endpoints at Wk 16 for SEC vs. PBO (overall and Chinese populations; Table). Serious AE rates were reported in 3.3% and 2.0% of SEC and PBO pts, respectively. Uveitis was reported in 1.0% (SEC) and 0.7% (PBO) of pts. No MACE, IBD or deaths were reported.

Conclusion: SEC demonstrated rapid and significant improvement in the signs and symptoms of AS in both the overall and Chinese populations. Secukinumab was well tolerated with no new safety signals identified.

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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 defined 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 findings. The frequency of adverse events (AEs) was comparable between groups (BAT1406 31(67.1%) vs ADA 16 (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 tolerability, safety and immunogenicity with ADA in active AS patients.

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