SUPPLEMENTARY APPENDIX

Safety, Immunogenicity, and Efficacy After Switching From Reference Infliximab to Biosimilar SB2 Compared With Continuing Reference Infliximab and SB2 in Patients With Rheumatoid Arthritis: Results of a Randomised, Double-Blind Phase III Transition Study

Josef S. Smolen, Jung-Yoon Choe, Nenad Prodanovic, Jaroslaw Niebrzydowski, Ivan Staykov, Eva Dokoupilova, Asta Baranauskaite, Roman Yatsyshyn, Mevludin Mekic, Wieskawa Porawska, Hana Ciferska, Krystyna Jedrychowicz-Rosiak, Agnieszka Zielinska, Younju Lee, Young Hee Rho

Table of Contents

Table S1. Investigational product dosage increment by treatment group during the transition period

Table S2. American College of Rheumatology (ACR) responses up to week 78

Figure S1. Graphical presentation of the study design

Figure S2. European League Against Rheumatism (EULAR) responses at week 78

Figure S3. American College of Rheumatology 20% (ACR20) responses by dose increment

Table S1. Investigational product dosage increment by treatment group during the transition period

	SB2 (N=201)	INF		
		Overall (N=195)	SB2 (N=94)	INF (N=101)
Week 54				
3.0 mg/kg	126/201 (62.7)	121/195 (62.1)	58/94 (61.7)	63/101 (62.4)
4.5 mg/kg	42/201 (20.9)	48/195 (24.6)	26/94 (27.7)	22/101 (21.8)
6.0 mg/kg	27/201 (13.4)	16/195 (8.2)	7/94 (7.4)	9/101 (8.9)
7.5 mg/kg	6/201 (3.0)	10/195 (5.1)	3/94 (3.2)	7/101 (6.9)
Week 62				
3.0 mg/kg	113/191 (59.2)	117/194 (60.3)	57/94 (60.6)	60/100 (60.0)
4.5 mg/kg	43/191 (22.5)	46/194 (23.7)	22/94 (23.4)	24/100 (24.0)
6.0 mg/kg	27/191 (14.1)	17/194 (8.8)	10/94 (10.6)	7/100 (7.0)
7.5 mg/kg	8/191 (4.2)	14/194 (7.2)	5/94 (5.3)	9/100 (9.0)
Week 70				
3.0 mg/kg	109/186 (58.6)	108/184 (58.7)	53/89 (59.6)	55/95 (57.9)
4.5 mg/kg	37/186 (19.9)	44/184 (23.9)	20/89 (22.5)	24/95 (25.3)
6.0 mg/kg	32/186 (17.2)	16/184 (8.7)	9/89 (10.1)	7/95 (7.4)
7.5 mg/kg	8/186 (4.3)	16/184 (8.7)	7/89 (7.9)	9/95 (9.5)

Values represent n/N (%) of patients where N is the number of patients who received investigational product at the given time point.

INF, reference infliximab.

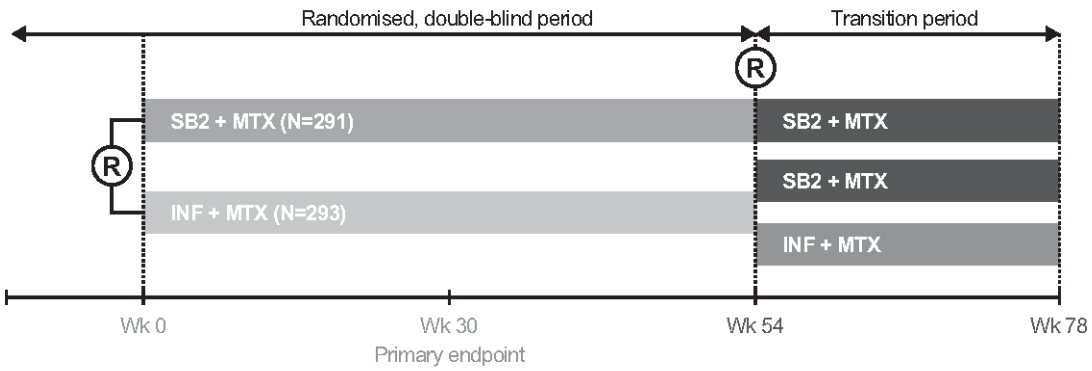
Table S2. American College of Rheumatology (ACR) responses up to week 78

	INF/SB2 (N=94)	INF/INF (N=101)	SB2/SB2 (N=201)
ACR20			
Week 2	29.8%	27.7%	33.3%
Week 6	50.0%	53.5%	52.5%
Week 14	57.4%	70.0%	61.2%
Week 22	67.0%	71.3%	63.2%
Week 30	69.1%	70.3%	66.7%
Week 38	63.8%	64.4%	63.0%
Week 46	69.1%	67.7%	65.2%
Week 54	71.3%	69.3%	65.7%
Week 62	72.3%	66.3%	66.8%
Week 70	69.3%	69.4%	65.6%
Week 78	63.5%	68.8%	68.3%
ACR50			
Week 2	8.5%	5.9%	8.0%
Week 6	22.3%	15.8%	13.5%
Week 14	31.9%	35.0%	30.3%
Week 22	38.3%	33.7%	39.8%
Week 30	39.4%	42.6%	36.8%
Week 38	41.5%	38.6%	37.5%
Week 46	46.8%	34.3%	39.8%
Week 54	41.5%	39.6%	43.3%
Week 62	44.7%	41.6%	40.9%
Week 70	40.9%	43.9%	43.3%
Week 78	37.6%	47.3%	40.6%
ACR70			
Week 2	0.0%	1.0%	4.0%
Week 6	6.4%	5.0%	6.0%
Week 14	9.6%	15.0%	10.4%
Week 22	14.9%	19.8%	15.9%
Week 30	19.1%	21.8%	19.4%
Week 38	20.2%	19.8%	21.5%
Week 46	24.5%	20.2%	21.4%
Week 54	26.6%	22.8%	24.4%
Week 62	23.4%	20.8%	21.2%
Week 70	20.5%	25.5%	25.6%
Week 78	22.4%	31.2%	25.6%

The responses before week 54 are retrospective analyses based on the extended full analysis set (Ex-FAS).

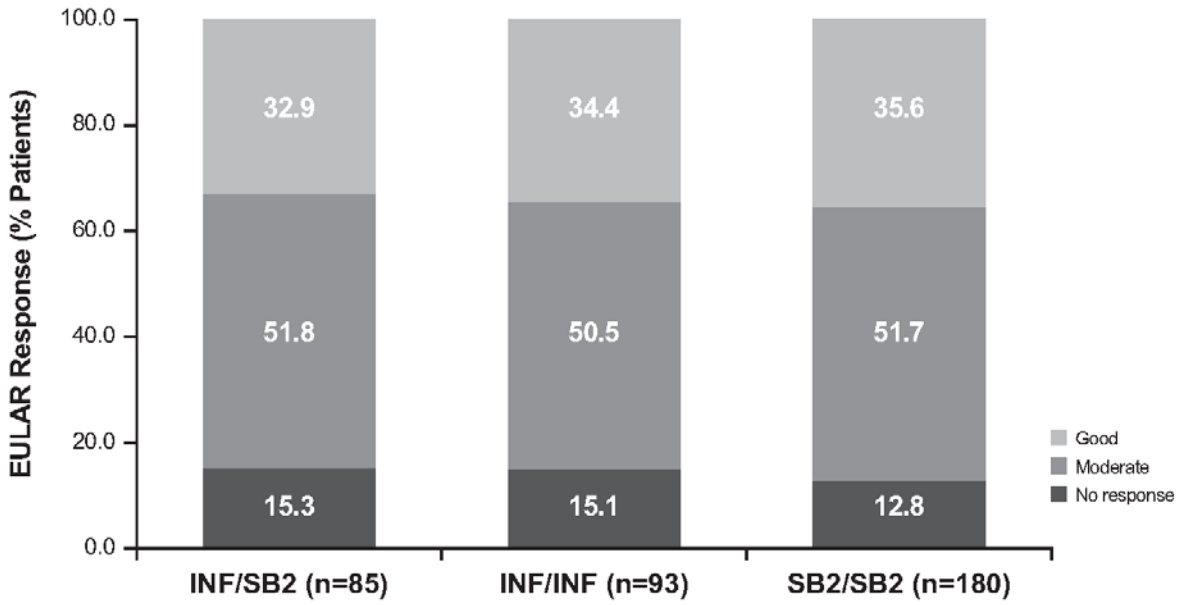
INF, reference infliximab.

Figure S1. Graphical presentation of the study design.



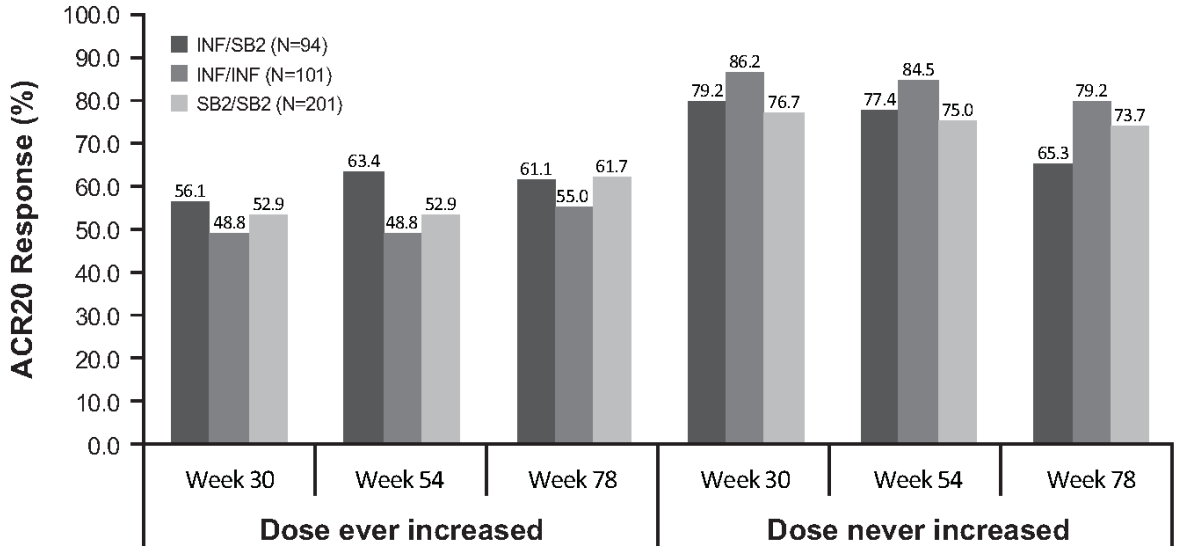
Intravenous infusions were administered at weeks 0, 2, and 6 and then every 8 weeks with 3 mg/kg until week 70. From week 30, the dose level may be increased step-wise by 1.5 mg/kg, up to a maximum of 7.5 mg/kg, every 8 weeks if the patient's RA symptoms were not well controlled by the existing dose. INF, reference infliximab; MTX, methotrexate; R, randomised; RA, rheumatoid arthritis; Wk, week.

Figure S2. European League Against Rheumatism (EULAR) responses at week 78.



INF, reference infliximab.

Figure S3. American College of Rheumatology 20% (ACR20) responses by dose increment.



Patients who had at least one dose increment after week 30 were classified as ever increased.

INF, reference infliximab.