Dupilumab reduces atopic dermatitis lesion severity and extent in children <12 years of age with moderate-to-severe AD: interim results from the PEDISTAD real-world registry

Lara Wine Lee1, Alan D. Irvine2, Michele Ramien3,4, Danielle Marcoux5,6, Eulalia Baselga7, Marlies de Graaf8, Martti Antila9, Nelson A. Rosario Filho10, Irene Lara-Corrales11, Joel C. Joyce12, Rajan Gupta13, Patrick Redman14, Annie Zhang13

1 Medical University of South Carolina, Charleston, SC, USA; 2 Trinity College Dublin, Dublin, Ireland; 3 Alberta Children’s Hospital, Calgary, AB, Canada; 4 University of Calgary, Calgary, AB, Canada; 5 University of Montreal, Montreal, QC, Canada; 6 CHU Sainte-Justine University Hospital Center, Montreal, QC, Canada; 7 Hospital Sant Joan de Déu, Barcelona, Spain; 8 University Medical Center Utrecht, Utrecht, Netherlands; 9 Clínica de Alergia, Sorocaba, Sao Paulo, Brazil; 10 Federal University of Paraná, Curitiba, Brazil; 11 The Hospital for Sick Children, Toronto, ON, Canada; 12 Endeavor Health, Skokie, IL, USA; 13 Sanofi, Cambridge, MA, USA; 14 Regeneron Pharmaceutical Inc., Tarrytown, NY, USA;

Introduction/Background:

In clinical trials, dupilumab has consistently improved disease severity in children with moderate-to-severe atopic dermatitis (AD).

Objectives:

To investigate the impact of systemic treatments on the individual anatomical regions that comprise the Eczema Area and Severity Index (EASI).

Methods:

PEDISTAD (NCT03687359) is an international, longitudinal, observational 10-year registry study of patients aged < 12 years with moderate-to-severe AD. This interim analysis reports mean Eczema
Area and Severity Index (EASI) scores of the head and neck and upper limbs at therapy start and last observation.

**Results:**

A total of 207 patients received dupilumab, 127 received methotrexate and 139 received cyclosporine. The mean observation period was 17.0 months, 18.7 months, and 14.3 months for dupilumab, methotrexate and cyclosporine respectively. Mean (SD) EASI scores for the head and neck area of dupilumab patients improved from 2.0 (0.2) at therapy start to 0.7 (0.1) at last observation. Improvement was also seen in patients receiving methotrexate (therapy start: 2.0 [0.2]; last observation: 1.0 [0.2]) and cyclosporine (therapy start: 2.2 [0.2]; last observation: 1.6 [0.2]). A numerically greater improvement in mean (SD) EASI scores of the upper limbs was observed in patients receiving dupilumab (therapy start: 4.5 [0.2]; last observation: 1.5 [0.2]) than methotrexate (therapy start: 3.8 [0.2]; last observation: 2.1 [0.2]) and cyclosporine (therapy start: 4.1 [0.2]; last observation: 2.9 [0.3]). Adverse events were experienced by 23.7%, 30.5% and 32.6% of patients receiving dupilumab, methotrexate and cyclosporine, respectively.

**Conclusion**

Children with moderate-to-severe AD receiving dupilumab, methotrexate, or cyclosporine had improvement in AD lesion severity and extent in individual anatomical regions, with the greatest numerical improvement observed in those receiving dupilumab.

**Keywords:** atopic dermatitis, pediatric, Eczema Area and Severity Index, dupilumab

**Acknowledgments**

Research was funded by Sanofi and Regeneron Pharmaceuticals, Inc. ClinicalTrials.gov Identifier: NCT03687359. Medical writing/editorial assistance was provided by Emma Thomas MSc of Excerpta Medica and was funded by Sanofi and Regeneron Pharmaceuticals, Inc., according to the Good Publication Practice guidelines.
Disclosures

LWL: Castle Creek Biosciences, Eli Lilly, Pfizer, Regeneron Pharmaceuticals Inc. – advisory board member; AbbVie, Amryt Pharma, Kimberly-Clark, Krystal Biotech, Novartis, Pyramid Biosciences – consultant; AbbVie, Amgen, Amryt Pharma, Arcutis Biotherapeutics, Castle Creek Biosciences, Celgene, Eli Lilly, Galderma, Incyte, Mayne Pharmaceuticals, Novartis, Pfizer, Regeneron Pharmaceuticals Inc., Sanofi, Target Pharma, Trevi Therapeutics, UCB – investigator; Amryt Pharma, Krystal Biotech – speaker. ADI: AbbVie, Arena Pharmaceuticals, BenevolentAI, Chugai Pharmaceutical, Dermavant, Eli Lilly, Genentech, LEO Pharma, Menlo Therapeutics, Novartis, Pfizer, Regeneron Pharmaceuticals Inc., Sanofi, UCB – consultant; AbbVie, Eli Lilly, LEO Pharma, Novartis, Pfizer, Regeneron Pharmaceuticals Inc., Sanofi – speaker; AbbVie, DS Biopharma, Inflazome, Novartis, Sanofi-Regeneron Pharmaceuticals Inc. – investigator. MR: AbbVie, Eli Lilly, LEO Pharma, Pfizer, Sanofi – consultant; Sanofi – registry study. DM: Apogee Therapeutics, Arcutis, Eli Lilly, Pfizer, Regeneron Pharmaceuticals Inc., Sanofi — advisory board member; AbbVie, Pfizer, Sanofi — consultant; AbbVie, Amgen, Celgene, Eli Lilly, Galderma, Incyte, Pfizer, Regeneron Pharmaceuticals Inc., Sanofi, UCB — investigator; Pfizer, Sanofi— speaker. EB: Almirall – speaker; AbbVie, Eli Lilly, Pfizer – investigator; Pierre Fabre Dermatologie – investigator, consultant; Regeneron Pharmaceuticals Inc., Sanofi – consultant; Venthera – co-founder, consultant. MdG: AbbVie, Eli Lilly, LEO Pharma, Novartis, Pfizer, Regeneron Pharmaceuticals Inc., Sanofi – investigator; AbbVie, Eli Lilly, LEO Pharma, Regeneron Pharmaceuticals Inc., Sanofi – consultant; AbbVie, LEO Pharma, Pfizer, Regeneron Pharmaceuticals Inc., Sanofi – speaker. MA: AbbVie AstraZeneca, EMS, Eurofarma, GSK, Humanigen, Janssen, Novartis, Sanofi, Veru – participation in clinical studies; Abbott, Aché, AstraZeneca, Chiesi, Eurofarma, IPI-ASAC, Sanofi – conferences and consultancy activities. NARF: AbbVie, AstraZeneca, Boehringer Ingelheim, Chiesi, Sanofi, Viatris – investigator, consultant and/or speaker. IL-C: AbbVie, Arcutis Biotherapeutics, Clementia Pharmaceuticals, EB Medical Research
Foundation, EB Research Partnership, Eli Lilly, La Roche-Posay, Mayne Pharma, Physicians Services Incorporated (PSI) Foundation, Regeneron Pharmaceuticals Inc., Sanofi, SkIN Canada, Timber Pharmaceuticals – investigator/research support; Abeona Therapeutics, Avicanna, Eli Lilly, Ipsen, Novartis, Sanofi – consultant/advisor; AbbVie, Eli Lilly, Sanofi – speakers bureau; DEBRA Canada, Camp Liberté and Children International Summer Villages (CISV) – other support: board of directors.

JCJ: Pfizer and Sanofi — consultant fees; AbbVie and Sanofi — speaker fees; AbbVie, Aclaris Therapeutics, Amgen, Apogee, AstraZeneca, Bayer, BMS, Eli Lilly, Galderma, Incyte, Janssen, LEO Pharma, NFlection Therapeutics, Novartis, Pfizer, Regeneron Pharmaceuticals Inc., Sanofi — study investigator. **Gupta R, Zhang A:** Sanofi – employees, may hold stock and/or stock options in the company. **Redman P:** Regeneron Pharmaceuticals Inc. – employee and shareholder.