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Efficacy and Safety of Ixekizumab in a Randomized, Double-Blinded, Placebo-Controlled, Phase 3b Clinical Trial in Patients With Moderate-to-Severe Genital Psoriasis

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SYNOPSIS
• Genital psoriasis is common (up to 60%) in patients with plaque psoriasis.
• Can have a significant impact on quality of life and sexual health.7
• Limited data exist from clinical trials on the efficacy of treatments for genital psoriasis.
• Ixekizumab is a high-affinity monoclonal antibody that selectively targets interleukin-17A and is approved for the treatment of plaque psoriasis.

OBJECTIVE
• To evaluate the effect of ixekizumab on the severity of genital psoriasis compared with placebo during weeks 12 of treatment.

STUDY DESIGN
IXORA-Q

Primary Endpoint
• Proportion of patients achieving sPGA of genitalia (0.1) (%)
  sPGA of Genitalia
  Measurement of the patient’s psoriasis severity in the genital region at a given time point on a 0-6 point scale:
  0 = clear
  1 = minimal
  2 = mild
  3 = moderate
  4 = severe
  5 = very severe

Major Secondary Endpoints
• Proportion of patients achieving overall static physician global assessment (sPGA) of genitalia (0.1)
• Proportion of patients achieving a ≥3-point improvement in genital itch numeric rating scale (gen-itch NRS)

RESULTS

Baseline Demographics and Disease Characteristics

Percentage of patients achieving sPGA of genitalia at Week 12

Safety Overview
Blinded Treatment Period, Safety Population

Overall NTEAs
33 (46.4) 42 (56.0)
Worst
15 (20.3) 23 (30.7)
Moderate
15 (20.3) 18 (24.6)
Severe
3 (4.1) 1 (1.3)

CONCLUSIONS
• Ixekizumab was superior to placebo for the primary and all major secondary endpoints at Week 12, and significant improvements versus placebo were observed as early as Week 1.
• Safety outcomes were consistent with the overall safety profile of ixekizumab.

Disclosures
• D Amato is a full-time employee of Eli Lilly and Company and has stocks.
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References