‘BENEFIT’ PAN-EUROPEAN OBSERVATIONAL STUDY TO EVALUATE REAL-WORLD EFFECTIVENESS OF SB4 FOLLOWING TRANSITION FROM ORIGINATOR ETANERCEPT (ETN) IN PATIENTS WITH RHEUMATOID ARTHRITIS (RA) OR AXIAL SPONDYLOARTHRITIS (AXSPA): A SUB ANALYSIS OF ITALIAN SUBJECTS

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A. Ianniello[1], E. Fusaro[2], M.C. Ditto[2], M. Matucci Cerinic[3], C. Bruni[3], E. Bellis[1], O. Viapiana[4], E Gremese[5], A. Migliore[6], M. Govoni[7], D. Russo[8], U. Freudensprung[9], M.F. Rezk[9], J. Addison[10], C.F. Selmi[11,12]

[1]ASL Novara; [2]Azienda Ospedaliero-Universitaria Città della Salute e della Scienza, Torino; [3]A.O.U.C. Azienda Ospedaliero-Universitaria Careggi, Firenze; [4]Azienda Ospedaliera Universitaria Integrata, Verona; [5]Università Cattolica del Sacro Cuore - Policlinico Gemelli, Roma; [6]Ospedale S. Pietro Fatebenefratelli, Roma; [7]Azienda Ospedaliero - Universitaria S. Anna, Ferrara; [8]Biogen Italia, Milano; [9]Biogen International GmbH, Baar, Switzerland; [10]Biogen Idec, Maidenhead, UK; [11]Humanitas Research Hospital, Rozzano; [12]Università degli Studi di Milano

Background. SB4, a biosimilar to the reference ETN, received EU marketing authorisation in January 2016, based on the totality of evidence from pre-clinical and clinical Phase I and III studies that demonstrated similar efficacy, bioequivalence, and comparable safety and immunogenicity to ETN. The BENEFIT study provides real world evidence on transition and outcomes of treatment switch in routine clinical practice.

Materials and Methods. Eligible patients had RA or axSpA and had initiated SB4 as part of routine clinical practice following treatment with a stable dose of originator ETN in a 6-month window. Data were captured from clinic records, retrospectively for 6 months prior and prospectively and/or retrospectively for 6 months after switch (M6). Outcomes include disease score (DAS-28 for RA, BASDAI for axSpA) over time, clinical characteristics, management and Serious Adverse Events (SAEs).

Results. Of the 557 subjects included in the BENEFIT study, 111 subjects were enrolled at 8 Italian study sites: 79 with RA and 32 axSpA. No clinically meaningful change in disease activity was observed between transition and M6. Over 80% of patients remained on the same dosing regimen (50 mg QW) from transition to M6. Only one SAE of uveitis was reported, considered by the physician as unrelated to SB4.

Conclusions. These data provide insight into clinical outcomes in a contemporary cohort of Italian patients with established RA and axSpA, who were switched from originator to the biosimilar SB4 in a study of clinical practice. Results indicate maintenance of disease status at 6 months post-switch, without the need for dose adjustment, in both RA and axSpA patients. No safety concerns were identified. These results provide pertinent information about 6-month outcomes in these populations, helping to inform evidence-based treatment decisions.

Disclosure: Biogen International GmbH funded and sponsored this study.

Conflicts of interest: Janet Addison, Mourad Farouk Rezk, Ulrich Freudensprung and Daria Russo are employees of and hold stocks in Biogen.

Keywords: *Biosimilar, etanercept, SB4, real Word evidence.*

Table I - Baseline characteristics of Italian subjects at transation, and 6-month outcomes.

	RA (N=79)		AxSpA (N=32)	
	Mean (SD)	**Q1, Q3**	**Mean (SD)**	**Q1, Q3**
Age in years	59.8 (11.04)	54.0; 68.0	54.8 (13.16))	47.0; 64.5
Women n (%)	63 (79.7)	–	9 (28.1)	–
Duration of disease, years	14.2 (8.96)	7.6; 19.9	11.1 (6.66)	6.7; 13.5
	Mean (SD)	**95% CI**	**Mean (SD)**	**95% CI**
Disease score (DAS-28, BASDAI) in 6 months prior to transition to SB4 (n = *79 RA, 31 axSpA*)	1.7 (0.67)	1.6, 1.9	1.7 (1.70)	1.1, 2.4
Disease score (DAS-28, BASDAI) at 6 months post-transition to SB4 (n = 60, 23)	1.8 (0.64)	1.6, 1.9	1.5 (1.56)	0.8, 2.1
Individual change in disease score (DAS-28, BASDAI) from baseline to 6 months post-transition to SB4 (n= *60, 23*)	-0.0 (0.85)	-0.2, 0.2	-0.1 (0.91)	-0.5, 0.3
ETN/ SB4 Dose Regimen:				
ETN regimen at transition, n (%):				
50mg QW	70 (88.6)		27 (84.4)	
50mg Other	5 (6.3)		2 (6.3)	
25 mg Other	4 (5.1)		3 (9.4)	
SB4 regimen at transition, n (%):				
50mg QW	71 (89.9)		27 (84.4)	
50mg Other	4 (5.1)		3 (9.4)	
25 mg Other	4 (5.1)		2 (6.3)	
SB4 regimen at M6, n (%):				
50mg QW	67 (89.3)		27 (84.4)	
50mg Other	4 (5.3)		3 (9.4)	
25 mg Other	4 (5.3)		2 (6.3)	

DAS-28, Disease Activity Score 28; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; SD, standard deviation, CI, Confidence interval

*** Based on Kaplan-Meier (KM) approach**