Disclosure of Interests: Alexander Smirnov: None declared, Inna Gaydukov Grant/research support from: JSC BIOCAD, Speakers bureau: payment from Pfizer, Novartis, Abbvie, Biocad, Selgene, MSD, Sanofi does not exceed 10 000 euros, V Mazurov Grant/research support from: JSC BIOCAD, Shandor Erdes Grant/research support from: JSC BIOCAD, Speakers bureau: JSC BIOCAD, Tatiana Dubinina: None declared, Olga Nesmeyanova Grant/research support from: JSC BIOCAD, Elena Ilivanova Grant/research support from: JSC BIOCAD, Alena Kundzer: None declared, Nikolaj Soroka: None declared, Anna Eremeeva Grant/research support from: JSC BIOCAD, Ekaterina Chernyaeva Employee of: JSC BIOCAD, Roman Ivanov Employee of: JSC BIOCAD.

Background: HS016, a proposed biosimilar to adalimumab, has an identical amino acid sequence, similar physicochemical and in vitro functional equivalence between HS016 and adalimumab. No significant difference to receive adalimumab. The ASAS 20 response rates at week 24 were 79.91% of 229 patients in adalimumab group developed ADAs, and 17.48% of 412 in HS016 and 18.78% of 229 in adalimumab group developed NAbs.

Conclusion: The results of efficacy, PK, safety, immunogenicity from the study conducted in Chinese AS patients support a high similarity between HS016 and the adalimumab.

A total of 458 pts were randomised; 327 (71.4%) from China (97.7% (298/305) and 97.4% (149/153) pts in the SEC and PBO groups, respectively, completed 16 wks. BL characteristics were comparable between groups. Approximately 24% of pts were anti-TNF-inadequate responders/intolerant. The primary endpoint was met; SEC (58.4%) significantly improved ASAS20 response at Wk 16 vs. PBO (36.6%; P < 0.01) in the 2 groups at different time points. Through week 24, 79.13% of 412 patients in HS016 and 79.91% of 229 patients in adalimumab group developed ADAs, and 17.48% of 412 in HS016 and 18.78% of 229 in adalimumab group developed NAbs.

The frequencies of ADA and NAB positive were similar between the two groups at different time points. Through week 24, 79.13% of 412 patients in HS016 and 79.91% of 229 patients in adalimumab group developed ADAs, and 17.48% of 412 in HS016 and 18.78% of 229 in adalimumab group developed NAbs.

Disclosure of Interests: None declared

Efficacy, Pharmacokinetics, Safety and Immunogenicity of the Biosimilar HS016 in Comparison with Adalimumab in Chinese Patients with Ankylosing Spondylitis: A Multicenter, Randomized, Double-Blind, Parallel-Group, Phase 3 Trial

Jinmei Su, LI Mengtao, Xiaofeng Zeng. Peking Union Medical College Hospital, Beijing, China

Background: HS016, a proposed biosimilar to adalimumab, has an identical amino acid sequence, similar physicochemical and in vitro functional properties to adalimumab originator.

Objectives: To assess the efficacy, pharmacokinetic (PK) equivalence, safety and immunogenicity of HS016 compared with adalimumab in Chinese patients with ankylosing spondylitis (AS).

Methods: In a multicenter, randomized, double-blind, parallel-controlled phase 3 study, patients with AS fulfilled with the Modified New York Criteria in 1984 in China were randomized 2:1 to receive HS016 or adalimumab with a dose of 40 mg every other week for 24 weeks. Blood samples for PK analyses were collected in about half of AS patients pre-dose every other week and during week 12 and week 14. Samples for anti-drug antibodies (ADA) and neutralizing antibodies (NAB) were analyzed in all patients. The primary endpoint was the proportion of patients achieving 20% improvement in Assessment in SpondyloArthritis International Society (ASAS 20) at week 24. Equivalent efficacy was concluded if 90% confidence interval (CI) of the difference in ASAS 20 response rate was between -15% and 15%. The secondary endpoints included the ASAS 20 response rate at week 12, ASAS 40, 50% improvement in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI 50), ASAS 6/6 response rate at week 12 and week 24, PK, safety and immunogenicity.

Results: 416 patients were randomly assigned to receive HS016 and 232 to receive adalimumab. The ASAS 20 response rates at week 24 were 87.50% and 90.09% in HS016 and adalimumab groups, respectively, and the difference was -2.59% (90%CI, -6.77% to 1.60%), demonstrating clinical equivalence between HS016 and adalimumab. No significant difference of the proportion of ASAS 40, BASDAI 50 and ASAS 5/6 between the two groups were detected at week 12 or week 24 (Table 1).

Conclusion: HS016 is non-inferior to adalimumab in the treatment of Chinese patients with active AS.

Disclosure of Interests: Alexander Smirnov: None declared, Inna Gaydukov Grant/research support from: JSC BIOCAD, Speakers bureau: payment from Pfizer, Novartis, Abbvie, Biocad, Selgene, MSD, Sanofi does not exceed 10 000 euros, V Mazurov Grant/research support from: JSC BIOCAD, Shandor Erdes Grant/research support from: JSC BIOCAD, Speakers bureau: JSC BIOCAD, Tatiana Dubinina: None declared, Olga Nesmeyanova Grant/research support from: JSC BIOCAD, Elena Ilivanova Grant/research support from: JSC BIOCAD, Alena Kundzer: None declared, Nikolaj Soroka: None declared, Anna Eremeeva Grant/research support from: JSC BIOCAD, Ekaterina Chernyaeva Employee of: JSC BIOCAD, Roman Ivanov Employee of: JSC BIOCAD.