PERFUSE: A French Prospective/Retrospective Non-interventional Cohort Study of Infliximab-naïve and Transitioned Patients Receiving Infliximab Biosimilar SB2; A First Interim Analysis

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Bruno Fautrel[1], Yoram Bouhnik[2], Guillaume Desjeux[3], Ulrich Freudensprung[4], Janet Addison[5], Amira Brigui[6]

[1]Pitié-Salpêtrière Hospital, Department of Rheumatology, AP-HP, Sorbonne University, UPMC university, Paris, France; [2]Beaujon Hospital, Department of Gastroenterology, AP-HP, Paris Diderot University, Clichy, France; [3]E-health Services Sanoïa, Digital CRO, Gémenos, France; [4]Biogen International GmbH, Baar, Switzerland; [5]Biogen UK, Maidenhead, UK; [6]Biogen France SAS, Paris, France.

Background/Purpose

SB2 (Flixabi) is a biosimilar infliximab (IFX). It was approved by the European Medicines Agency based on a demonstration of similarity to reference IFX in terms of physicochemical and biological characteristics, pharmacokinetics and clinical efficacy, safety and immunogenicity. There is limited real-world evidence published on persistence or effectiveness of SB2, either in patients initiated on SB2 as their first IFX (IFX-naïve) or in those transitioning from reference IFX or another IFX biosimilar.

Methods

PERFUSE is an ongoing non-interventional study of 1,372 patients receiving SB2 as routine therapy for immune-mediated inflammatory disease, with the objective of describing clinical characteristics, effectiveness, treatment persistence and safety in patients initiating SB2 in routine clinical practice and followed for 24 months at 21 specialist sites (12 gastroenterology, 9 rheumatology) across France. This poster describes results obtained from an interim analysis of the rheumatology patient cohort, based on a data extract of 24th October 2019. Eligible adult patients have a diagnosis of Rheumatoid Arthritis (RA), Psoriatic Arthritis (PsA) or Ankylosing Spondylitis (AS) and initiated SB2 in routine clinical practice after September 2017, either as their first IFX or transitioning from treatment with reference IFX or another IFX biosimilar. Data are captured prospectively and/or retrospectively from patient records obtained during routine clinic visits, being entered by clinic staff into a study-specific database. There are no protocol-specified assessments. Outcome measures include persistence on SB2, clinical characteristics at baseline (time of initiation of SB2), disease scores (from 3 months prior to baseline through to M12) i.e. Disease Activity Score 28 (DAS28), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) and Serious Adverse Events (SAEs).

Results

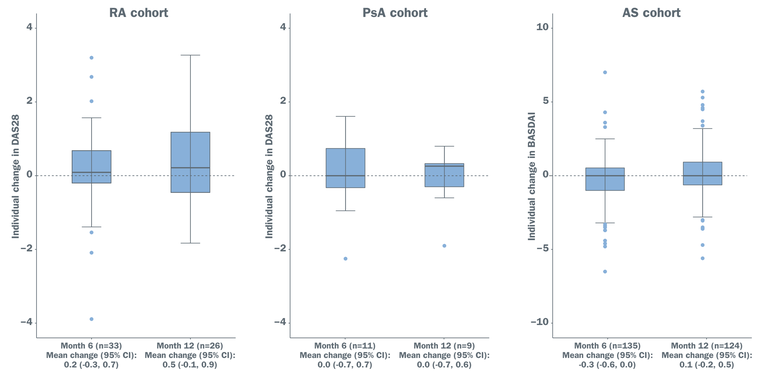
This interim analysis includes 498 patients (98 with RA, 62 with PsA and 338 with AS).

Table 1. Clinical characteristics at baseline

	RA cohort (N=98)	PsA cohort (N=62)	AS cohort (N=338)
Age, years, mean (SD)			
IFX-Naïve	53.0 (16.0)	49.2 (12.4)	43.4 (10.9)
Transitioned from Reference IFX	55.8 (13.6)	50.9 (10.0)	47.5 (12.6)
Transitioned from Biosimilar IFX	58.8 (12.6)	54.7 (15.3)	50.2 (12.6)
Women, n (%)			
IFX-Naïve	16 (72.2)	5 (38.5)	25 (31.3)
Transitioned from Reference IFX	31 (86.1)	10 (41.7)	34 (30.6)
Transitioned from Biosimilar IFX	30 (75.0)	6 (24.0)	48 (32.7)
Duration of disease, years, mean (SD)			
IFX-Naïve	11.2 (9.9)	5.7 (6.1)	7.2 (9.3)
Transitioned from Reference IFX	21.4 (7.6)	11.8 (7.8)	15.4 (10.0)
Transitioned from Biosimilar IFX	13.7 (8.3)	13.4 (14.0)	17.5 (12.6)
Prior IFX treatment, n (%)			
IFX-Naïve	22 (22.0)	13 (21.0)	80 (23.7)
Transitioned from Reference IFX	36 (37.0)	24 (39.0)	111 (32.8)
Transitioned from Biosimilar IFX	40 (41.0)	25 (40.0)	147 (43.5)

AS=ankylosing spondylitis; IFX=infliximab; PsA=psoriatic arthritis; RA=rheumatoid arthritis; SD=standard deviation

Figure 1. Individual change in disease score from baseline to Month 6 and Month 12 in patients transitioned from reference or biosimilar IFX



In IFX-naïve patients, mean (95% CI) disease scores at baseline, M6 and M12, were as follows:

- **For the RA cohort, DAS28 was 4.0 (2.9, 5.1), 3.5 (2.6, 4.2) and 3.1 (2.2, 4.0), respectively.**
- **For the AS cohort, BASDAI was 5.8 (5.2, 6.4), 4.0 (3.0, 5.0) and 3.2 (2.0, 4.3), respectively.**

Insufficient baseline data precluded analysis for IFX-naïve patients in the PsA cohort.

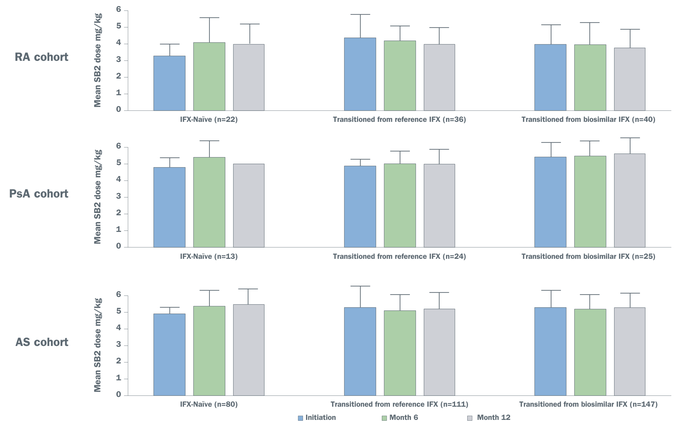
Mean disease scores over time in patients transitioned from from reference or biosimilar IFX are presented in Table 2.

Table 2. Disease scores and change from baseline to Month 6 and to Month 12

	RA DAS28			PsA DAS28			AS BASDAI		
Disease score at	**n**	**Mean**	**95% CI**	**n**	**Mean**	**95% CI**	**n**	**Mean**	**95% CI**
Baseline	47	2.5	(2.2, 2.8)	20	3.1	(1.1, 5.0)	201	3	(2.7, 3.3)
M6	46	2.5	(2.2, 2.8)	14	2.1	(1.4, 2.7)	153	2.7	(2.4, 3.0)
M6-baseline	33	0.2	(-0.3, 0.7)	11	0.0	(-0.7, 0.7)	135	-0.3	(-0.6, -0.0)
M12	36	2.7	(2.3, 3.1)	13	1.9	(1.4, 2.4)	135	2.8	(2.5, 3.2)
M12-baseline	26	0.5	(-0.1, 0.9)	9	-0.0	(-0.7, 0.6)	124	0.1	(-0.2, 0.5)

BASDAI=Bath Ankylosing Spondylitis Disease Acitivity Index; DAS28=disease activity score 28

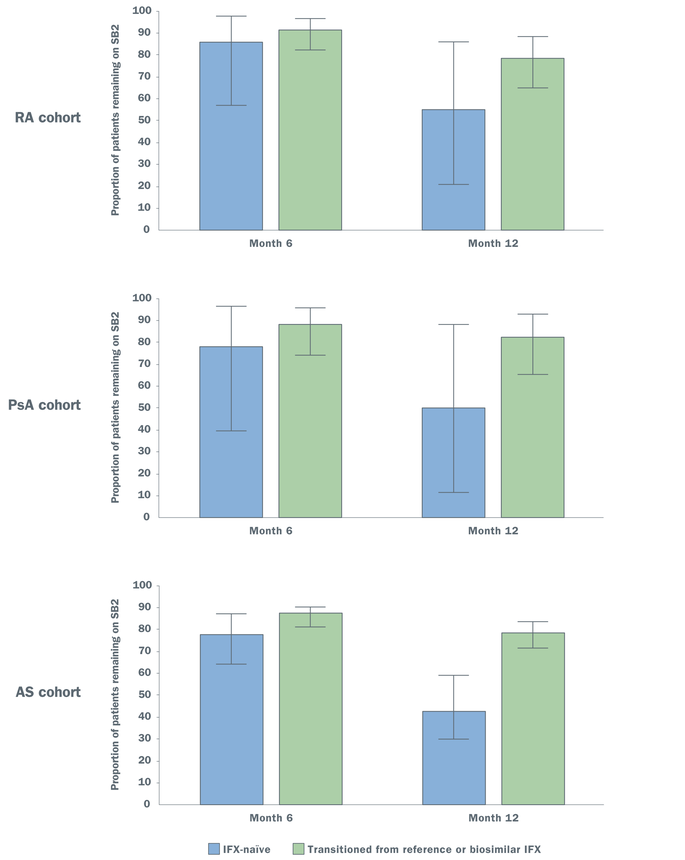
Figure 2. SB2 dose at initiation, Month 6 and Month 12



Overall persistence on SB2 at M12 was 75% (95% CI 62.6, 85.0), 77.5% (95% CI 61.5, 89.2) and 71.4% (95% CI 65.5, 76.8) in RA, PsA and AS respectively.

Persistence in IFX-naïve patients and patients transitioned from reference or biosimilar IFX is presented in Figure 3.

Figure 3. Persistence on SB2 at Month 6 and Month 12 in IFX-naïve patients and patients transitioned from reference or biosimilar IFX



Seven SAEs were reported: prostate carcinoma and ductal carcinoma in situ in two patients in the RA cohort; nephrotomy, alcohol poisoning, epistaxis, cutaneous lesion and malleolar fracture in five patients in the AS cohort. None of these events were considered to be causally related to SB2 administration.

Conclusions

This interim analysis indicates that patients with chronic inflammatory rheumatism can be successfully transitioned from reference IFX or biosimilar IFX to SB2, with no loss of disease control and without safety concerns. Over 75% of patients transitioned from reference IFX or another IFX biosimilar continued SB2 treatment at M12 post-initiation. Subsequent to these preliminary data, the study will provide ongoing, pertinent information about long-term outcomes in these populations, helping to inform evidence-based treatment decisions.

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