A Randomized Pharmacokinetic Study in Healthy Male Subjects Comparing a High-concentration, Citrate-free SB5 Formulation (40mg/0.4mL) and Prior SB5 (Adalimumab Biosimilar)

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Supplementary Table 1: VAS scores (mm) for pain at the injection site after treatment (Safety Set)

Time points after injection		SB5-HC N = 94	SB5-LC N = 94
Before injection			
	Mean ± SD	0.2 ± 0.75	0.3 ± 0.67
	Median (min- max)	0.0 (0 - 6)	0.0 (0 - 4)
	75th percentile	0.0	0.0
	90th percentile	1.0	1.0
Immediately after injection			
	Mean ± SD	3.1 ± 4.98	9.2 ± 12.98
	Median (min - max)	1.0 (0 - 26)	4.0 (0 - 61)
	75th percentile	3.0	12.0
	90th percentile	9.0	23.0
15 minutes			
	Mean ± SD	0.5 ± 1.34	1.7 ± 3.55
	Median (min - max)	0.0 (0 - 9)	0.0 (0 - 25)
	75th percentile	1.0	2.0
	90th percentile	1.0	5.0
24 hours			
	Mean ± SD	0.1 ± 0.28	0.3 ± 0.76
	Median (min - max)	0.0 (0 - 1)	0.0 (0 - 4)
	75th percentile	0.0	0.0
	90th percentile	0.0	1.0
48 hours			
	Mean ± SD	0.1 ± 0.38	0.2 ± 0.66
	Median (min - max)	0.0 (0 - 2)	0.0 (0 - 4)
	75th percentile	0.0	0.0
	90th percentile	1.0	1.0
96 hours			
	Mean ± SD	0.1 ± 0.26	0.1 ± 0.28
	Median (min - max)	0.0 (0 - 1)	0.0 (0 - 1)
	75th percentile	0.0	0.0
	90th percentile	0.0	0.0

max = maximum; min = minimum; N = number of subjects in the safety set analysis; SB5-HC = 40 mg/0.4 mL SB5 in pre-filled syringe; SB5-LC = 40 mg/0.8 mL SB5 in pre-filled syringe; SD = standard deviation; VAS = visual analogue scales.

Supplementary Table 2: Summary of pharmacokinetic parameters by post-dose ADA status (PK Analysis Set)

Parameter [unit]		ADA positive SB5-HC N = 93	ADA positive SB5-LC N = 94	ADA negative SB5-HC N = 93	ADA negative SB5-LC N = 94
AUC_{inf} [h·µg/mL]					
	n	87	88	6	5
	Mean ± SD	2800.1 ± 1237.37	2990.7 ± 1126.3	4086.0 ± 853.17	4872.5 ± 1479.42
C_{max} [µg/mL]					
	n	87	89	6	5
	Mean ± SD	4.300 ± 1.3903	4.332 ± 1.3434	4.205 ± 1.4513	4.354 ± 1.5174
AUC_{last} [h·µg/mL]					
	n	87	89	6	5
	Mean ± SD	2437.7 ± 836.64	2566.4 ± 808.18	2925.9 ± 689.44	3472.9 ± 960.83
T_{max} [h]					
	n	87	89	6	5
	Median (min-max)	142.733 (23.95-410.17)	142.650 (24.02-336.45)	130.825 (95.18-263.65)	146.283 (118.92-214.80)
V_z/F [mL]					
	n	87	88	6	5
	Mean ± SD	6620.9 ± 2587.60	6827.9 ± 2842.05	10923.4 ± 5243.75	9444.6 ± 3442.82
λ_z [1/h]					
	n	87	88	6	5
	Mean ± SD	0.00312 ± 0.001863	0.00307 ± 0.002664	0.00113 ± 0.000682	0.00096 ± 0.000217
$t_{1/2}$ [h]					
	n	87	88	6	5
	Mean ± SD	331.71 ± 222.946	366.53 ± 229.402	738.01 ± 266.893	749.36 ± 168.422
CL/F [mL/h]					
	n	87	88	6	5
	Mean ± SD	17.498 ± 8.8979	15.917 ± 8.0035	10.269 ± 2.7965	8.818 ± 2.5541
$\%AUC_{extrap}$ [%]					
	n	87	88	6	5
	Mean ± SD	9.435 ± 9.9882	10.657 ± 10.1195	28.266 ± 11.7484	28.171 ± 5.8826

ADA = anti-drug antibody; AUC_{inf} = area under the concentration-time curve (AUC) from time zero to infinity; AUC_{last} = AUC from time zero to the last quantifiable concentration; CL/F = apparent total body clearance; C_{max} = maximum serum concentration; max = maximum; Mean = arithmetic mean; min = minimum; N = number of subjects in the PK analysis set; n = number of subjects who contributed to summary statistics; SB5-HC = 40 mg/0.4 mL SB5 in pre-filled syringe; SB5-LC = 40 mg/0.8 mL SB5 in pre-filled syringe; SD = standard deviation; $t_{1/2}$ = terminal half-life; T_{max} = time to reach C_{max}; V_z/F = apparent volume of distribution during the terminal phase; λ_z = terminal rate constant; $\%AUC_{extrap}$ = percentage of AUC_{inf} due to extrapolation from time of last measurable concentration (T_{last}) to infinity. One subject in the SB5-HC group was excluded from the PK analysis set due to major protocol deviations. For one subject in the SB5-LC group only C_{max}, T_{max}, and AUC_{last} were included in the PK analysis as the regression slope could not be reliably estimated due to observations being below the lower limit of quantification during the elimination phase.