

Baseline Characteristics of Atopic Dermatitis (AD) and AD Treatments in a Cohort of Adult AD Patients Initiating Dupilumab in a Real-World Registry (PROSE)

Daniel I. Shrager¹, Scott Guenthner², David Cohen³, Haixin Zhang⁴, Daniel Richman⁵, Andrew Korotzer⁴, Shikha Bansal⁴

¹Alpha Dermatology of PA, LLC., Sellersville, PA; ²The Indiana Clinical Trials Center, PC; ³Skin Care Physicians of Georgia, Macon, GA; ⁴Regeneron Pharmaceuticals, Inc., Tarrytown, NY; ⁵Sanofi Genzyme, Cambridge, MA; USA

Background: Randomized clinical trials of dupilumab have demonstrated rapid and sustained efficacy with an acceptable safety profile in patients with moderate-to-severe atopic dermatitis (AD), but real-world data are limited. To understand disease severity and treatment burden in a real-world setting, we analyzed baseline AD disease severity and baseline concomitant AD treatments used by patients initiating dupilumab in the PROSE registry.

Methods: PROSE (NCT03428646) is an ongoing, multicenter, longitudinal, prospective, up-to-5-years, observational registry in the USA and Canada characterizing dupilumab-treated AD patients in a real-world setting. Patients who were prescribed dupilumab as standard of care for AD according to the country-specific prescribing information were eligible for this study. Patients were recruited upon being prescribed dupilumab, and baseline was defined as the date of the first dupilumab injection (up to 84 days following recruitment).

Results: At data cutoff for this analysis (July 2019), 315 patients were included in PROSE, with a mean age (standard deviation [SD]) of 42.5 (16.99) years. 174 (55.2%) patients were female. Baseline mean Eczema Area and Severity Index was 16.9 (13.36), with 176 (55.9%) and 105 (33.3%) patients having their disease classified as moderate and severe, respectively, according to the Overall Disease Severity instrument. Mean (SD) Peak Pruritus Numerical Rating Scale (NRS) score in PROSE patients was 6.9 (2.30), mean Patient-Oriented Eczema Measure was 18.5 (6.65), and mean Dermatology Life Quality Index was 19.0 (7.71). 166 (52.7%) patients had Skin Sensitivity NRS score of ≥ 3 points, and 171 (54.3%) patients had Sleep Disturbance NRS score of ≥ 3 points. At PROSE baseline, 182 (57.8%) patients were receiving ≥ 1 medication for AD.

Conclusions: Patients initiating dupilumab in routine clinical practice had significant burden of disease as determined by both patient- and clinician-assessed outcomes of AD lesions and quality of life. AD symptomatology extended beyond itch and included skin sensitivity to touch and sleep disturbance. More than half of the patients were on ≥ 1 AD medication at study start, signifying a high treatment burden.