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.

REFERENCES:

- [1] Baeten D, et al. *N Engl J Med*. 2015;373:2534-48.
- [2] Pavelka K, et al. *Arthritis Res Ther*. 2017;19:285.
- [3] Kivitz AJ, et al. *Rheumatol Ther*. 2018;5:447-62.

Table. Wk 16 data

	Overall		Chinese	
	SEC 150 mg (N=305)	PBO (N=153)	SEC 150 mg (N=218)	PBO (N=109)
ASAS20 ¹	58.4*	36.6	56.0 [§]	38.5
ASAS40 ¹	43.9*	17.0	41.7*	16.5
hsCRP ^{2,3}	0.39*	1.05	0.33*	0.97
ASAS5/6 ¹	47.2*	17.6	45.9*	17.4
BASDAI ²	-2.79*	-1.50	-2.63*	-1.37
SF-36 PCS ²	7.43*	4.60	7.18*	4.07
ASQoL ²	-4.83*	-2.93	-4.50*	-2.50
ASAS PR ¹	16.7 [§]	6.5	15.1 [‡]	6.4

* $P < 0.0001$; [†] $P < 0.001$; [§] $P < 0.01$; [‡] $P < 0.05$ vs. PBO (P -values are adjusted for overall and un-adjusted for Chinese populations). NRI for binary and MMRM for continuous variables.

¹% responders; ²LS mean change from BL; ³ratio of post-BL/BL; LS, least squares; N, total number of randomised pts

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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 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 $\pm 15\%$ margin was required for equivalence. Secondary outcomes included ASAS40, ASAS5/6, 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 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.

REFERENCES:

- [1] Park W, Yoo DH, Miranda P, et al. Efficacy and safety of switching from reference infliximab to CT-P13 compared with maintenance of CT-P13 in ankylosing spondylitis: 102-week data from the PLANETAS extension study. *Annals of the rheumatic diseases*. 2017;76(2):346-354.
- [2] Park W, Yoo DH, Jaworski J, et al. Comparable long-term efficacy, as assessed by patient-reported outcomes, safety and pharmacokinetics, of CT-P13 and reference infliximab in patients with ankylosing spondylitis: 54-week results from the randomized, parallel-group PLANETAS study. *Arthritis research & therapy*. 2016;18:25.
- [3] Chingcuanco F, Segal JB, Kim SC, Alexander GC. Bioequivalence of Biosimilar Tumor Necrosis Factor- α Inhibitors Compared With Their Reference Biologics: A Systematic Review. *Ann Intern Med*. 2016;165(8):565-574.
- [4] Kneepkens EL, Wei JC, Nurmohamed MT, et al. Immunogenicity, adalimumab levels and clinical response in ankylosing spondylitis patients during 24 weeks of follow-up. *Annals of the rheumatic diseases*. 2015;74(2):396-401.
- [5] Kanters TA, Stevanovic J, Huys I, Vulto AG, Simoons S. Adoption of Biosimilar Infliximab for Rheumatoid Arthritis, Ankylosing Spondylitis, and Inflammatory Bowel Diseases in the EU5: A Budget Impact Analysis Using a Delphi Panel. *Front Pharmacol*. 2017;8:322.

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