Figure 1. ACR20, ACR50, and ACR70 Response Rates (IXEQ4W treatment) at Each Post-Baseline Visit by Concomitant cDMARD Use. Abbreviations: ACR, American College of Rheumatology; AE, adverse event; cDMARD, conventional synthetic disease-modifying antirheumatic drugs; IXEQ4W, ixekizumab 80 mg every 4 weeks; mNRI, modified non-responder imputation.

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SAT0411

EFFICACY AND SAFETY OF IXEKIZUMAB IN PATIENTS WITH PSORIATIC ARTHRITIS AND INADEQUATE RESPONSE TO TNF INHIBITORS: THREE YEAR RESULTS FROM A PHASE 3 STUDY (SPIRIT-P2)

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Background: Ixekizumab (IXE) is a high affinity monoclonal antibody that selectively targets interleukin-17A. In the SPIRIT-P2 study, IXE every 4 (Q4W) or 2 (Q2W) weeks was superior to placebo (PBO) in improving the signs and symptoms of psoriatic arthritis (PsA) at Week 24 in patients (pts) with prior inadequate response or intolerance to 1 or 2 tumor necrosis factor inhibitors (TNFi).

Objectives: To determine efficacy and safety of IXE treatment up to 3 years in pts with PsA.

Methods: In SPIRIT-P2 (NCT02349295), 310 pts entered the extension period where pts maintained their original ixekizumab dose, and placebo pts received IXEQ4W or IXEQ2W (1:1). Pts failing to demonstrate $\geq 20\%$ improvement in both tender and swollen joint counts at Week 32, or any subsequent visit, were discontinued (mandatory discontinuation criteria). Efficacy outcomes were ACR20/50/70 response, Psoriasis Area and Severity Index (PASI) 75/90/100 response, Leeds Enthesitis Index (LEI), Leeds Dactylitis Index-Basic (LDI-B), Minimal Disease Activity (MDA), and Disease Activity in Psoriatic Arthritis (DAPSA). Ad-hoc efficacy data are presented for intent-to-treat (ITT) pts initially randomized to IXE at Week 0. Observed and modified non-responder imputation (mNRI; missing data treated as non-response for pts discontinued due to lack of efficacy or adverse events [AEs]) was applied to categorical measures. Observed and modified baseline observation carried forward (mBOCF) was applied to continuous efficacy measures. Safety was analysed in pts exposed to at least one dose of IXE.

Results: Of the 245 pts initially randomized to IXE at Week 0 (ITT), 64 (26.1%) pts discontinued due to lack of efficacy and 22 (9.0%) pts due to mandatory discontinuation criteria. Efficacy results are summarized below (Figure 1). Pts in SPIRIT-P2 who received IXEQ4W and IXEQ2W for 156 weeks reported sustained improvement in ACR responses and manifestations of PsA, including enthesitis, dactylitis, and skin outcomes. Treat-to-target measures such as MDA and DAPSA (Low Disease Activity or Remission) were achieved by 30.8% and 47.7% of pts, respectively on IXEQ4W, and by 29.2% and 40.7% of pts, respectively on IXEQ2W. Incidence rates (IR) of treatment-emergent adverse events (TEAEs) are provided below (Figure 2). Most TEAEs were mild or moderate in severity, and 38 out of 337 (5.9%) pts (safety population) discontinued due to AEs. The most common TEAEs were infections (IR=33.1) and injection site reactions (IR=5.4). Three deaths were reported in the study.

Figure 1. Efficacy Outcome Measures at Week 156 (Intent-to-treat Population). ACR=American College of Rheumatology; IXE=ixekizumab; LEI=Leeds Enthesitis Index; LDI-B=Leeds Dactylitis Index-Basic; mNRI=modified non-responder imputation; PASI=Psoriasis Area and Severity Index; Q2W=every two weeks; Q4W=every four weeks.

Figure 2. Safety Outcome Measures (Weeks 0-156). Safety was analysed in patients exposed to at least one dose of ixekizumab. During the double-blind treatment period (Weeks 0-24), one patient reported serious adverse events of anal fistula and anal abscess, which were considered by the sponsor to be IBD; however, an independent adjudication committee of external experts reviewed the case and determined the events to be "Not IBD."

Conclusion: In pts treated with IXE who had prior inadequate response or intolerance to 1 or 2 TNFi, improvements in the signs and symptoms of PsA persisted up to 3 years. No unexpected safety signals were observed, and the safety profile was consistent with previous studies of IXE.

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SAT0412

ACCURACY OF AN INSTRUMENT FOR SCREENING PSORIATIC ARTHRITIS AMONG PSORIATIC PATIENTS: RESULTS FROM THE MULTICENTRE ITALIAN STUDY HERACLES (SCREENING STRATEGIES FOR RHEUMATOLOGICAL REFERRAL OF PSORIATIC SUBJECTS AIMED TO DISCLOSE PSORIATIC ARTHRITIS)

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