

A new ERA for global Dermatology 10 - 15 JUNE 2019 MILAN, ITALY

PSORIASIS

## IXEKIZUMAB DEMONSTRATES HIGH SUSTAINED EFFICACY AND A FAVORABLE SAFETY PROFILE IN PATIENTS WITH MODERATE-TO-SEVERE PSORIASIS THROUGH FIVE YEARS OF TREATMENT

Craig Leonardi<sup>(1)</sup> - Peter Foley<sup>(2)</sup> - Hideshi Torii<sup>(3)</sup> - Sascha Gerdes<sup>(4)</sup> - Hany Elmaraghy<sup>(5)</sup> - Gaia Gallo<sup>(5)</sup> - David Shrom<sup>(5)</sup> - Ann Leung<sup>(6)</sup> - Kim Papp<sup>(7)</sup>

Central Dermatology, Dermatology, St. Louis, United States<sup>(1)</sup> - The University Of Melbourne And Skin & Cancer Foundation, Dermatology, Melbourne, Australia<sup>(2)</sup> - Division Of Dermatology, Tokyo Yamate Medical Center, Dermatology, Tokyo, Japan<sup>(3)</sup> - Psoriasiscenter At The Department Of Dermatology, University Medical Center Schleswig-holstein, Campus Kiel, Dermatology, Kiel, Germany<sup>(4)</sup> - Eli Lilly And Company, Immunology, Indianapolis, United States<sup>(5)</sup> - Syneos Health, Statistics, Raleigh, United States<sup>(6)</sup> - K. Papp Clinical Research And Probity Medical Research Inc., Dermatology, Waterloo, Canada<sup>(7)</sup>

Introduction: Ixekizumab (IXE), a high-affinity monoclonal antibody targeting interleukin-17A, is approved for moderate-to-severe plaque psoriasis and active psoriatic arthritis.

Objective: To evaluate long-term efficacy and safety through 5 years of treatment with IXE.

Materials and Methods: We report the results from the extension period of UNCOVER-1 (NCT01474512) through 5 years for patients who continuously received the labeled dose of IXE through Week 60 (160 mg starting dose, 80-mg IXE every 2 weeks [Q2W] through Week 12, and every 4 weeks [Q4W] thereafter). Patients who were static Physician's Global Assessment (sPGA) 0/1 responders at Week 12 and who completed 60 weeks of treatment could enter the extension period (N=110). Efficacy outcomes included the proportion of patients achieving sPGA 0/1 or at least 75%, 90%, or 100% improvement from baseline in the Psoriasis Area and Severity Index (PASI 75/90/100). During Weeks 60-264, patients and investigators could elect to escalate to IXE Q2W dosing through end of study to achieve or maintain efficacy. Efficacy is summarized by observed case. Safety is summarized by incidence rate (IR) per 100 patient-years.

Results: At the start of the extension period (Week 60), the PASI 75/90/100 response rates were 92.7%, 82.7%, and 56.4%, respectively. These response rates were maintained





**International League of Dermatological Societies** *Skin Health for the World* 







through Week 264, at which point PASI 75/90/100 response rates were 94.3%, 81.8%, and 46.6%, respectively. Overall, 23 (20.9%) patients escalated to IXE Q2W dosing; clinical response was consistent regardless of whether visits with escalated dosing were included in analyses. During Weeks 60-264, treatment-emergent adverse events occurred in 99 (IR=31.0) patients, serious adverse events occurred in 24 (IR=7.5) patients, and no deaths occurred (319.4 total patient-years).

Conclusions: Patients receiving IXE maintained high rates of improvement in plaque psoriasis with no unexpected safety outcomes for up to 5 years of treatment.



24<sup>TH</sup> WORLD CONGRESS OF DERMATOLOGY MILAN 2019



International League of Dermatological Societies Skin Health for the World

