Posters

LEBRIKIZUMAB FOR PAEDIATRIC PATIENTS AGED ≥6 MONTHS WITH MODERATE-TO-SEVERE AD: PHASE 3 ADORABLE-1 WEEK-16 RESULTS

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Atopic dermatitis (AD) is the most prevalent chronic inflammatory skin condition impacting 15—20% of children globally, with limited treatment options. Lebrikizumab (LEB) inhibits interleukin (IL)-13, a key driver of AD, and is approved for patients (pts) ≥12 years (y), ≥40kg with moderate-to-severe (mod-sev) AD inadequately treated with topicals. The ADorable 1 double-blind phase 3 study (NCT05559359) evaluated 16 week (W) efficacy and safety of LEB and topical corticosteroids (TCS) vs placebo (PBO) and TCS in pts aged 6 months (m) to <18y with mod-sev AD. 363 pts were randomised 2:1 to LEB (n=245) or PBO (n=118), stratified by age, region, and baseline (BL) Investigator's Global Assessment (IGA; 3 vs 4). Low-to-mid potency TCS were initiated 2 weeks pre-randomisation. Dosing was weight-based (≥40kg: 500mg W0 and W2, 250mg every 2W from W4; 15–<40kg: 250mg W0, 250mg every 4W [Q4W] from W2; 6–<15kg: 125mg W0, 125mg Q4W from W2). Co-primary endpoints were IGA (0,1) with ≥2-point improvement and ≥75% improvement from BL in Eczema Area and Severity Index (EASI) at W16. Efficacy analyses used the Intent-to-Treat population; safety analyses used the Safety population. The study is ongoing. Data are reported as LEB vs PBO, respectively. At BL, mean age: 7.7y vs 7.6y; female: 47.3% vs 54.2%. BL disease characteristics: IGA 3, 74.6% vs 76.3%; prior systemic therapy use, 58.4% vs 67.8%, with prior dupilumab use 12.2% vs 11.0%. Co-primary endpoints at W16: IGA (0,1) and EASI 75 were achieved by 43.5% vs 15.2% (p<0.001) and 62.6% vs 21.6% (p<0.001). Key secondary endpoints at W16: EASI 90, 38.6% vs 11.0% (p<0.001); EASI 100, 13.7% vs 4.6% (p=0.007); ≥6-point improvement in Children's Dermatology Life Quality Index (4-17y, BL≥6), 61.6% vs 36.2% (n=238, p=0.001); ≥4-point improvement in Pruritus Numeric Rating Scale (NRS); (≥6y, BL≥4), 34.5% vs 5.5% (n=196, p<0.001). 41.6% vs 0.0% (n=66, p<0.001) had ≥4-point improvement in Worst Scratching/Itching NRS (<6y, BL≥4). 57.1% vs 59.3% reported adverse events mostly mild/moderate in severity, with no trial discontinuations. Injection site reactions were similar in the LEB and PBO arms, with no injection site pain reported. LEB was superior to PBO for the co-primary endpoints at W16 in pediatric pts 6m-<18 y with mod-sev AD. No new safety findings were identified at W16 from available data. These results support LEB as a potential first selective IL-13 inhibitor treatment option for this paediatric population.