The Disease and Family Burden of Moderate-to-Severe Atopic Dermatitis (AD) in Children Aged <12 Years: PEDISTAD Observational Study

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Objective: To describe the real-world burden of moderate-to-severe atopic dermatitis (AD), including atopic comorbidities and disease characteristics in patients aged <12 years in PEDISTAD.

Methods: PEDISTAD (NCT03687359) is an ongoing, international, observational study in patients aged <12 years with moderate-to-severe AD inadequately controlled with topical therapies or for whom such therapies are inappropriate. Baseline atopic comorbidities, AD treatments, Eczema Area and Severity Index (EASI; range 0–72), AD-affected body surface area (BSA; 0–100%), Patient-Oriented Eczema Measure (POEM; 0–28), Infants' Dermatitis Quality of Life (IDQOL) Index (≤3 years; 0–30)/Children's Dermatology Life Quality Index (CDLQI; 4–<12 years, 0–30), and Dermatitis Family Impact (DFI) score (0–30) are reported by age groups of 0–<2, 2–<6, and 6–<12 years.

Results: Among 1,329 children (53.1% males; mean±SD age 6.0±3.2 years), 60.5% had atopic comorbidities, most commonly food allergy (33.9%), allergic rhinitis (33.8%), and asthma (22.9%). 88.0% children were receiving non-systemic AD treatment(s), mainly topical corticosteroids (75.5%) and topical calcineurin inhibitors (36.0%). 31.6% were receiving systemic therapies, including dupilumab (12.0%), systemic corticosteroids (10.2%), cyclosporine A (9.3%), and methotrexate (8.7%). Mean±SD EASI was 14.6±11.0; BSA affected, 33.1±21.0%; POEM, 15.5±7.3; IDQOL, 10.8±6.2; CDLQI, 10.9±6.8; and DFI score, 11.1±7.4. The most impacted POEM domains were itchy and dry/rough skin; CDLQI domains, itchy skin and sleep; DFI domains, expenditure, sleep, tiredness, and emotional distress. Atopic comorbidities

increased with age (32.7% of 0–<2-year-olds, 67.6% of 6–<12-year-olds), as did treatment with systemic AD therapies (12.4% and 39.0%, respectively); average disease severity and impact scores were comparable across age groups.

Discussion: Baseline characteristics of children enrolled in PEDISTAD reflect a multidimensional AD disease burden despite receiving standard treatment. The high burden observed in this real-world dataset suggests a major unmet need for effective and safe therapies for moderate-to-severe AD in children <12 years.

Disclosures

Oliveira De Carvalho V: Expanscience, Galderma, Johnson & Johnson Consumer Health, Mantecorp Skincare, Megalabs, Royal Canin – speaker; Sanofi – investigator. **de Bruin-Weller M:** AbbVie, Almirall, Arena Pharmaceuticals, Aslan Pharmaceuticals, Eli Lilly, Galderma, Janssen, LEO Pharma, Pfizer, Regeneron Pharmaceuticals, Inc., Sanofi– consultant, advisory board member, and/or speaker. **Ardusso LRF:** AstraZeneca, GSK, Novartis, Sanofi – consultant and/or advisory board member, and/or speaker**. Pasmans S:** LEO Pharma, Novartis, Regeneron Pharmaceuticals, Inc., Sanofi – consultant and/or advisory board member, and/or speaker. **Toledo-Bahena M:** AbbVie, Expanscience, Janssen, LEO Pharma, Pierre Fabre – speaker; Pfizer, Sanofi – investigator. **Gupta R:** TechData Service – employee; holds no stock and/or stock options in any pharmaceutical company. **Bates L:** Regeneron Pharmaceuticals, Inc. – employee and shareholder. **Zhang A:** Sanofi – employee, may hold stock and/or stock options in the company.