THU0525 SAFETY OF ADALIMUMAB ± METHOTREXATE FOR THE TREATMENT OF POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): STRIVE REGISTRY

N. Ruperto¹, H. Brunner², K. Nanda², M. Toth², I. Foeldvari¹, J. Bohnsack², D. Milojevic², C. Rabinovich², D. Kingsbury², K. Marzan², P. Quartier¹, K. Minden¹, E. Chalom², G. Horneff¹, R. Kuester¹, J. Dare², M. Bereswill³, J. Kalabic³, H. Kupper³, A. Martini¹, D. Lovell². ¹PRINTO-IRCCS Gaslini, Genova, Italy; ²PRCSG, Cincinnati Children's Hospital Medical Center, Cincinnati, United States; ³AbbVie Deutschland GmbH & Co. KG, Ludwigshafen, Germany

Background: JIA is the most common chronic inflammatory rheumatic disease of childhood. TNF inhibitors are used for long-term control of pJIA disease.

Objectives: To evaluate the 7 year (y) safety of Adalimumab treatment with or without methotrexate (ADA±MTX) when used in current clinical practice for treatment of patients (pts) with active pJIA.

Methods: This is a 7 y interim analysis of an ongoing, multicenter, non-interventional, observational registry of pts with pJIA with up to 10 y safety follow-up. Included pts were treated with ADA±MTX or MTX alone as comparison arm according to routine clinical care in PRINTO/PRCSG centres in EU, USA and Australia. MedDRA observational adverse events (AEs) were recorded from 1st day in the registry through last contact, irrespective of duration of registry treatment.

Results: In January 2014, enrollment was complete. As of June 1, 2016 cut-off date, 838 pts (301- MTX arm and 537 - ADA±MTX arm) were treated in the registry. There were 39 pts who rolled over from MTX to ADA±MTX arm. At registry entry mean pJIA disease duration was 1.3 y and 3.7 y and mean AJC71 was 5.8 and 5.2 for MTX and ADA±MTX arms, respectively. CHAQ disability index was 0.6 for both arms. Mean duration of study drug exposure in registry was 2.0 y (range: 0.0 – 7.1) and 2.5 y (range: 0.0 – 7.9) for MTX and ADA±MTX arms, respectively. Mean duration of observation in registry was 3.9 y (range: 0.0 – 7.2) and 3.5 y (range: 0.0 – 7.9) for MTX and ADA±MTX arms, respectively. Overall, 213 pts (70.8%) in MTX and 225 pts (41.9%) in ADA±MTX arms discontinued registry drug through 7 y. Main reasons (not exclusively) for registry drug discontinuation for MTX arm: pts required additional therapy (32.6%), other (13.3%), lack of efficacy (11.6%), AEs (9.3%), or pts achieved JIA remission (8.6%); for ADA±MTX arm: lack of efficacy (17.9%), other (7.3%), lost to follow-up (5.6%), AEs (5.4%), or pts achieved JIA remission (5.0%). Frequencies and rates of treatment-emergent AEs (from 1st dose date of registry drug in registry up to last dose + 70 days in registry, excluding AEs occurring during treatment interruption) were similar to those reported for observational AEs (from 1st day in registry up to last contact irrespective of drug treatment duration) (Table). Rate of serious infections was similar between MTX and ADA±MTX arms. One pt (0.2%) reported an event of opportunistic infection (fungal oesophagitis) in ADA±MTX arm. No reports of deaths, malignancies, active tuberculosis, oral candidiasis, demyelination, or congestive heart failure.

Table. Overview of the Observational Adverse events

	MTX		ADA±MTX			
			ADA only		ADA + MTX*	
	N=301 n (%)	PYs=1170.3 E (E/100 PYs)	N=160 n (%)	PYs=517.0 E (E/100 PYs)	N=377 n (%)	PYs=1338.5 E (E/100 PYs)
Any AE	157 (52.2)	505 (43.2)	66 (41.3)	216 (41.8)	178 (47.2)	553 (41.3)
AE at least "possibly drug related" per the investigator	87 (28.9)	197 (16.8)	30 (18.8)	66 (12.8)	88 (23.3)	177 (13.2)
Severe AE	17 (5.6)	23 (2.0)	14 (8.8)	22 (4.3)	25 (6.6)	41 (3.1)
Serious AE	32 (10.6)	52 (4.4)	21 (13.1)	39 (7.5)	56 (14.9)	95 (7.1)
AE leading to discontinuation of study drug or study	28 (9.3)	36 (3.1)	13 (8.1)	19 (3.7)	25 (6.6)	40 (3.0)
Infectious AE	87 (28.9)	179 (15.3)	38 (23.8)	75 (14.5)	105 (27.9)	187 (14.0)
Serious infectious AE	14 (4.7)	17 (1.5)	6 (3.8)	8 (1.5)	22 (5.8)	30 (2.2)
Injection site-related AE	6 (2.0)*	8 (0.7)	5 (3.1)	6 (1.2)	24 (6.4)	32 (2.4)

E, events; PYs, patient years (Observation time irrespective of study drug treatment duration). *3 patients experienced injection site-related AEs with etanercept injections. During the registry, 52 (17.3%) pts in MTX arm and 45 (8.4%) pts in ADA arm started with a biologic DMARD. *MTX was used at any point of time during the course of the registry.

Conclusions: Overall, ADA±MTX was well-tolerated in these pts with pJIA with

Abstract THU0526 – Table 1

	Baseline	1st week	2nd week	1st month	3rd month	6th month	1st year	2nd year	3rd year
Visual acuity mea±SD	0.57±0.35	0.55±0.35	0.56±0.35	0.59±0.33	0.6±0.32*	0.63±0.32*	0.63±0.35*	0.59±0.32*	0.45±0.34*
Anterior chamber cells median [IQR]	1 [0–1]	0.75 [0–1]*	0.5 [0–1]*	0 [0–0.5]*	0 [0–0]*	0 [0–0]*	0 [0–0]*	0 [0–0]*	0 [0–0]*
Vitritis median [IQR]	0 [0–0]	0 [0–1]	0 [0–0]	0 [0–0]	0 [0–0]*	0 [0–0]*	0 [0–0]*	0 [0–0]*	0 [0–0]
OCT (microns) mean±SD	358.69±92.17	351.4±108.29	336.5±100.9*	313.4±91.28*	280.7±35.03*	274.9±101.33*	245.4±29.4*	239.6±33.5	ND

*p<0.05 compared with basal.

no new safety signals. The retention rate for registry drug was higher in ADA±MTX arm compared to MTX arm.

Acknowledgements: AbbVie sponsored the study & contributed with PRINTO & PRCSG to analysis, review, approval of the abstract. X. Leahy & A. Deshmukh (AbbVie) contributed to research. Medical writing: G. Patki (AbbVie).

Disclosure of Interest: N. Ruperto Grant/research support from: AbbVie Inc., AstraZeneca, Bristol-Myers Squibb, Janssen Biologics B.V., Eli Lilly and Co., "Francesco Angelini", GlaxoSmithKline, Italfarmaco, Novartis, Pfizer, Roche, Sanofi Aventis, Schwarz Biosciences GmbH, Xoma, and Wyeth Pharmaceuticals, Employee of: GASLINI Hospital, Speakers bureau: Astellas, AstraZeneca, Bristol-Myers Squibb, Italfarmaco, Janssen Biologics B.V., MedImmune, Roche, and Wyeth/Pfizer, H. Brunner Consultant for: AbbVie Inc., AstraZeneca, Centocor, Bristol-Myers Squibb, Boehringer-Ingelheim, Pfizer, Regeneron, Hoffman La-Roche, Novartis, Takeda, UCB, and Genentech, Speakers bureau: Genentech Pharmaceuticals, K. Nanda Consultant for: Medac Pharma, Inc., M. Toth: None declared, I. Foeldvari Consultant for: AbbVie and Novartis, J. Bohnsack Consultant for: Novartis, D. Milojevic Consultant for: Genentech and Novartis, C. Rabinovich Grant/research support from: UCB Pharma, Janssen, D. Kingsbury: None declared, K. Marzan Grant/research support from: AbbVie, P. Quartier Grant/research support from: AbbVie, Novartis, Pfizer, BMS, Chugai-Roche, MedImmune, Servier, and Swedish Orphan Biovitrum, Consultant for: AbbVie, Novartis, Pfizer, BMS, Chugai-Roche, MedImmune, Servier, Swedish Orphan Biovitrum, and Sanofi, K. Minden Grant/research support from: Pfizer, AbbVie and Roche/Chugai, Consultant for: Pfizer, Roche, and Pharma-Allergan, Speakers bureau: Pfizer, Roche, and Pharma-Allergan, E. Chalom Speakers bureau: AbbVie, G. Horneff Grant/research support from: AbbVie, Pfizer, Novartis, and Roche, Speakers bureau: AbbVie, Novartis, Sobi, Pfizer, and Roche, R. Kuester Grant/research support from: AbbVie Inc. and Wyeth/Pfizer, J. Dare Grant/research support from: AbbVie, AstraZeneca, Bristol-Myers Squibb, Horizon Pharma, Medac, Pfizer, Roche, and UCB, M. Bereswill Shareholder of: AbbVie, Employee of: AbbVie, J. Kalabic Shareholder of: AbbVie, Employee of: AbbVie, H. Kupper Shareholder of: AbbVie, Employee of: AbbVie, A. Martini Grant/research support from: AbbVie Inc., AstraZeneca, Bristol-Myers Squibb, Janssen Biologics B.V., Eli Lilly and Co., "Francesco Angelini", GlaxoSmithKline, Italfarmaco, Novartis, Pfizer, Roche, Sanofi Aventis, Schwarz Biosciences GmbH, Xoma, and Wyeth Pharmaceuticals, Employee of: GASLINI Hospital, Speakers bureau: Astellas, AstraZeneca, Bristol-Myers Squibb, Italfarmaco, and MedImmune, D. Lovell Consultant for: AstraZeneca, Centocor, Bristol-Myers Squibb, Pfizer, Regeneron, Hoffman La-Roche, Novartis, UCB, Xoma, Genentech, Amgen and Forest Research, Speakers bureau: Wyeth Pharmaceuticals

DOI: 10.1136/annrheumdis-2017-eular.2010

THU0526 SHORT AND LONG-TERM FOLLOW-UP OF TOCILIZUMAB FOR SEVERE JUVENILE IDIOPATHIC ARTHRITIS-ASSOCIATED UVEITIS

N. Vegas-Revenga¹, V. Calvo-Río¹, M. Santos-Gómez², I. Calvo³, M. González-Fernández³, B. López-Montesinos³, M. Mesquida⁴, A. Adán⁴, M. Hernández⁴, O. Maiz⁵, A. Atanes⁵, B. Bravo⁷, C. Modesto⁶, G. Díaz-Cordovés⁹, N. Palmou-Fontana¹, J. Loricera¹, M. González-Vela¹, R. Demetrio-Pablo¹, L. Domínguez-Casas¹, C. Fernández-Díaz¹, J. Hernández¹, M. González-Gay¹, R. Blanco¹. ¹HUMV, Santander; ²H, Torrelavega; ³H Fe, Valencia; ⁴H Clinic, Barcelona; ⁵H, Donostia; ⁶HUAC, A Coruña; ⁷H Nieves, Granada; ⁸H V d'Hebron, Barcelona; ⁹H, Málaga, Spain

Objectives: To assess the efficacy of tocilizumab (TCZ) at short and long term follow-up for severe juvenile idiopathic arthritis-associated uveitis.

Methods: Multicentre study of 25 patients who had inadequate response to traditional treatment with corticosteroids and at least one conventional immunosuppressive drug including biological therapy. The outcome variables were the degree of inflammation, visual acuity and macular thickness. The results are expressed as mean±SD for normally distributed variables, or median [IQR] when are not. Comparison of continuous variables was performed using the Wilcoxon test.

Results: We studied 25 patients (21 women/4 men); mean age 18.6±8.3. Uveitis was bilateral in 22. JIA subsets were oligoarthritis (n=17), polyarthritis (5), psoriatic (2) and enthesitis-related arthritis (1). Ocular sequelae at TCZ onset were cataracts (13), glaucoma (7), synechiae (10), band keratopathy (12), maculopathy (9), and amblyopia (5). Pattern of uveitis was: anterior (17), panuveitis (4), intermediate (2) and posterior (2). Before TCZ, they had received corticosteroids, conventional immunosuppressive drugs and biologics, including adalimumab (24), etanercept (8), infliximab (7), abatacept (6), rituximab (2), anakinra (1), and golimumab (1). TCZ dosage regimen was 8 mg/kg IV/4 weeks (21), every 2 weeks (2), every 8 weeks (1), or 2.9 mg/kg sc every week (1). All outcome variables showed a rapid and maintained improvement (Table 1) after