Abstract N°: 2008

Title: Long-Term Efficacy of Dupilumab in Adults With Moderate-to-Severe Atopic Dermatitis: Results From an Open-Label Extension Trial up to 172 Weeks

Lisa Beck[1], Diamant Thaçi[2], Mette Sondergaard Deleuran[3], Andrew Blauvelt[4], Jacob Thyssen[5], Robert Bissonnette[6], Marjolein De Bruin-Weller[7], Zhen Chen[8], Noah Levit[8], Ainara Rodríguez Marco[9]

[1] University Of Rochester Medical Center, Rochester, United States, [2] University Of Lübeck, Institute And Comprehensive Center For Inflammation Medicine, Lübeck, Germany, [3] Department Of Dermatology And Venereology, Aarhus Universitetshospital, Aarhus N, Denmark, [4] Oregon Medical Research Center, Portland, United States, [5] University Of Copenhagen, Bispebjerg Hospital, Copenhagen, Denmark, [6] Innovaderm Research, Montreal, Canada, [7] University Medical Center, Utrecht, Netherlands, [8] Regeneron Pharmaceuticals, Inc., Tarrytown, United States, [9] Sanofi Genzyme, Madrid, Spain

Introduction

Moderate-to-severe atopic dermatitis (AD) is often poorly controlled by topical therapies, and long-term use of systemic immunosuppressants can be limited due to safety concerns, or side-effects. Dupilumab is a fully human monoclonal antibody that blocks the shared receptor component for interleukin (IL)-4 and IL-13, key and central drivers of type 2 inflammation in multiple diseases. Data from an open-label extension (OLE) study (NCT01949311) demonstrated acceptable safety and sustained efficacy in adult patients for up to 148 weeks. Here, we present long-term efficacy and safety of dupilumab in adult patients with moderate-to-severe AD up to 172 weeks.

Material and Methods

Adult patients with moderate-to-severe AD who had previously participated in any dupilumab parent study (phase 1 to 3) were enrolled in this long-term, multicenter, open-label extension (OLE) study (LIBERTY AD OLE, NCT01949311), with an initial duration of 3 years. Protocol amendments in June 2017 and January 2018 allowed for patient re-entry and treatment extension for up to 5 years in certain countries. Participants entering this OLE study were treated with 300 mg dupilumab every week for up to 172 weeks. Concomitant treatments for AD, including topical corticosteroid (TCSs) and topical calcineurin inhibitors (TCIs), were permitted. Data shown are for the overall study population.

Results

2,677 patients were enrolled in this OLE study. 2,207 (82%) patients completed up to Week 52, 1,064 (40%) to Week 100, 534 (20%) to Week 148, 253 (10%) to Week 172, and 215 (8%) had treatment duration longer than 172 weeks. Following protocol amendments in June 2017 and January 2018, 113 and 272 patients re-entered the trial with 102 and 207 patients having a treatment interruption of > 8 weeks between study weeks 148 and 164. Most patient withdrawals (60%) were due to the regulatory approval and commercialization of dupilumab. At Week 172, 98.7%/94.6%/82.6% of patients achieved 50%/75%/90% reductions from parent study baseline in Eczema Area and Severity Index (EASI) score, respectively. Mean (standard deviation [SD]) EASI at Week 172 was 1.82 (3.21), with an absolute change from parent study baseline of −30.97 (14.18). In the Peak Pruritus Numerical Rating Scale (PP-NRS) score, 80.5%/64.5% of patients achieved a ≥ 3/≥ 4-point reduction from parent study baseline to Week 172. Mean (SD) PP-NRS score at Week 172 was 2.20 (1.70), with an absolute change from

parent study baseline of −4.60 (2.23). Treatment-emergent adverse events (TEAEs) were reported in 2,268 (84.7%) patients, with 96 (3.6%) having TEAEs resulting in permanent study drug discontinuation.

Discussion

In this long-term, 172-week, open-label study, dupilumab given on a weekly basis, showed robust and sustained efficacy substantiated by incremental improvement of AD signs and symptoms in patients with moderate-to-severe AD. Safety data were consistent with the known dupilumab safety profile.