of targeted response. PsAID-12 appears to be an effective composite index for retaining the response of the treatment in biological registry.
Disclosure of Interest: None declared
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AB0954 A RANDOMISED, DOUBLE-BLIND TRIAL COMPARING THE EFFICACY, SAFETY AND IMMUNOGENICITY OF MSB11022, A PROPOSED BIOSIMILAR OF ADALIMUMAB, VERSUS ADALIMUMAB ORIGINATOR IN PATIENTS WITH MODERATE-TO-SEVERE PLAQUE PSORIASIS

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Background: Adalimumab is a fully human anti-TNF mAb, indicated for the treatment of multiple inflammatory disorders. MSB11022 is a proposed adalimumab biosimilar that has shown analytical similarity [1] and bioequivalence to US-licensed and EU-approved adalimumab originator, as well as comparable safety, tolerability and immunogenicity in a phase I trial [2].
Objectives: The aims of this multicentre, double-blind, parallel-group, 52-week phase III study (AURIEL-PsO, NCT02660580) were to demonstrate equivalence in efficacy (Psoriasis Area and Severity Index [PASI] 75) and to compare the safety and immunogenicity of MSB11022 vs. adalimumab originator in patients with moderate-to-severe chronic plaque psoriasis. This study was designed in-line with the biosimilar regulatory framework as part of the totality of evidence to confirm similarity and rationale for extrapolation.
Methods: A total of 443 eligible patients (391 evaluable, including 43 with psoriatic arthritis) from 69 sites in 12 countries were randomised 1:1 and treated with MSB11022 (n=202) or adalimumab originator (n=189) (80 mg subcutaneously [SC] on day 1; 40 mg SC every other week from weeks 2−14). The primary endpoint was PASI 75 at week 16; equivalence was established if the 95% confidence interval (CI) for the treatment difference was within ±18%. Secondary endpoints included % change from baseline in PASI (equivalence confirmed if 95% CI within ±15%), Physician Global Assessment (PGA), quality of life (QoL), immunogenicity and safety. Interim results at week 16 are presented.
Results: Patient baseline characteristics were comparable between MSB11022 and adalimumab originator groups: mean age 44.8 vs. 42.4 years, male 66.8% vs. 68.3%, mean PASI score 20.7 vs. 21.2, respectively. PASI 75 scores were 89.6% for MSB11022 and 91.5% for adalimumab originator (difference −1.9% [95% CI −7.82–4.16]). Mean % change from baseline in PASI was −90.6% for MSB11022 and −91.7% for adalimumab originator (difference −1.0% [95% CI −1.23–2.98]). PGA and QoL scores were comparable between treatment groups. The incidence of treatment-emergent adverse events (TEAEs)/serious TEAEs was 51.1/3.6% for MSB11022 and 53.2/2.7% for adalimumab originator. Immunogenicity profiles of MSB11022 and adalimumab originator were also similar and consistent.
Conclusions: Week 16 results of this phase III confirmatory study demonstrated equivalent efficacy and similar safety and immunogenicity profiles for MSB11022 vs. adalimumab originator at 16 weeks in patients with moderate-to-severe chronic psoriasis.

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AB0955 TILDRAKIZUMAB EFFICACY OVER TIME BY WEEK 28 RESPONSE LEVELS IN TWO PHASE 3 CLINICAL TRIALS IN PATIENTS WITH CHRONIC PLAQUE PSORIASIS

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Background: Tildrakizumab (TIL), a high affinity, humanised, IgG1/κ monoclonal antibody for IL-23p19, recently demonstrated efficacy in patients with chronic plaque psoriasis in two, phase 3 clinical trials.
Objectives: To examine efficacy from baseline to week 52 among TIL patients achieving various Psoriasis Area and Severity Index (PASI) responses at week 28.
Methods: ReSURFACE 1 (NCT01722331) and reSURFACE 2 (NCT01729754) were double-blind, randomised controlled trials in subjects with moderate-to-severe chronic plaque psoriasis[1]. Part 1 (0–12 weeks) was placebo controlled; Part 2 (12–28 weeks) re-randomised placebo patients to TIL; Part 3 (28–64 weeks, reSURFACE 1; 28–52 weeks, reSURFACE 2) patients with ≥PASI 50 were re-randomised to continue or increase TIL dose or to placebo based on response at week 28. In this post-hoc pooled analysis, patients on TIL 100 mg and 200 mg from baseline to week 52 were classified in 5 mutually exclusive groups based on their week-28 PASI response: PASI <50, PASI 50–74, PASI 75–89, PASI 90–99, and PASI 100. Baseline characteristics and% PASI improvement from baseline up to week 52 (observed data) were examined for each group.
Results: This analysis included 575 (TIL 100 mg) and 581 (TIL 200 mg) patients; the overall pooled Week 28 PASI 75/90/100 responses were 77%/54%/23% (TIL 100 mg) and 78%/58%/29% (TIL 200 mg). At week 28, 133 (23.1%), 175 (30.4%), 137 (23.8%), 82 (14.3%), and 48 (8.3%) TIL 100 mg patients and 170 (29.3%), 169 (29.1%), 114 (19.6%), 105 (18.1%), and 23 (4.0%) TIL 200 mg achieved PASI 100, PASI 90–99, PASI 75–89, PASI 50–74, and PASI <50, respectively. On average, PASI 100 patients were younger, lighter, and had shorter disease duration at baseline compared to other response groups. For TIL 100 mg,% PASI improvement was highest for PASI 100 and least for PASI <50 patients for all visits up to week 28 (week 4: 53%, 46%, 38%, 30%, and 16%; week 28: 100%, 95%, 83%, 64%, and 33% for PASI 100, PASI 90–99, PASI 75–89, PASI 50–74, and PASI <50 categories, respectively). Among patients achieving PASI >50 at week 28 and continued up to 52 weeks,% PASI improvement remained consistent or improved from week 28 to week 52. Similar results were observed for TIL 200 mg as well as subgroup analysis with bio-naive and bio-experienced patients, respectively.
Conclusions: The majority of TIL 100 and 200 mg patients achieved PASI>50 response at week 28, and PASI improvement was maintained from week 28 to week 52. Among patients achieving ≥PASI 90 at week 28, TIL 100 and 200 mg were associated with rapid improvement by week 4.
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