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Biosimilar BAT1406 versus Adalimumab Therapy on Active Ankylosing Spondylitis: A Randomized, Double-Blinded, Multicenter, Controlled Phase 3 Trial

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Background: Adalimumab has been proved to be effective and safety in management of ankylosing spondylitis (AS) in several clinical trials. In China, small proportion of AS patients had ever used TNF inhibitors and most of them discontinued because of expensive cost. BAT1406 and ADA have demonstrated comparable in protein structure, physicochemical properties, biological activity and immunological characteristics.

Objectives: To compare the effects, safety and immunogenicity of biosimilar BAT1406 vs. adalimumab (ADA) in patients with active AS.

Methods: A multicenter, randomized, non-inferiority, double-blinded, ADA controlled clinical trial with 24 weeks of follow-up was conducted in China. Participants with active AS were randomized as BASDAI >4 and average back pain score (VAS 0-10) ≥4 were eligible for participation. Participants were randomly assigned to receive BAT1406 (40mg q2w) or adalimumab (40mg q2w) at a ratio of 2:1 for 24 weeks. Primary outcome was the proportion of patients achieving ASAS20 response at 12 weeks. Inclusion of the 95% CI of the ASAS20 response difference within a ± 15% margin was required for equivalence. Secondary outcomes included ASAS40, ASAS50, BASDAI50 response, patient reported outcomes, safety and immunogenicity. This trial is approved by China Food and Drug Administration (number 2015L05751).

Results: 554 eligible patients were enrolled from Jan 2017 to Aug 2017 and randomly assigned to receive BAT1406 (n=363) or Adalimumab (n=191) participants, 514 completed the study. Patients (86.5% of whom were male and whose mean age was 31.6 years) had a mean disease duration was 5.82 years. Over 12 weeks, 75.69% of patients in BAT1406 group and 73.68% in ADA group (between group difference 1.6%, 95% CI [-6.82% to 10.03%]) achieved ASAS20 response (per-protocol set; adjusted treatment difference 2.16%, 95% CI [-6.9% to 11.22%]). Outcomes for secondary end points were consistent with the primary efficacy finding. The frequency of adverse events (AEs) was comparable between groups (BAT1406 316[87.1%] vs ADA 162 [85.3%]), as well as serious AEs, adverse drug reactions and discontinuations due to AEs. Similar positive rate was found in two groups for anti-drug antibodies up to week 24.

Conclusion: The study met the primary endpoint of demonstrating equivalent efficacy of BAT1406 and ADA. BAT1406 was comparable in tolerance, safety and immunogenicity with ADA in active AS patients.

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