Abstract N°: 2950

Dupilumab provides sustained effectiveness in patient-reported outcomes and favorable safety in patients with moderate-to-severe atopic dermatitis: up to 5-year results from the daily practice Bioday Registry

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Introduction & Objectives: Previous studies have demonstrated the long-term effectiveness of dupilumab for up to 4 years in patients with moderate-to-severe atopic dermatitis (AD) in open-label studies. Long-term daily practice data particularly those encompassing a range of patient-reported outcome measures (PROMs) is lacking, which could be helpful to fully capture the disease burden and gain further insight into the effectiveness of dupilumab from patients’ perspectives. In the present study, we aimed to assess PROMs and safety profile for up to 5 years in patients with AD of all ages treated with dupilumab in daily practice.

Materials & Methods: Data were extracted from the prospective, multicenter BioDay registry of patients with moderate-to-severe AD treated with dupilumab (October 2017-2022). Several (proxy) PROMs were captured every 3-6 months, including Patient-Oriented Eczema Measure (POEM), Dermatology Life Quality Index (DLQI), Numeric Rating Scale (NRS) weekly average itch and pain, Work Productivity and Activity Impairment (WPAI), Patient Global Assessment of Disease Status (PGADS). Clinical phenotyping of AD was defined using NRS-Itch combined with Eczema Area and Severity Index (EASI) with the cutoff value of 4 and 21, respectively, as follows: mild-moderate itch and lesions (MI-ML), mild-moderate itch and severe lesions (MI-SL), severe itch and mild-moderate lesions (SI-ML), and severe itch and lesions (SI-SL). Adverse events (AEs) were also evaluated.

Results: A total of 1223 patients, 1108 adult and 115 pediatric patients, were included (mean±standard deviation (SD) 38.5±17.2 years, 56.8% males, 2281 patient-years (PY)), with up to 5 years of follow-up for the adult population (n=2), and 2.75 years for the pediatric population (n=2). For adult patients at year 4 (n=131), mean±SD POEM, DLQI, NRS-Itch, NRS-pain, overall work impairment was 8.7±6.2, 3.8±4.1, 2.9±2.2, 1.2±1.9 and 15.4%±23.5, respectively, with 80.6% reporting ‘good/very good/excellent’ disease status. Taken together, 68.1% of adult patients at year 4 achieved ≥2 of the following absolute cut-off scores: POEM≤7, DLQI≤5, and NRS-Itch≤4, with being males and clinical responders at week 4 more likely to achieve it using the multivariate binary logistic regression model. Concomitant systemic treatments was reported by 2.4% of adult patients at year 4. For pediatric patients at year 1 (n=46), mean±SD POEM, DLQI, NRS-Itch, and NRS-pain was 10.9±7.8, 6.4±5.6, 3.7±2.5, 1.7±2.2, respectively, with 45.7% reporting ‘good/very good/excellent’ disease status. In total 50.0% of pediatric patients at year 1 achieved ≥2 of the following cut-off values: POEM≤7, DLQI≤5, and NRS-Itch≤4. Only one pediatric patient had concomitant systemic treatment at year 1. Moreover, most patients had MI-ML, followed by MI-SL after 1-year until 5-year of treatment, regardless of ages. There were 1696 AEs being reported (74.4/100 PY) and 66.8% of patients reporting at least one AE. The most reported AE was conjunctivitis in 33.7% of patients; of those 69.2% had moderate-to-severe conjunctivitis.

Conclusion: In addition to favorable safety, dupilumab provides a long-term efficacy based on a range of PROMs
in both adult and pediatric populations, including disease-specific symptoms, improvement on quality of life, work productivity and activity impairment, and patients’ assessment of disease status. This underscore the benefit of dupilumab treatment from patients’ perspectives.