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A Multicenter, Randomized, Double-Blind, Parallel-Arm, Phase 3 Study to Compare Efficacy and Safety of BAT2206 with Ustekinumab in Patients with Moderate to Severe Plaque Psoriasis

Xiaoyong Man[1], Katya Zaharieva[2], Grazyna Pulka[3], Agnieszka Zebrowska[4], Yunhua Deng[5], Lally Mekokishvili[6], Xiaolei Yang[7], Yunpeng Qi[7], Cailing Gu[7], Qingfeng Dong[7], Min Zheng*[1]

[1]The Second Affiliated Hospital of Zhejiang University School of Medicine, Hangzhou, China,[2]Diagnostic-Consultative Center XXVIII-Sofia EOOD, Sofia, Bulgaria, [3]Grażyna Pulka Centrum Medyczne All-Med, Krakow, Poland, [4]NZOZ ALL-MED Centrum Medyczne Specjalistyczne Gabinety Lekarskie, Lodz, Poland,[5]Tongji Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan, China, [6]Petre Shotadze Tbilisi Medical Academy, Tbilisi, Georgia, [7]Bio-thera Solutions Ltd., Guangzhou, China

Introduction & Objectives: BAT2206 is being developed as a biosimilar to Ustekinumab, the human IgG1 monoclonal antibody targeting IL-12/23 p40. This is a multicenter, randomized, double-blind, parallel-arm, Phase 3 study with the primary objective of demonstrating equivalent efficacy of BAT2206 and Ustekinumab in subjects with moderate to severe psoriasis. The safety, pharmacokinetics (PK), and immunogenicity of BAT2206 and Ustekinumab were compared as well.

Materials & Methods: This study composed of a 28-week initial treatment period (TP1) and a 24-week secondary treatment period (TP2). Subjects with moderate to severe psoriasis were enrolled in the study and randomly assigned to BAT2206 or Ustekinumab group in a 1:1 ratio at baseline. BAT2206 or Ustekinumab were administered at Week 0, 4, and then every 12 weeks until Week 40, followed by a 12-week efficacy and safety follow up period up to Week 52. Subjects who achieved a ≥PASI-75 response at Week 28 entered into TP2, in which those in the BAT2206 group in TP1 continued treatment with BAT2206, whereas those in Ustekinumab group in TP1 were re-randomized 1:1 to either continue on Ustekinumab or switch to BAT2206 in TP2. The primary endpoint was percent change from baseline (CfB) in PASI score to Week 8 or Week 12, and the equivalence was to be concluded if the 2-sided 90% or 95% confidence interval (CI) fell entirely within the predefined equivalence margins, depending on the regulatory agencies for submission.

Results: A total of 556 European and Chinese subjects were enrolled in the study, with 544 subjects (97.8%) and 515 (92.6%) subjects completed TP1 and TP2, respectively. At week 8, the least square mean (standard error, SE) of CfB in PASI score were -76.507 (2.6526) and -75.543 (2.6847) for Ustekinumab or BAT2206, respectively, with the least square (LS) mean difference 95% CI (-2.751, 4.679) completely falling within the predefined equivalence margin. At week 12, the LS mean (SE) of CfB in PASI score were -86.813 (2.0105) and -85.039 (2.0731) for Ustekinumab or BAT2206, respectively, with the LS mean difference 90% CI (-0.679, 4.227) and 95% CI (-1.149, 4.697) completely falling within the predefined equivalence margins. The primary estimand was comparable for the subgroups between BAT2206 and Stelara with no major effects seen. Overall 344 subjects (62.0%) experienced 924 treatment-emergent adverse events (TEAEs), in which 234 were treatment related. The proportion of subjects who had at least 1 TEAE or treatment-related TEAE was similar across the treatment groups in both TP1 and TP2, with most TEAEs or treatment-related TEAE being mild. Fifteen subjects (2.7%) experienced 19 serious TEAEs and 4 subjects (0.7%) experienced 4 treatment-related serious TEAEs. No TEAE led to death during the study. Immunogenicity was comparable across treatment arms throughout the entire study, and the transition from Ustekinumab to BAT2206 in TP2 did not lead to an increased immunogenicity. No major differences were observed between the overall geometric means of serum concentrations of Ustekinumab and BAT2206 in TP1, nor for the Ustekinumab-Ustekinumab or Ustekinumab-BAT2206 groups compared with BAT2206 alone in TP2.**

Conclusion: The current study showed that BAT2206 and Ustekinumab are similar in terms of efficacy, safety, PK, and immunogenicity. Additionally, the transition from Ustekinumab to BAT2206 in TP2 had no impact on efficacy, safety, PK, or immunogenicity.