Dupilumab Treatment Improves Health-Related Quality of Life in Children Aged 6 Months to 5 Years With Moderate-to-Severe Atopic Dermatitis

Amy S. Paller[1,2], Eric L. Simpson[3], Elaine C. Siegfried[4,5], Michael J. Cork[6], Andreas Wollenberg[7], Peter D. Arkwright[8], Haixin Zhang[9], Zhixiao Wang[9], Ainara Rodríguez Marco[10]

[1]Northwestern University Feinberg School of Medicine, Chicago, IL, USA; [2]Ann and Robert H. Lurie Children's Hospital, Chicago, IL, USA; [3]Oregon Health and Science University, Portland, OR, USA; [4]Saint Louis University, St. Louis, MO, USA; [5]Cardinal Glennon Children's Hospital, St. Louis, MO, USA; [6]Sheffield Dermatology Research, University of Sheffield, Sheffield, UK; [7]Ludwig-Maximiliam University, Munich, Germany; [8]University of Manchester, Manchester, UK; [9]Regeneron Pharmaceuticals, Inc., Tarrytown, NY, USA; [10]Sanofi, Madrid, Spain

Background

Health-related quality of life (HRQoL) is severely impaired in children aged 6 months to 5 years with moderate-to-severe atopic dermatitis (AD) with a lack of approved systemic treatments available for this population. Previous studies showed that dupilumab substantially improved AD-associated signs, symptoms, and HRQoL with an acceptable safety profile in adults, adolescents, and children aged over 6 years.

Methods

In LIBERTY AD INFANT/PRE-SCHOOL (NCT03346434), a double-blind, placebo-controlled trial, children aged 6 months to 5 years with moderate-to-severe AD (Investigator's Global Assessment score ≥ 3) inadequately controlled with topical therapies were randomized 1:1 to subcutaneous dupilumab every 4 weeks (200 mg if baseline weight ≥ 5 to < 15 kg, 300 mg if ≥ 15 to < 30 kg) or placebo for 16 weeks with concomitant low-potency TCS. 162 patients were randomized to dupilumab (n = 83) or placebo (n = 79). Reported HRQoL measures include patient-reported Children's Dermatology Life Quality Index validated in patients aged ≥4 years (CDLQI; score range: 0 [no effect on child's life] – 30 [maximum effect on child's life], recall period: one week), caregiver-reported Infants' Dermatology Quality of Life Index validated in patients aged <4 years (IDQoL; score range: 0 [no effect on infant's life] – 30 [maximum effect on infant's life], recall period: one week) and Dermatitis Family Impact (DFI; score range: 0 [no impact on life of family] – 30 [maximum impact on life of family], recall period: one week). CDLQI and

IDQoL measures aim to assess how much AD has affected the patients QoL while DFI assesses the impact of AD on the QoL of parents and family members of affected children.

Results

Baseline QoL measures demonstrated moderate to large impact of AD on the quality of life of patients and their families. Baseline CDLQI scores (± standard deviation [SD]) in pediatric patients aged ≥ 4 years were similar in both dupilumab (17.5 [5.5]) and placebo (17.7 [6.3]) treatment arms. Baseline IDQoL scores (±SD) in patients aged < 4 years were similar in both dupilumab and placebo treatment arms (17.4 [5.4] vs 17.1 [5.4]). Baseline DFI scores (±SD) in dupilumab and placebo treatment arms were 17.2 (6.0) and 17.6 (7.2) respectively. Dupilumab vs placebo treatment improved CDLQI scores: least squares (LS) mean change (± standard error [SE]) from baseline starting from Week 2 (–5.0 [1.5] vs –2.3 [1.6]; $P < 0.05$), with this improvement continuing to Week 16 (–10.0 [1.6] vs –2.5 [1.7]; $P < 0.0001$). Dupilumab vs placebo treatment also improved IDQoL scores: LS mean change (± SE) from baseline beginning at Week 2 (–6.6 [1.0] vs –2.2 [1.0]; $P = 0.0005$), with this improvement continuing to Week 16 (–10.9 [1.2] vs –2.0 [1.1]; $P < 0.0001$). Caregivers of patients treated with dupilumab reported rapid and significant improvement in DFI scores: LS mean change (± SE) from baseline vs placebo beginning at Week 2 (–5.5 [0.7] vs –2.2 [0.7]; $P = 0.0002$), which continued to improve to Week 16 (–10.5 [0.8] vs –2.7 [0.8]; $P < 0.0001$). Dupilumab was well tolerated with an acceptable safety profile.

Conclusions

Dupilumab treatment with concomitant low-potency TCS for 16 weeks provided rapid and significant improvement to HRQoL measures, including CDLQI, IDQoL, and DFI in patients with AD aged 6 months to 5 years and their caregivers.

Acknowledgements and funding sources

Research sponsored by Sanofi and Regeneron Pharmaceuticals, Inc. ClinicalTrials.gov Identifier: NCT03346434. Medical writing/editorial assistance was provided by Holly Rocliffe, PhD, of Excerpta Medica, and was funded by Sanofi and Regeneron Pharmaceuticals, Inc., according to the Good Publication Practice guideline.

Disclosures

Paller AS: AbbVie, AnaptysBio, Eli Lilly, Incyte, Janssen, KrystalBio, Regeneron Pharmaceuticals, Inc., UCB – investigator; AbbVie, Abeona Therapeutics, Alcimed, Almirall, Amagma, AnaptysBio, Arena, Azitra, BiomX, Boehringer Ingelheim, Castle Biosciences, Catawba, Dermira, Eli Lilly, Exicure, Forte, Kamari, LEO Pharma, LifeMax, NAOS, Novartis, Pfizer, Phoenix, Pierre Fabre Dermo-Cosmetics, Regeneron Pharmaceuticals, Inc., Sanofi, Seanergy, Trifecta, UCB – consultant with honorarium; AbbVie, Bausch, Galderma, Novan – Data Safety Monitoring Board. **Simpson EL:** AbbVie, Eli Lilly, Galderma, Kyowa Hakko Kirin, LEO Pharma, Merck, Pfizer, Regeneron Pharmaceuticals, Inc. – investigator; AbbVie, Boehringer Ingelheim, Dermavant, Eli Lilly, Forté, Incyte, LEO Pharma, Menlo Therapeutics, Pfizer, Pierre Fabre Dermo-Cosmetics, Regeneron Pharmaceuticals, Inc., Sanofi, Valeant – consultant fees. **Siegfried E:** Dermavant, Eli Lilly, Pfizer, Regeneron Pharmaceuticals, Inc., Verrica Pharmaceuticals – consultant; GlaxoSmithKline, LEO Pharma, Novan – data and safety monitoring board; Eli Lilly, Janssen, Regeneron Pharmaceuticals, Inc., Stiefel, Verrica Pharmaceuticals – Principal Investigator in clinical trials. **Cork MJ:** AbbVie, Astellas Pharma, Boots, Dermavant, Galapagos, Galderma, Hyphens Pharma, Johnson & Johnson, LEO Pharma, L'Oréal, Menlo Therapeutics, Novartis, Oxagen, Pfizer, Procter & Gamble, Reckitt Benckiser, Regeneron Pharmaceuticals, Inc., Sanofi– investigator and/or consultant**. Wollenberg A**: Beiersdorf, Eli Lilly, Galderma, LEO Pharma, MedImmune, Novartis, Pfizer, Regeneron Pharmaceuticals, Inc., Sanofi– investigator; AbbVie, Almirall, Anacor Pharmaceuticals, Eli Lilly, Galapagos, Galderma, LEO Pharma, MedImmune, Novartis, Pfizer, Regeneron Pharmaceuticals, Inc., Sanofi – consultant; Beiersdorf, LEO Pharma, Pierre Fabre – research grants. **Arkwright PD:** Sanofi– advisory board and project grant funding. **Zhang H, Wang Z:** Regeneron Pharmaceuticals, Inc. – employees and shareholders. **Rodríguez Marco A:** Sanofi– employee, may hold stock and/or stock options in the company.