EA CONGRESS DV
BERLIN 11-14 OCTOBER 2023
EUROPEAN ACADEMY OF DERMATOLOGY AND VENEREOLOGY

Abstract N°: 1320

A Randomised, Double-blind, Phase III Study Demonstrating Clinical Similarity of SB17 (Proposed Ustekinumab Biosimilar) to Reference Ustekinumab in Patients with Moderate to Severe Plaque Psoriasis

Steven Feldman*[1], Joanna Narbutt[2], Giampiero Girolomoni[3], Jan Brzezicki[4], Nataliya Reznichenko[5], Maria Zegadlo-Mylik[6], Grazyna Pulka[7], Magdalena Dmowska-Stecewicz[8], Elżbieta Kłujszo[9], Dmytro Rekalov[10], Lidia Rajzer[11], Jiyoon Lee[12], Minkyung Lee[12], Young Hee Rho[12]

[1]Wake Forest University School of Medicine, Winston Salem, United States,[2]Dermoklinika Centrum Medyczne s.c. M. Kierstan, J. Narbutt, A. Lesiak, Łódź, Poland, [3]University of Verona, Verona, Italy, [4]Centrum Kliniczno Badawcze J. Brzezicki, B. Gornikiewicz-Brzezicka Lekarze Spolka Partnerska, Elbląg, Poland, [5]Military Hospital (Military Unit A3309) of Military Medical Clinical Center of Eastern Region, Zaporizhzhia, Ukraine, [6]ETG WARSZAWA, Warsaw, Poland, [7]Centrum Medyczne All-med BADANIA KLINICZNE, Kraków , Poland,[8]ETG Siedlce, Siedlce, Poland, [9]Prywatny Gabinet Dermatologiczny Elżbieta Kłujszo, Kielce, Poland, [10]Medical Center of LLC “Suchasna klinika”, Zaporizhzhia, Ukraine, [11]L.Rajzer Specjalistyczny Gabinet Dermatologiczno-Kosmetyczny, Kraków, Poland, [12]Samsung Bioepis, Co. Ltd, Incheon, Korea, Rep. of South

Introduction & Objectives:

SB17 is a human monoclonal antibody and proposed biosimilar to reference ustekinumab (UST). SB17 and UST had equivalent pharmacokinetics (PK) in healthy subjects in a Phase I Study1. This Phase III study was a randomized double-blind study to compare efficacy, safety, PK, and immunogenicity of SB17 with UST in patients with moderate to severe plaque psoriasis. Results up to 28 weeks are presented in this abstract.

Materials & Methods:

In this randomized, double-blind, Phase 3 multicentre study (NCT04967508), moderate to severe plaque psoriasis patients less than 95 kg were randomized 1:1 to receive either 45 mg of SB17 or UST subcutaneously at Week 0, Week 4, and Week 16. At Week 28, patients initially randomized to UST were re-randomized in a 1:1 ratio to switch to SB17 or maintain UST; patients initially randomized to SB17 continued to receive SB17 every 12 weeks up to Week 40. The primary endpoint was the percent change from baseline in Psoriasis Area Severity Index (PASI) at Week 12. The equivalence between SB17 and UST was declared if the 95% confidence interval (CI) of the Least Squares Means (LSMeans) difference of percent change from baseline in PASI at Week 12 is entirely contained within the pre-defined equivalence margin of [−15%, 15%] for the per protocol set (PPS). The 90% CI of the LSMeans difference was also estimated for the full analysis set (FAS) with a margin of [−10%, 10%]. Other secondary efficacy and safety endpoints were also measured.

Results:

Among 503 subjects included, 249 subjects were randomized to SB17 and 254 subjects to UST. The adjusted difference in LSMeans of percent change from baseline in PASI at Week 12 was −0.6 and the 95% CI of the adjusted treatment difference was [−3.780 to 2.579] for the PPS, which was entirely contained within the pre-defined equivalence margin of [−15%, 15%] (Table 1). For the FAS, the adjusted difference in LSMeans was −0.7 and 90% CI was [−3.343, 1.933], which was also within the pre-defined equivalence margin of [−10%, 10%]. The percent change from baseline in PASI up to Week 28 was comparable between the treatment groups (Figure 1). Physician’s Global Assessment and Dermatology Life Quality Index were also comparable up to Week 28. The proportions of patients with any treatment-emergent adverse events (TEAEs) were comparable between

treatment groups up to Week 28 (SB17: 48.2% and UST: 48.8%) and the incidences of serious adverse events and adverse events of special interest were also comparable between the treatment groups (Table 2). The PK profiles were comparable between SB17 and UST. The overall incidence of anti-drug antibodies up to Week 28 was 13.3% with SB17 and 39.4% with UST.

Conclusion:

This study demonstrated biosimilarity of SB17 to UST through equivalent efficacy and comparable safety and PK up to Week 28.

Reference:

\1. HS Jeong et al. AAD 2023, Poster 41531

Table 1. Primary Efficacy analysis of Percent Change from Baseline in PASI at Week 12 (ANCOVA)

Analysis Set	Treatment	n	LSMeans (SE)	Difference (SB17–UST)		
				LSMeans (SE)	95% CI	90% CI
Per protocol set	SB17	243	85.7 (2.53)	−0.6 (1.62)	[−3.780, 2.579]	[−3.267, 2.066]
	UST	249	86.3 (2.41)			
Full analysis set	SB17	249	85.7 (2.43)	−0.7 (1.60)	[−3.849, 2.439]	[−3.343, 1.933]
	UST	254	86.4 (2.32)			

Percent change from baseline in PASI was adjusted for baseline PASI and region. Equivalence was declared if the 95% CI was contained within [-15%, 15%] for the PPS and the 90% CI was contained within [-10%, 10%] for the FAS. For the FAS, missing values were imputed through multiple imputation.

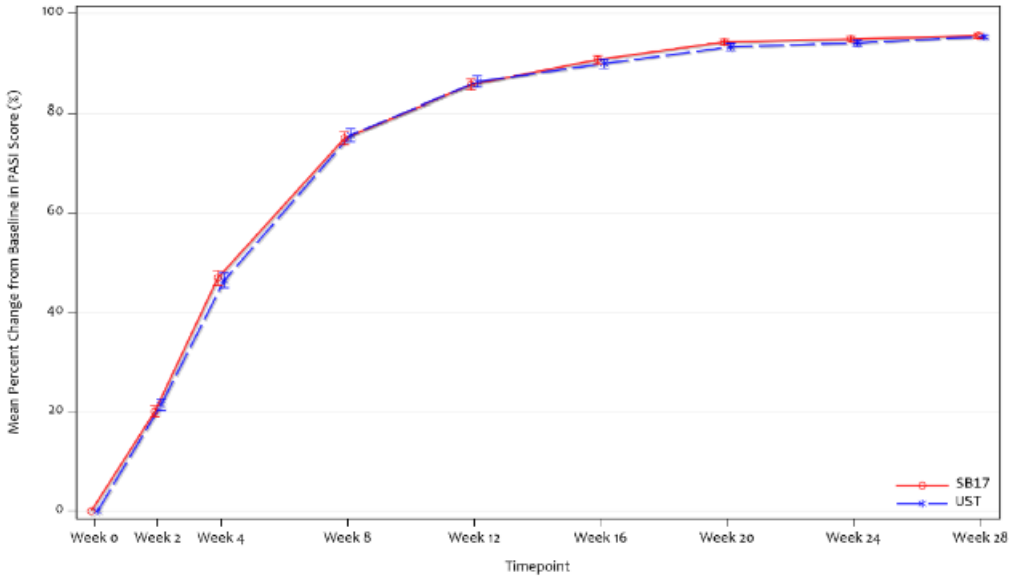

Figure 1. Percent Change from Baseline in PASI up to Week 28 (Full Analysis Set)

Table 2. Summary of Adverse Events Up to Week 28 (Safety Set 1)

Number of Subjects Experiencing	SB17 N=249 n (%)	UST N=254 n (%)	Total N=503 n (%)
TEAE	120 (48.2)	124 (48.8)	244 (48.5)
TEAE severity			
Mild	76 (30.5)	87 (34.3)	163 (32.4)
Moderate	42 (16.9)	36 (14.2)	78 (15.5)
Severe	2 (0.8)	1 (0.4)	3 (0.6)
TEAE causality			
Related	11 (4.4)	12 (4.7)	23 (4.6)
Not related	109 (43.8)	112 (44.1)	221 (43.9)
TEAE of special interest	70 (28.1)	76 (29.9)	146 (29.0)
Systemic hypersensitivity	0 (0.0)	2 (0.8)	2 (0.4)
Infections	70 (28.1)	75 (29.5)	145 (28.8)
Injection site reaction	0 (0.0)	2 (0.8)	2 (0.4)
TEAE leading to discontinuation of IP	0 (0.0)	1 (0.4)	1 (0.2)
Treatment-emergent SAE	6 (2.4)	3 (1.2)	9 (1.8)
TEAE leading to death	0 (0.0)	0 (0.0)	0 (0.0)
COVID-19 related TEAEs	21 (8.4)	24 (9.4)	45 (8.9)

COVID-19: Coronavirus Disease 19; IP: Investigational product

N: Total number of subjects in Safety Set 1

n: Number of subjects with available data within each category

Percentages were based on the number of subjects in the Safety Set 1.