**14148**

**Pharmacokinetics, safety, and efficacy of dupilumab in children aged ≥2 to <6 years with severe uncontrolled atopic dermatitis (LIBERTY AD PRE-SCHOOL)**

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Limited treatment options are available for children with moderate to severe atopic dermatitis (AD). Dupilumab is a fully human monoclonal antibody that inhibits signaling of interleukin-4 and interleukin-13, cytokines that are key drivers of type 2 inflammation. Dupilumab is approved for subcutaneous administration every 2 weeks for patients aged ≥12 years with moderate to severe AD in the USA. We report pharmacokinetics, safety, and efficacy of dupilumab in children with severe AD inadequately controlled with topical therapies from the LIBERTY AD PRE SCHOOL trial (NCT03346434). Patients aged ≥6 months to <6 years (n = 40), stratified by age and region, were randomized 1:1 to a single subcutaneous dose of dupilumab 3 mg/kg or 6 mg/kg. We report data for the ≥2- to <6-year-old cohort (n = 10 per treatment group). Treatment groups had similar baseline characteristics. Single doses of dupilumab resulted in a slightlyless than dose-proportional increase in mean serum concentrations. Treatment-emergent adverse events were similar across groups. 1 serious adverse event (anaphylactic reaction due to existing peanut allergy) was reported in the 3 mg/kg group. At wk 4, for the 3 mg/kg and 6 mg/kg treatment groups, respectively, patients had improvements from baseline in Eczema Area and Severity Index (EASI): mean percentage change (standard deviation) −26.6 (47.4)/−48.7 (28.9) ($P = .1097$/$P = .0005$); and EASI-50/EASI-75 was observed in 30%/40% and 20%/30% patients. Single doses of dupilumab in children aged ≥2 to <6 years showed a slightly less than dose proportional increase in mean serum concentrations and caused improvements in AD signs and symptoms. Dupilumab was well tolerated; safety was generally consistent with previous findings in children.

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**14152**

**Patient-reported outcomes in a head-to-head, randomized, double-blinded clinical trial of ixekizumab and guselkumab in patients with moderate to severe plaque psoriasis**

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Background: Ixekizumab was shown to be more effective than guselkumab at week 12 in the IXORA-R study. Here we present 12-week patient-reported outcomes (PROs) from this head-to-head study of ixekizumab, an interleukin-17A inhibitor, and guselkumab, an interleukin-23p19 inhibitor.

Methods: IXORA-R (NCT03573323), a 24-week ongoing study, included adults with moderate to severe plaque psoriasis (sPGA ≥3, PASI ≥12, BSA ≥10%). Patients were randomized (1:1) to ixekizumab or guselkumab (dosing per label). PROs for Dermatology Life Quality Index (DLQI), itch (numeric rating scale; NRS), skin pain (visual analog scale; VAS), and Patient's Global Assessment of Disease Severity (PatGA) were completed through week 12. Comparisons were made by Cochran-Mantel-Haenszel test adjusted by pooled site using nonresponder imputation for missing data. Analyses for itch and skin pain were performed only for patients with baseline itch NRS ≥4 and skin pain VAS >0, respectively.

Results: 1027 pts were randomized (n = 520 ixekizumab, n = 507 guselkumab). Baseline demographics and clinical characteristics were generally well balanced between groups. At week 4, significantly more patients on ixekizumab vs guselkumab reported DLQI 0/1 (33.7% ixekizumab vs 20.9% guselkumab, $P <$ .001), and differences remained statistically significant through week 12 ($P < .05$). Ixekizumab was also superior to guselkumab for itch NRS improvement ≥ 4 (weeks 1, 2, 4, 6, and 8, $P < .05$), PatGA 0/1 (weeks 1, 2, 4, 6, 8, 10, and 12, $P < .05$), and skin pain VAS [0] (weeks 4, 6, 8, and 10, $P < .05$).

Conclusions: More patients on ixekizumab than guselkumab reported improvement at early timepoints for quality of life, itch, skin pain, and disease activity.

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**14157**

**Speed of improvement in genital psoriasis, genital itch, sexual impact, and health-related quality of life in patients with moderate to severe genital psoriasis treated with ixekizumab**

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Introduction: Ixekizumab is approved for moderate to severe genital psoriasis (GenPs). We assessed median time to improvement with ixekizumab in the signs and symptoms of moderate to severe GenPs.

Methods: Post hoc analyses of Kaplan-Meier estimates of time to first response were conducted on patients (n = 74) from IXORA-Q (NCT02718898) who were randomized to 80-mg ixekizumab every 2 weeks through week 12 (160-mg starting dose) and entered the open-label treatment period (weeks 12-52). Outcomes included static Physician's Global Assessment of Genitalia of 0 or 1 (sPGA-G (0,1)) or 0 (sPGA-G (0)) (0 = clear and 1 = minimal GenPs), Genital Itch Numeric Rating Scale of 0 (Genital Itch NRS = 0, indicating resolution of genital itch), GenPs Sexual Frequency Questionnaire Item 2 of 0 or 1 (GenPs SFQ item 2 (0,1), indicating GenPs never or rarely impacted frequency of sexual activity), and Dermatology Life Quality Index of 0 or 1 (DLQI (0,1), indicating no impact on quality of life).

Results: Median (95% confidence interval) time to sPGA-G (0,1) or sPGA-G (0) was 26 (16-35) and 59 (56-86) days, respectively. Median time to Genital Itch NRS = 0 (patients with ≥1 at baseline) was 50 (34-73) days. Median time to GenPs SFQ Item 2 (0,1) (patients with ≥2 at baseline) was 22 (10-28) days. Median time to first DLQI (0, 1) response was 88 (81-167) days.

Conclusions: Response with ixekizumab was most rapid for improvement in the impact of GenPs on the frequency of sexual activity, followed by improvement in genital skin, genital itch resolution, quality of life, and complete clearance of genital skin.

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**14159**

**Sustained improvements in itch, skin pain, and health-related quality of life through 5 years of treatment with ixekizumab in patients with moderate to severe plaque psoriasis**

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Introduction: Ixekizumab (IXE) is approved for moderate to severe plaque psoriasis, psoriatic arthritis, and ankylosing spondylitis. We describe patient-reported outcomes through 5 years of treatment in patients with moderate to severe plaque psoriasis.

Methods: Results are summarized as-observed for patients in UNCOVER-1 who received label dosing of IXE through week 60. Analyses included patients (n = 110) who achieved static Physician's Global Assessment (0,1) at week 12, completed week 60, and entered long-term extension (weeks 60-264). Outcome measures included Itch numeric rating scale ≥4-point improvement from baseline (Itch NRS ≥4) for patients with baseline ≥4, Itch NRS = 0 for patients with baseline >0, skin pain visual analog scale 0 (skin pain VAS = 0), Dermatology Life Quality Index 0 or 1 (DLQI 0,1), mean change from baseline (CFB) in the Psoriasis Skin Appearance Bothersomeness (PSAB) measure (0 [best] to 30 [worst]), and mean CFB in the Short Form Health Survey (SF-36) Physical (PCS) or Mental Component Summaries (MCS) (0 [worst] to 100 [best]). Baseline was week 0.

Results: At week 264, responses were 82.4% (n = 61/74) for Itch NRS ≥4, 51.7% (n = 45/87) for Itch NRS = 0, 59.3% (n = 51/86) for skin pain VAS = 0, and 75.0% (66/88) for DLQI (0,1). Mean (SD) CFB was −21.33 (8.05) for PSAB, 4.37 (7.33) for SF-36 PCS, and 3.43 (10.71) for SF-36 MCS.

Conclusions: IXE provided clinically meaningful and sustained improvements in itch, skin pain, DLQI, PSAB, and SF-36 PCS and MCS through 5 years of treatment in patients with moderate to severe plaque psoriasis.

*Commercial disclosure: 100% sponsored by Eli Lilly and Company.*