Ixekizumab Demonstrates Sustained High Efficacy and Consistent Safety in Patients with Moderate-to-Severe Psoriasis: 5 Years of Follow-up from UNCOVER-3

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BACKGROUND

- Ixekizumab, a high-affinity monoclonal antibody that selectively targets interleukin-17A, is approved for treating moderate-to-severe plaque psoriasis
- In the Phase 3 UNCOVER-3 trial (NCT01646177), ixekizumab has previously demonstrated high efficacy with a consistent safety profile in patients with moderate-to-severe psoriasis

OBJECTIVE

- To evaluate the efficacy and safety findings through 5 years of treatment with the approved ixekizumab dosing regimen (starting dose of 160 mg, then 80 mg every 2 weeks up to and including Week 12, followed by 80 mg every 4 weeks thereafter) in UNCOVER-3

STUDY DESIGN

- Ixekizumab was approved under an accelerated approval protocol of 160 mg dosing every 2 weeks up to and including Week 12, followed by 80 mg dosing every 4 weeks thereafter

KEY ELIGIBILITY CRITERIA

Inclusion criteria:
- ≥18-years of age with moderate-to-severe plaque psoriasis
- Psoriasis Area and Severity Index (PASI) ≥12 at both screening and baseline visits
- ≥10% body surface area affected at both screening and baseline visits
- Static Physician’s Global Assessment (sPGA) score ≥3 at both screening and baseline visits

Exclusion criteria:
- Prior exposure to etanercept

PATIENT DISPOSITION

- Received at least 1 dose in LTE n=917
- Completed n=186
- Escalated to IXE Q2W n=12
- Escalated to IXE Q4W n=3

KEY RESULTS

Figure 1. Ixekizumab PASI 75 Response Rates Through 5 Years of Treatment, As Observed and mNRI

Figure 2. Ixekizumab PASI 90 Response Rates Through 5 Years of Treatment, As Observed and mNRI

Figure 3. Ixekizumab PASI 100 Response Rates Through 5 Years of Treatment, As Observed and mNRI

Table 1. Treatment-emergent Adverse Events Through Week 264 of Ixekizumab Treatment

Table 2. Adverse Events of Special Interest Through Week 264 of Ixekizumab Treatment

CONCLUSIONS

- This study demonstrated that high-efﬁcacy response with ixekizumab was durable on a long-term horizon, with sustained response through 5 years of continuous treatment
- The safety proﬁle remained consistent with prior ﬁndings, with no new or unexpected safety concerns

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ABBREVIATIONS

- AE=adverse event; ETN=etanercept; IR=incidence rate; ITT=intent-to-treat; IXE=ixekizumab; IXE Q2W=80 mg ixekizumab every 2 weeks; IXE Q4W=80 mg ixekizumab every 4 weeks; MedDRA= Medical Dictionary for Regulatory Activities; PY=patient-years; sPGA (0,1) or (0)=static Physician’s Global Assessment response of clear/minimal or clear plaque psoriasis; TEAEs=treatment-emergent adverse events

REFERENCE


This study was sponsored by Eli Lilly and Company. Medical writing services were provided by Nancy Tan, PharmD, of Eli Lilly and Company.