POS0614

PERFUSE: A FRENCH PROSPECTIVE/RETROSPECTIVE NONINTERVENTIONAL COHORT STUDY OF INFliximab-NAïVE AND TRANSITIONED PATIENTS RECEIVING INFliximab BIOSIMILAR SB2; 12-MONTH ANALYSIS

B. Fautrel¹, Y. Bouhnik², M. Dougados³, U. Freudensprung⁴, J. Addison⁵.

¹Sorbonne University, Pitié-Salpêtrière Hospital, AP-HP, Paris, France; ²Beaujon Hospital, Paris Diderot University, Department of Gastroenterology, AP-HP, Clichy, France; ³CHU Paris Centre - Hôpital Cochin, Service de Rhumatologie B, Paris, France; ⁴Biogen GmbH, Medical Data Science and Analytics, Biosimilars, Baar, Switzerland; ⁵Biogen IDEC, Clinical Research, Biosimilars, Maidenhead, United Kingdom

Background: SB2 is approved in the EU as an infliximab (IFX) biosimilar, having demonstrated bioequivalence and similar efficacy, safety and immunogenicity as the reference. PERFUSE is an ongoing non-interventional study of 1233 patients (496 with rheumatology diagnoses, 737 with gastroenterology diagnoses) receiving SB2 as routine therapy.

Objectives: The aim of the study is to provide data on long-term outcomes in patients initiating SB2 in the real-world setting.

Methods: Adult patients eligible for inclusion in the rheumatology study cohorts have a diagnosis of Rheumatoid Arthritis (RA), Psoriatic Arthritis (PsA) or Axial Spondyloarthritis (axSpA) and had initiated SB2 in routine clinical practice after September 2017, either as their first IFX or transitioning from treatment with IFX reference or another IFX biosimilar. Outcome measures include SB2 dose, disease activity scores and persistence on SB2, over time and up to 24 months after initiation. This interim analysis is the first complete analysis of 12 month data on all rheumatology patients enrolled into the study at 9 specialist sites and followed up to the data extract date of 29th October 2020. The analysis provides an overview of baseline characteristics, disease scores, SB2 dose and persistence at 12 months post-initiation of SB2.

RESULTS:

Table 1. This 12-month interim analysis includes 496 patients (336 with axSpA, 98 with RA and 62 with PsA)

	axSpA cohort (N=336; IFX naïve 81, IFX-prior 255)		RA cohort (N=98; IFX naïve 22, IFX- prior 76)		PsA cohort (N=62; IFX naïve 14, IFX- prior 48)	
Baseline characteristics						
Age in years, mean (SD):						
IFX-naïve	43.1	(11.1)	53.1	(15.9)	48.5	(12.2)
Transitioned from IFX	48.9	(12.4)	57.3	(13.1)	53.1	(13.0)
Disease duration in years, mean (SD):						
IFX-naïve	7.2	(9.3)	11.3	(9.8)	4.2	(3.9)
Transitioned from IFX	16.6	(11.6)	17.3	(8.8)	12.9	(11.3)
Women, n (%):						
IFX-naïve	26	(32.1)	16	(72.7)	6	(42.9)
Transitioned from IFX	79	(31.0)	60	(78.9)	15	(31.3)
SB2 Dose: n, mean mg/kg (SD)						
IFX-naïve:						
Baseline	81	383.8 (85.5)	22	266.2 (145.9)	14	395.4 (108.9)
Month 12	47	436.8 (153.3)	13	285.5 (90.7)	6	508.0 (147.6)
Transitioned from IFX:						
Baseline	255	396.7 (109.6)	76	291.8 (103.4)	48	408.5 (91.3)
Month 12	195	392.1 (105.5)	60	287.8 (106.6)	41	421.4 (101.6)
Disease score, mean (SD)						
IFX-naïve:						
Baseline	n	BASDAI	n	DAS28	n	DAS28
Baseline	54	5.8 (2.1)	14	4.3 (1.6)	-*	-*
Month 12	30	3.5 (2.7)	9	3.2 (1.2)		
Transitioned from IFX:						
Baseline	206	3.0 (2.0)	62	2.6 (1.2)	20	2.2 (1.2)
Month 12	151	3.0 (2.1)	47	2.7 (1.2)	19	2.1 (0.9)
KM estimate of persistence on SB2 by Month 12; proportion, (95% CI)						
IFX-naïve	56.26	(44.43; 66.51)	59.09	(36.10; 76.21)	64.29	(34.33; 83.31)
Transitioned from IFX	79.86	(74.37; 84.30)	80.26	(69.42; 87.60)	85.04	(71.11; 92.58)

*Blank as disease score data for both baseline and Month 12 were provided by a single patient who was IFX-naïve and had PsA; IFX = infliximab; axSpA = Axial Spondyloarthritis; RA = Rheumatoid Arthritis; PsA = Psoriatic Arthritis; BASDAI = Bath Ankylosing Spondylitis Disease Activity Index; DAS28 = Disease Activity Score 28; CI = confidence interval; SD = standard deviation; KM = Kaplan Meier.

Conclusion: This 12-month analysis indicates that patients with axSpA or RA can be successfully initiated on SB2 as the first infliximab therapy, and patients with axSpA, RA or PsA can be transitioned from originator or biosimilar IFX to SB2 without loss of disease control and with no dose penalty over 12 months post-transition. Over 56% of IFX-naïve patients and over 79% of patients transitioned from prior IFX remained on SB2 at 12 months post-initiation. With follow-up of patients ongoing to 24 months post-initiation of SB2, the study will continue to provide pertinent information about clinical

outcomes of initiation on SB2 as first IFX or after transition from reference or IFX biosimilar to SB2.

Acknowledgements: Data management for the study was provided by Sanoia E-health services, Digital CRO, Gémenos, France; funding was provided by Biogen International GmbH.

Disclosure of Interests: Bruno Fautrel Speakers bureau: AbbVie, Biogen, Boehringer-Ingelheim, BMS, Celgene, Janssen, Lilly, Medac, MSD, NORDIC Pharma, Novartis, Pfizer, Roche, SOBI, UCB., Consultant of: AbbVie, Biogen, Boehringer-Ingelheim, BMS, Celgene, Janssen, Lilly, Medac, MSD, NORDIC Pharma, Novartis, Pfizer, Roche, SOBI, UCB., Grant/research support from: AbbVie, MSD, Pfizer., Yoram Bouhnik Speakers bureau: AbbVie, Biogaran, Biogen, Boehringer Ingelheim, CTMA, Ferring, Gilead, Hospira, ICON, Inception IBD, Janssen, Lilly, Mayoly Spindler, Merck, Merck Sharp & Dohme, Norgine, Pfizer, Roberts Clinical Trials, Roche, Sanofi, Shire, Takeda, UCB, Vifor Pharma., Consultant of: AbbVie, Biogaran, Biogen, Boehringer Ingelheim, CTMA, Ferring, Gilead, Hospira, ICON, Inception IBD, Janssen, Lilly, Mayoly Spindler, Merck, Merck Sharp & Dohme, Norgine, Pfizer, Roberts Clinical Trials, Roche, Sanofi, Shire, Takeda, UCB, Vifor Pharma., Maxime Dougados Grant/research support from: Biogen, Ulrich Freudensprung Shareholder of: Biogen, Employee of: Biogen, Janet Addison Shareholder of: Biogen, Employee of: Biogen

DOI: 10.1136/annrheumdis-2021-eular.1642

POS0615

TOCILIZUMAB IS SAFE AND EFFECTIVE IN ELDERLY PATIENTS WITH RHEUMATOID ARTHRITIS

C. Specker¹, M. Aringer², G. R. Burmester³, M. Peters⁴, M. W. Hofmann⁵, H. Kellner⁶, F. Moosig⁷, H. P. Tony⁸, G. Fliehn⁹. ¹Clinic Essen-Mitte, Clinic of Rheumatology and Clinical Immunology, Essen, Germany; ²Dresden University of Technology, University Medical Centre Carl Gustav Carus, Dresden, Germany; ³Free University and Humboldt University Berlin, Department of Rheumatology and Clinical Immunology Charité - Universitätsmedizin Berlin, Berlin, Germany; ⁴Roche Pharma AG, Grenzach-Wyhlen, Germany; ⁵Chugai Pharma Germany GmbH, Rheumatology, Frankfurt am Main, Germany; ⁶Rheumatology and Gastroenterology Specialty Practice, Rheumatology, Munich, Germany; ⁷Rheumatology Centre Schleswig-Holstein Middle, Rheumatology, Neumünster, Germany; ⁸Medical Clinic II, Department of Rheumatology and Clinical Immunology, University Clinic Würzburg, Würzburg, Germany; ⁹Rheumatology Practice, Osnabrück, Germany

Background: Average life spans of patients with rheumatoid arthritis (RA) are approaching those of the general population. This results in a large proportion of RA patients being elderly at some point and underlines effective RA treatments needed for this population. Pivotal clinical trials have demonstrated the efficacy of tocilizumab (TCZ) for the treatment of RA. However, real-world studies that explore the effectiveness of TCZ especially in the elderly are lacking. ICHIBAN was a large, observational study that followed patients with RA treated with TCZ under real-world conditions in Germany for up to 2 years.

Objectives: In this analysis of ICHIBAN, we examined the safety and effectiveness of long-term TCZ treatment according to patient baseline (BL) age (<50, 50–65, >65 years).

Methods: ICHIBAN (NCT01194401) was a prospective, non-interventional study that observed adult patients with active moderate to severe RA in German rheumatology clinics and practices. Patients were treated with TCZ according to the local label. The safety analyses set (SAF) included all patients who received at least one dose of TCZ. The effectiveness set (EFF) included all patients from the SAF who had no prior TCZ therapy. Patient-reported outcomes (PROs) were assessed using the visual analogue scale. Last observation carried forward was used to substitute for missing values.

Results: At baseline (BL), 3,164 patients were included in the SAF: 29.2% <50 years, 47.3% 50–65 years, and 23.5% >65 years old (1.2% ≥80 years). Patients >65 years old were not only the most likely to have comorbidities such as hypertension, anaemia, renal insufficiency, osteoporosis, diabetes, and coronary heart disease, but also had the highest BL disease activity according to Disease Activity Score-28 erythrocyte sedimentation rate (DAS28-ESR) and Clinical Disease Activity Index (CDAI) (Table 1).

Proportions of patients with adverse events (AEs) considered related to treatment were similar in patients <50 (22.3%), 50–65 (21.9%) and >65 years (22.2%). More patients >65 years (20.2%) and 50–65 years (14.4%) experienced serious AEs (SAEs) than patients <50 years (11.5%). Slightly more patients >65 years old experienced infectious SAEs (4.8%) than younger patients (<50 years, 3.2% and 50–65 years, 3.1%). Yet, similar proportions of patients across all age groups discontinued TCZ due to AE (7.0% <50 years; 9.6% 50–65 years; 7.8% >65 years). 2,902 patients were included in the EFF. Patients <50 years experienced DAS28-ESR remission at least once during the treatment period (65.4%) more often than patients aged 50–65 years (59.8%) or >65 years (59.5%). However, patients >65 years had numerically greater improvements in DAS28-ESR (Table 1). Patients <50 years had the best physical functioning at BL and the greatest reduction in