA (mod 2011) 0/1 (clear or almost clear) response rates over 1 year following treatment with secukinumab pooled from 4 phase 3 trials (ERASURE, FIXTURE, FEATURE, and JUNCTURE) involving patients with moderate-to-severe plaque psoriasis.
METHODS: Secukinumab (300 mg or 150 mg) or placebo was administered at Baseline, Weeks 1, 2 and 3, and then every 4 weeks from Week 4 to 48. In FIXTURE, etanercept (50 mg) was administered twice weekly for 12 weeks, then once weekly.
RESULTS: Of 2396 patients, 691, 692, 326, and 687 were randomized to secukinumab 300 mg, secukinumab 150 mg, etanercept, and placebo, respectively. Significantly more patients receiving secukinumab 300 mg compared with placebo achieved IGA (mod 2011) 0/1 (clear or almost clear) responses as early as Week 2 (after 2 doses of secukinumab) and IGA (mod 2011) 0 (clear) responses as early as at Week 8 (after 5 doses of secukinumab). A significantly greater proportion of patients achieved IGA (mod 2011) 0/1 (clear or almost clear) responses at Week 12 (after 6 doses of secukinumab) with secukinumab 300 mg (65.0%) and secukinumab 150 mg (51.4%) compared with etanercept (27.2%) and placebo (2.2%; $P < .0001$ for both secukinumab doses vs. etanercept and placebo). IGA (mod 2011) 0/1 (clear or almost clear) responses were sustained at Week 52 for secukinumab 300 mg (64.9%), secukinumab 150 mg (47.4%), and etanercept (37.2%; $P < .0001$ for secukinumab 300 mg vs. etanercept). At Week 12, a significantly greater proportion of patients achieved IGA (mod 2011) 0 (clear) responses with secukinumab 300 mg (29.9%) and secukinumab 150 mg (15.1%) compared with etanercept (5.3%) and placebo (0.3%; $P < .0001$ for both secukinumab doses vs. etanercept and placebo). IGA (mod 2011) 0 (clear) responses were sustained at Week 52 for secukinumab 300 mg (37.8%), secukinumab 150 mg (21.6%), and etanercept (9.6%; $P < .0001$ for secukinumab 300 mg vs. etanercept).
CONCLUSION: Secukinumab 300 mg provides early and sustained complete or near-complete skin clearance in up to 65% of patients with moderate-to-severe plaque psoriasis.
SPONSORS: This research was sponsored by Novartis Pharma AG, Basel, Switzerland.
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DISCLOSURES: A Blauvelt: Scientific adviser and clinical study investigator for AbbVie, Amgen, Boehringer-In-

gelheim, Celgene, Dermira, Genentech, GlaxoSmithKline, Janssen, Lilly, Merck, Novartis, Pfizer, Regeneron, Sandoz, Sanofi Genzyme, Sun Pharmaceutical Industries, UCB, Valeant; paid speaker for Lilly, Regeneron, Sanofi Genzyme. A Armstrong: Investigator and/or advisor to AbbVie, Amgen, Celgene, Janssen, Merck, Lilly, Novartis, Pfizer. P Rich: Consultant, investigator, speaker, and/or advisor for, and/or received travel and/or research grants from Lilly, Novartis, Boehringer-Ingelheim, Janssen, Pfizer, Merck, Amgen, AbbVie. R Kisa, A Guana, and X Meng: Employees of Novartis Pharmaceuticals Corporation. K Callis Duffin: Grant/research support from Amgen, Lilly, Janssen, Stiefel, AbbVie, BMS, Celgene, Novartis; consultant for Amgen, Lilly, Janssen, Stiefel, AbbVie, BMS, Celgene, Pfizer, Novartis.

PA-32: Secukinumab Provides Rapid and Sustained Pain Relief in Psoriatic Arthritis: 2-Year Results From the FUTURE 2 Study

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BACKGROUND: Secukinumab, a fully human monoclonal antibody that selectively neutralizes IL-17A, has been shown to have significant efficacy in the treatment of moderate to severe psoriasis and psoriatic arthritis (PsA) with a rapid onset of action, sustained responses and a favorable safety profile.1-3 Pain remains a major clinical challenge in treatment.4,5
OBJECTIVES: This posthoc analysis evaluated change in pain scores from baseline to Week 104 in PsA patients receiving secukinumab in the FUTURE 2 study.
METHODS: FUTURE 2 study design has been reported.3 Mean change from baseline in pain VAS and SF-36 bodily pain domain scores were evaluated using mixed-effect model for repeated measures (MMRM) through Week 16 and as observed through Week 104. Proportion of patients reporting improvements ≥clinically meaningful differences in pain VAS (mean change from baseline ≥20%) was assessed. Results are reported for secukinumab 300 and 150 mg in overall population and stratified by prior use of TNF inhibitor (TNFi; TNFi-naïve vs. inadequate responder/intolerant [TNFi-IR]). EQ–5D-3L pain item scores (no-, moderate- or extreme-pain/discomfort) were assessed as proportions.
RESULTS: Mean changes from baseline in pain VAS were greater with secukinumab vs. placebo (PBO) by Week 3 (least squares mean [LSM]: -16.9, -12.6 with secukinumab 300 and 150 mg, respectively vs. -5.8 with PBO; $P < .05$), and Week 16 (LSM: -24.0 and -23.0 for secukinumab 300 and 150 mg, respectively vs. -8.41 with PBO; $P < .05$). Mean changes were sustained through Week 104 (-26.1 and -25.9 with secukinumab 300 and 150 mg, respectively). In both secukinumab groups, >50% patients reported improvements of ≥20% by Week 3 and this increased through Week 104. Similarly, SF-36 bodily pain domain scores improved from baseline by Week 4 and 16 with secukinumab vs. PBO, exceeding minimum clinically important differences of 5.0 (Week 4: LSM: 16.2 and 16.3 for secukinumab 300 and 150 mg, respectively vs. 5.9 with PBO; $P < .05$ and Week 16: LSM: 21.1 and 22.1 for secukinumab 300 and 150 mg, respectively vs. 6.9 with PBO; $P < .05$). Improvements in pain were consistent in TNFi-naïve and TNFi-IR patients; and of greater magnitude in naïve subgroup. At Week 16, mean changes from baseline in pain VAS were -27.8, -25.1, and -11.3 for secukinumab 300, secukinumab 150 mg, and placebo, respectively in TNFi-naïve patients ($P < .0001$ for secukinumab 300 mg vs placebo and $P < .001$ for secukinumab 150 mg vs placebo) and -18.2, -21.1, and -4.4 for secukinumab 300, secukinumab 150 mg, and placebo, respectively in TNFi-IR patients ($P < .05$ for secukinumab 300 mg vs placebo and $P < .01$ for secukinumab 150 mg vs placebo). Mean changes from baseline in pain VAS were maintained to Week 104 with improvement of -29.6 and -28.3 for secukinumab 300 and secukinumab 150 mg, respectively in TNFi-naïve patients and -19.3 and -20.4 for secukinumab 300 and secukinumab 150 mg, respectively in TNFi-IR patients. Based on the EQ–5D-3L pain/discomfort item, 99% patients reported moderate to extreme pain or discomfort at baseline. At Week 4, proportion of patients with no pain or discomfort was greater for secukinumab 300 mg (15%) and 150 mg (9%) vs. PBO (5%) and increased through Week 104 to 28% and 16% with secukinumab 300 and 150 mg, respectively.
CONCLUSIONS: Secukinumab provided rapid and sustained pain relief through 2 years in patients with PsA as assessed by multiple clinically relevant patient-reported measures of pain. Improvements were reported by patients regardless of their prior TNFi therapy status.
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DISCLOSURES: K Reich: Advisor and/or paid speaker for and/or participated in clinical trials sponsored by Abbvie, Amgen, Biogen, Boehringer Ingelheim Pharma, Celgene, Centocor, Covagen, Forward Pharma, GlaxoSmithKline, Janssen-Cilag, Leo, Lilly, Medac, Merck Sharp & Dohme Corp., Novartis, Ocean Pharma, Pfizer, Regeneron, Take-

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PA-33: Secukinumab Provides Sustained Improvement in Signs and Symptoms of Patients with Active Psoriatic Arthritis up to 3 Years: Data from FUTURE 1 and FUTURE 2 Studies

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BACKGROUND: Secukinumab, a fully human mAb, which selectively neutralizes IL-17A, has been shown to have significant efficacy in the treatment of moderate to severe psoriasis1 and psoriatic arthritis (PsA)2,3 with a favorable safety profile.
OBJECTIVES: To present the efficacy and safety of secukinumab in patients (pts) with PsA through 3 years (yrs) in extension phase of the FUTURE 1 (NCT01892436) and through 2 yrs in the FUTURE 2 (NCT01752634) studies.
METHODS: The study designs of FUTURE 1 and 2 have been reported.2,3 After 2-yr core trial of FUTURE 1 study, 460 (75.9%) of the overall 606 randomized pts entered the 3-yr extension phase. In FUTURE 2 study, 397 pts were randomized. Efficacy results are presented from pts originally randomized to secukinumab 150 mg in FUTURE 1 (n = 161) at Week (Wk) 156 and to secukinumab 300 and 150 mg in FUTURE 2 (n = 200) at Wk 104. Efficacy endpoints assessed included ACR20/50/70, PASI 75, DAS28-CRP, SF-36 PCS, HAQ-DI, dactylitis and enthesitis. Analyses used multiple imputation (MI) for binary and mixed-effect model repeated measures (MMRM) for continuous variables. Analyses stratified by anti-TNF status (naïve/inadequate response or intolerance to these agents) were prespecified. Safety analyses included all pts who received ≥1 dose of secukinumab.
RESULTS: In FUTURE 1, 435 pts (94.6%) completed 156 wks (151/161 [93.8%] pts in IV up to a dose of 150 mg group. In FUTURE 2, 303 pts (76.3%) completed 104 wks (86/100 [86%] and 76/100 [76%] in secukinumab 300 and 150 mg, respectively). ACR20/50/70 responses were achieved in FUTURE 1 by 77%/55%/33% of patients and in FUTURE 2 by 69%/51%/33% of patients receiving secukinumab 300 mg and by 64%/36%/23% of patients receiving secukinumab 150 mg. PASI 75 was achieved by 76% of patients in FUTURE 1 and by 80% and 73% of patients in FUTURE 2 receiving secukinumab 300 mg and 150 mg, respectively. The mean change from baseline for DAS28-CRP was -1.9 in FUTURE 1 and -1.9 and -1.7 in FUTURE 2 with secukinumab 300 mg and 150 mg, respectively. Among patients with dactylitis or enthesitis at baseline, resolution of dactylitis/enthesitis was reported in 88%/77% of patients from FUTURE 1 and in 80%/72% and 78%/62% of patients from FUTURE 2 receiving secukinumab 300 mg and 150 mg, respectively. Responses were sustained, regardless of prior anti-TNF status in both studies. Secukinumab was well tolerated across both studies in the entire safety period.
CONCLUSIONS: Secukinumab provided sustained improvements in the signs and symptoms, and multiple clinical domains of active PsA up to 3 yrs. Secukinumab had a favorable safety profile with no unexpected safety signals.[1-3]
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DISCLOSURES: AB Gottlieb: Consultant/advisory board member for Amgen Inc, Astellas, Akros, Centocor (Janssen), Celgene, BMS, Beiersdorf, Abbott Labs. (AbbVie), TEVA, Actelion, UCB, Novo Nordisk, Novartis, Dermipsor Ltd., Incyte, Pfizer, Canfite, Lilly, Coronado, Vertex, Karyopharm, CSL Behring Biotherapies for Life, GlaxoSmithKline, Xenoport, Catabasis, Meiji Seika Pharma Co. Ltd, Takeda, Mitsubishi Tanabe Pharma Development America, Inc, Genentech, Baxalta; research/educational grants, paid to Tufts Medical Center, from Centocor (Janssen), Amgen, Abbott Labs. (AbbVie), Novartis, Celgene, Pfizer, Lilly, Coronado, Levia, Merck, Xenoport, Dermira, Baxalta. IB McInnes: Research grants, consultation fees, or speaker honoraria from AbbVie, Amgen, BMS, Celgene, Janssen, Lilly, Novartis, Pfizer, UCB. PJ Mease: Grant/research support from AbbVie, Amgen, BMS, Celgene, Crescendo Bioscience, Genentech, Janssen, Lilly, Merck, Novartis, Pfizer, UCB; consultant for AbbVie, Amgen, BMS, Celgene, Crescendo Bioscience, Genentech, Janssen, Lilly, Merck, Novartis, Pfizer, UCB; speakers' bureau for AbbVie, Amgen, BMS, Celgene, Crescendo Bioscience, Genentech, Janssen, Lilly, Merck, Novartis, Pfizer, UCB. EM

Delicha, P Pellet, R Kajekar, and L Pricop: Employees of Novartis.

PA-34: Secukinumab Reduces Endothelial Dysfunction in Subjects With Moderate-to-Severe Plaque Psoriasis Over 52 Weeks: Results of the Exploratory CARIMA Study

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BACKGROUND: An increased incidence of cardiovascular (CV) events has been reported in psoriasis subjects. Secukinumab, a fully human monoclonal antibody that selectively neutralizes IL-17A, has significant efficacy in moderate-to-severe psoriasis and psoriatic arthritis.
OBJECTIVES: CARIMA explored the effect of secukinumab on CV risk markers in psoriasis.
METHODS: CARIMA was a 52-week, multicenter, exploratory, randomized, double-blind, placebo-controlled trial (NCT02559622). Subjects with moderate-to-severe plaque psoriasis but without manifest CV diseases were eligible. The primary outcome measure was endothelial function, a marker of early atherosclerosis, measured by flow-mediated dilation (FMD).
RESULTS: 151 subjects (mean age 45 years, 68% male) were randomized. Of these, 48 and 54 subjects received 300 mg and 150 mg secukinumab, respectively and 26 and 23 subjects received placebo followed by 300 mg or 150 mg secukinumab, respectively. A baseline FMD (mean±SD) of 4.6% (±3.5), 4.6% (±4.6), 3.9% (±3.9), and 3.7% (±3.2) was observed for subjects assigned to 300 or 150 mg secukinumab or placebo followed by 300 mg or 150 mg secukinumab. At week 12, the baseline-adjusted FMD showed a numerically larger improvement in subjects receiving 300 mg secukinumab vs. the pooled placebo group (Δ = 1.2%, CI [-.7; 3.1], P=.223) than in subjects receiving 150 mg secukinumab vs. the pooled placebo group (Δ = .8%, CI [-1.0; 2.6], P=.403). At week 52, FMD was increased by 2.1% in subjects receiving 300 mg secukinumab (CI [0.8; 3.3], P=.002) and by 2.1% in subjects receiving 150 mg secukinumab (CI [.7; 3.4], P=.003) vs. baseline. There were no deaths and no myocardial infarctions in the study. There was one case of a cerebral infarction which was not suspected to be related to study medication.
CONCLUSIONS: Although subjects with established CV diseases were excluded, the comparably large CARIMA study population confirmed earlier findings of endothelial dysfunction associated with subclinical atherosclerosis in psoriasis. A numerical, clinically meaningful improvement of FMD was observed after 12 weeks (secukinumab 300 mg). The difference reached statistical significance after 52 weeks (150 and 300 mg). The safety profile of secukinumab was comparable to prior studies and there were no new safety signals. Secukinumab may improve endothelial function, which could help to prevent cardiovascular disease progression in psoriatic subjects.
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PA-35: Secukinumab Treatment in Moderate-to-Severe Psoriasis Patients Demonstrates Sustained Low Absolute PASI Scores up to 4 Years: Results From the SCULPTURE Extension Study

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BACKGROUND: Secukinumab, a fully human monoclonal antibody that selectively neutralizes interleukin-17A (IL-17A), exhibits significant efficacy in the treatment of moderate-to-severe psoriasis and psoriatic arthritis, demonstrating a rapid onset of action and a favorable safety profile. Psoriasis Area and Severity Index (PASI) is a measure of psoriasis severity; achieving a low absolute PASI score is the desired clinical outcome and an important measure of treatment efficacy.
OBJECTIVES: To assess the sustained efficacy of secukinumab in moderate-to-severe psoriasis patients treated for up to 4 years.
METHODS: In the core SCULPTURE study, PASI 75 responders at Week 12 were randomized to a double-blind maintenance treatment of subcutaneous secukinumab 300 mg or 150 mg, administered either at a 4-week fixed-interval (FI) or in a retreatment-as-needed regimen. Patients who completed 52 weeks of treatment continued into the extension study (NCT01640951), and received the same blinded maintenance treatment regimen and dose up to the end of Year 3. In the fourth year, the study was open-label, and treatment was mainly self-administered by patients with site visits occurring every 12–16 weeks. Herein, we report absolute PASI ≤1/≤2/≤3/≤5 responses at Week (Wk) 52 and 208, focusing on the 300 mg FI treatment arm in line with the approved dosing regimen. Data are reported as observed.
RESULTS: In the overall study population, 79.8% of secukinumab patients completed treatment through to Wk 208 (Baseline [n=168], Wk 52 [n=168], and Wk 208 [n=134]). Secukinumab 300 mg demonstrated sustained efficacy over 4 years of treatment in patients with moderate-to-severe psoriasis (mean baseline PASI 23.5 ± 8.8, mean baseline BSA [body surface area] involvement 33.1% ± 18.9); concomitant psoriasis therapy was prohibited. Absolute PASI ≤1/≤2/≤3/≤5 responses at Wk 52 (58.6%/67.9%/74.1%/87.7%) were well-sustained to Year 4 (58.8%/71.0%/77.1%/84.0%). Treatment adherence in Year 4, when patients were mainly self-administering therapy, was 99.5%. The favorable safety profile of secukinumab was also maintained to Year 4, with no cumulative or unexpected safety signals identified. The most commonly reported adverse events were nasopharyngitis and upper respiratory tract infection.
CONCLUSION: Secukinumab 300 mg demonstrates sustained efficacy up to 4 years of treatment in patients with moderate-to-severe psoriasis as seen by low absolute PASI scores; achieving significant levels of skin clearance and with a favorable safety profile.
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DISCLOSURES: R Bissonnette: Honoraria or acted as a consultant, investigator, or speaker for AbbVie, Amgen, Apopharma, Astellas, Boehringer-Ingelheim, Celgene, Dermira, Lilly, Galderma, GlaxoSmithKline-Stiefel, Incyte, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Tribute. T Luger: Honoraria as an advisory board member from AbbVie, Amgen, CERIES, Celgene, Clinuvel, Lilly, Galderma, Janssen-Cilag, La Roche Posay, MEDA Pharma, Mundipharma, Pfizer, Sandoz, Symrise; grants as an investigator from Biogen Idec, Janssen-Cilag, MEDA Pharma, Pfizer, Wolff; honoraria as a speaker/consultant from Novartis, AbbVie, Astellas, Galderma, La Roche Posay, MEDA Pharma, Janssen-Cilag; honoraria as a clinical trial investigator from Janssen-Cilag, Lilly, Novartis, Pfizer. D Thaçi: Honoraria as an investigator from AbbVie, Almirall, Amgen, Astellas, Biogen-Idec, Boehringer-Ingelheim, Celgene, Dignity, Lilly, Forward-Pharma, GlaxoSmithKline, LEO Pharma, Janssen-Cilag, Maruho, MSD, Mitsubishi Pharma, Novartis, Pfizer, Roche, Sandoz; honoraria as a consultant from AbbVie, Biogen-Idec, Celgene, Dignity, Galapagos, Maruho, Mitsubishi, Novartis, Pfizer, Xenoport; honoraria as a scientific advisory board member from AbbVie, Amgen, Biogen-Idec, Celgene, GlaxoSmithKline, Janssen, Lilly, Mundipharma, Novartis, Pfizer, Sandoz. D Toth: Honoraria as an advisory board member, investigator, and/or speaker from AbbVie, Amgen, Celgene, Lilly, Galderma, Genentech, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Regeneron. S Xia, R Mazur, and M Milutinovic: Employees of Novartis. C Leonardi: Honoraria as a consultant for AbbVie, Amgen, Dermira, Janssen, Lilly, LEO, Sandoz, UCB, Pfizer; as an investigator for Actavis, AbbVie, Amgen, Celgene, Coherus, Dermira, Lilly, Galderma, Janssen, Merck, Pfizer, Sandoz, Stiefel, LEO, Novartis, Wyeth; speakers' bureau for AbbVie and Celgene.

PA-36: Spontaneous resolution of a giant keratoacanthoma and its satellite lesion

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CASE: Keratoacanthoma (KA) is a common tumor of the skin which originates from the follicular infundibulum. A distinct feature of KA is a clinical course characterized by rapid proliferative phase followed by a variable period of lesion stability and subsequent spontaneous regression. When a KA develops into a large lesion measuring more than, it is referred to as giant keratoacanthoma (GKA).

GKA is rare and has a predilection for the nose. Although spontaneous resolution should eventually occur, these lesions can cause considerable anatomical destruction and cosmetic disfigurement. KAs may share overlapping histological features with well-differentiated squamous cell carcinomas, posing diagnostic difficulties. Very often, the diagnosis remains in question until the tumor regresses.
CONCLUSION: Spontaneous resolution of GKAs are rarely reported in the literature. We report a case of GKA of the nose with photographic documentation of its resolution.
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DISCLOSURE: The author has nothing to disclose

PA-37: Subgroup analysis of efficacy and safety of guselkumab compared with placebo and adalimumab for the treatment of patients with a baseline Investigator's Global Assessment of 3 (moderate) from the phase III VOYAGE 1 and 2 trials

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INTRODUCTION/OBJECTIVE: VOYAGE 1 and 2 were two phase 3, double-blind, placebo- and active-comparator-controlled studies that evaluated the efficacy and safety of guselkumab (GUS) in patients with moderate-to-severe psoriasis (PsO). Here we report the efficacy and safety of GUS in the subset of patients with moderate psoriasis, defined by a baseline Investigator Global Assessment (IGA) of 3, and were compared with placebo and adalimumab (ADA).
METHODS: Through Week 24, VOYAGE1 and 2 were similarly designed with patients randomized to GUS 100 mg at wks0/4/12/20; placebo at wks0/4/12 then GUS 100 mg at wks16/20 or ADA 80mg at wk0, 40mg at wk1, and q2wk through wk23. The placebo controlled phase was week 0 through week 16 and the active comparator controlled phase was week 0 through week 24 for efficacy and week 28 for safety. Physician assessed measures (IGA, PsO Area and Severity Index [PASI]) and Dermatology Life Quality Index [DLQI] are presented.
RESULTS: Among moderate psoriasis subjects, baseline demographics were comparable across treatment groups. GUS was superior ($P < .001$) to placebo at week 16 and to ADA at week 24 in achieving an IGA score of 0 (cleared), IGA score of 0 or 1 (minimal), and PASI75, PASI90, PASI100, and DLQI of 0 or 1 responses (Table). The proportion of GUS patients with ≥1 adverse events (AEs) was comparable to placebo through week 16 [GUS (N=318, 50.4%), placebo (N=162, 50.3%)] and ADA through week 28 [GUS (N=386, 61.2%), ADA (N=279, 64.0%)].
CONCLUSION: For patients with moderate PsO, defined by a baseline IGA score of 3, GUS demonstrates superior efficacy and greater improvement in health-related quality-of-life compared with placebo and ADA.
DISCLOSURES: Drs. Christopher Griffiths, Peter Foley, Kim Papp-investigators for Janssen Research & Development, LLC, Spring House, PA. Drs. Michael Song, Yasmine Wasfi, Shu Li, Reginald Villacorta, Yaung-Kaung Shen, Chenglong Han, Sean McElligott-all employees of Janssen Research & Development, LLC, Spring House, PA

PA-38: The burden of nail psoriasis: a real world analysis from the Corrona Psoriasis Registry

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OBJECTIVE: Nail psoriasis (PsO) is often correlated with more severe psoriatic disease and is difficult to treat; only a few studies have shown its association with significant functional and psychosocial impairment. The objective of this study was to describe the impact of nail PsO on clinical and patient reported outcomes (PROs) among patients enrolled in the Corrona PsO Registry.
METHODS: Adult PsO patients enrolled in the Corrona PsO registry between 4/2015 – 4/2017, who initiated an eligible systemic therapy at enrollment were included. Descriptive analyses of demographics, disease severity (BSA, PASI), PROs (overall itch, pain visual analog scale (VAS 0-100), Dermatology Life Quality Index (DLQI), Work Productivity and Activity Impairment (WPAI), EQ-VAS 0-100) and treatment history were compared between patients affected by nail PsO and those without, using appropriate statistical tests (t-test/chi-square tests for continuous and categorical variables respectively).
RESULTS: Of 1,037 patients initiating an eligible systemic therapy at enrollment, 163 patients (15.7%) had nail PsO. Patients with nail PsO were similar in age (mean age: 50.6 vs. 49.4 yrs) but were less likely female (43% vs 52%), with longer disease duration (mean: 20.4 vs 14.3 yrs) and presence of psoriatic arthritis (PsA) (48% vs 36%) compared to

patients without nail PsO (all $P < .05$). Significantly more patients with nail PsO had received a biologic treatment (67% vs 55%, $P < .05$), with ~60% (vs 50%) having history of ≥2 prior biologic use. Patients with nail PsO had more severe disease (mean BSA: 20.2 vs 14.7; mean PASI: 12.7 vs 8.3, PASI >10: 45% vs 29%) and a higher proportion had inverse (16% vs 5%), scalp (82% vs 28%) and palmoplantar (25% vs 10%) PsO, compared to patients without nail PsO (all $P < .05$). Overall work impairment (mean percent: 20.0 vs 19.0) and quality of life (mean DLQI: 9.6 vs 9.0) were similar in patients with nail PsO vs. without nail PsO, respectively. However, patients with nail PsO reported significantly higher symptoms (mean itch: 20.2 vs 14.7, mean pain: 43.2 vs 36.6), anxiety (mean 26% vs 20%), and impaired health status (mean EQ-VAS: 62.8 vs 70.4) compared to patients without nail PsO, respectively, (all $P < .05$).

CONCLUSION: This real world study showed that patients with nail PsO have a significantly greater clinical, symptom and emotional burden compared to patients without nail PsO.

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