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DOI: 10.1136/annrheumdis-2019-eular.7477

THU0516

LONG-TERM SAFETY OF SUBCUTANEOUS TOCILIZUMAB ADMINISTRATION IN SYSTEMIC AND POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS

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Background: Tocilizumab (TCZ) administered intravenously (IV) was effective for the treatment of polyarticular (p)JIA and systemic (s)JIA.^{1,2}

Objectives: To evaluate the long-term safety and efficacy of subcutaneous (SC) TCZ in patients (pts) with pJIA or sJIA enrolled in a long-term extension (LTE) phase of two 52-week, open-label studies.

Methods: Pts aged 1-17 years received body weight (BW)-based TCZ SC: pJIA pts who failed/could not tolerate MTX received TCZ 162 mg every 3 weeks for BW <30 kg or every 2 weeks (Q2W) for BW ≥30 kg; sJIA pts with inadequate response to NSAIDs and glucocorticoids received TCZ 162 mg Q2W for BW <30 kg or weekly for BW ≥30 kg. All pts discontinued biologic DMARDs (approximately 50% switched from TCZ IV to TCZ SC). After 52 weeks, pts continued BW-based TCZ in a separate LTE study; safety data (adverse events [AEs], serious AEs [SAEs]) in the LTE study to clinical cutoffs December 1, 2017 (pJIA), and February 28, 2018 (sJIA), are reported for all pts who received ≥1 dose of TCZ SC and had ≥1 postdose safety assessment.

Results: Most pJIA (n=44) and sJIA (n=38) pts were female (72.7% and 55.3%) and white (88.6% and 84.2%); median (range) age was 9.0 (2-18) years. AE rates (Table) were similar regardless of BW. Most AEs were grade 1 or 2; grade ≥3 AEs were reported by 10/44 (20.8%) pJIA pts and 4/38 (10.5%) sJIA pts, most commonly nasopharyngitis (pJIA, 17/44 [38.6%]; sJIA, 11/38 [28.9%]). Other AEs reported in ≥15% of pts included arthralgia, gastroenteritis, cough, vomiting, diarrhea, pyrexia, headache, and oropharyngeal pain (pJIA) and upper respiratory tract infection, cough, pyrexia, arthralgia, and rash (sJIA). No opportunistic infections developed. Neutropenia AEs were reported by 6/44 (13.6%) pJIA pts and 7/38 (18.4%) sJIA pts. SAEs occurred in 5/44 (11.4%) pJIA pts (furuncle, appendicitis, pneumonia, eye pain/headache, infectious mononucleosis) and 2/38 (5.3%) sJIA pts (pneumonia, craniocerebral injury from a fall); only pneumonia (pJIA) was considered treatment related. Neutralizing anti-TCZ antibodies developed in 2 (4.7%) pJIA pts and no sJIA patients. No deaths were reported in the LTE study.

Conclusion: In this LTE study in children with pJIA or sJIA, SC TCZ continues to have an acceptable tolerability profile with no new safety concerns.

Abstract THU0516 –Table 1.

Table 1: Safety Summary	pJIA		sJIA	
	TCZ SC Q2W (n=44)	TCZ SC Q2W (n=38)	TCZ SC Q2W (n=44)	TCZ SC Q2W (n=38)
Adverse Events				
AEs	24 (54.5%)	24 (63.2%)	17 (38.6%)	17 (44.7%)
SAEs	10 (22.7%)	4 (10.5%)	5 (11.4%)	2 (5.3%)
Deaths	0	0	0	0
Discontinuation due to AEs	1 (2.3%)	1 (2.6%)	1 (2.3%)	1 (2.6%)
Discontinuation due to other reasons	1 (2.3%)	1 (2.6%)	1 (2.3%)	1 (2.6%)
Discontinuation due to unknown reasons	0	0	0	0
Discontinuation due to other reasons	0	0	0	0
Discontinuation due to unknown reasons	0	0	0	0

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- [1] Brunner HI et al. *Ann Rheum Dis.* 2015;74:1110-1117.
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Disclosure of Interests: Fabrizio De Benedetti Grant/research support from: Abbvie, SOBI, Novimmune, Roche, Novartis, Sanofi, Pfizer, Nicolino Ruperto Grant/research support from: The Gaslini Hospital, where NR works as full-time public employee, has received contributions (> 10.000 USD each) from the following industries in the last 3 years: BMS, Eli-Lilly, GlaxoSmithKline, F Hoffmann-La Roche, Janssen, Novartis, Pfizer, Sobi. This funding has been reinvested for the research activities of the hospital in a fully independent manner, without any commitment with third parties., Consultant for: Received honoraria for consultancies or speaker bureaus (< 10.000 USD each) from the following pharmaceutical companies in the past 3 years: Ablynx, AbbVie, Astrazeneca-Medimmune, Biogen, Boehringer, Bristol-Myers Squibb, Eli-Lilly, EMD Serono, GlaxoSmithKline, Hoffmann-La Roche, Janssen, Merck, Novartis, Pfizer, R-Pharma, SanofiServier, Sinergie, Sobi and Takeda., Speakers bureau: Received honoraria for consultancies or speaker bureaus (< 10.000 USD each) from the following pharmaceutical companies in the past 3 years: Ablynx, AbbVie, Astrazeneca-Medimmune, Biogen, Boehringer, Bristol-Myers Squibb, Eli-Lilly, EMD Serono, GlaxoSmithKline, Hoffmann-La Roche, Janssen, Merck, Novartis, Pfizer, R-Pharma, SanofiServier, Sinergie, Sobi and Takeda., Athimalaipet Ramanam Consultant for: AbbVie, UCB, Sobi, Eli Lilly, Speakers bureau: Speaker fees/honoraria from Abbvie, SOBI, Eli Lilly and UCB, Speakers bureau: AbbVie, UCB, Sobi, Eli Lilly, Ruben Cuttica Grant/research support from: Roche, Pfizer, Lilly, Bristol Myers Squibb, Novartis, Sanofi Aventis, UCB, Janssen., Consultant for: Roche, Pfizer, Lilly, Bristol Myers Squibb, Novartis, Sanofi Aventis, UCB, Janssen., Speakers bureau: Roche, Pfizer, Lilly, Bristol Myers Squibb, Novartis, Sanofi Aventis, UCB, Janssen., Jennifer E. Weiss: None declared, Michael Henrickson: None declared, Heinrike Schmeling Grant/research support from: F. Hoffmann-La Roche Ltd, Jordi Anton Grant/research support from: Grant/research support, consultant or speakers bureau from AbbVie, Alexion, Bristol-Myers Squibb, ChemoCentryx, Gebro, GlaxoSmithKline, Novartis, Novimmune, Pfizer, Roche, Sanofi and Sobi, Consultant for: Grant/research support, consultant or speakers bureau from AbbVie, Alexion, Bristol-Myers Squibb, ChemoCentryx, Gebro, GlaxoSmithKline, Novartis, Novimmune, Pfizer, Roche, Sanofi and Sobi, Speakers bureau: Grant/research support, consultant or speakers bureau from AbbVie, Alexion, Bristol-Myers Squibb, ChemoCentryx, Gebro, GlaxoSmithKline, Novartis, Novimmune, Pfizer, Roche, Sanofi and Sobi, Kirsten Minden Consultant for: AbbVie, Gerd Horneff: None declared, Maria Luz Gámir Gámir: None declared, Markus Hufnagel: None declared, Wendy Douglass Shareholder of: Roche, Employee of: Roche, Chris Wells Employee of: Roche Products Ltd, Navita L. Mallalieu Shareholder of: Roche, Employee of: Roche, Alberto Martini: None declared, Daniel J Lovell Consultant for: Consulting fees and/or honoraria from Astra Zeneca, Wyeth Pharma, Amgen, Abbott, Pfizer, F. Hoffmann-La Roche, Novartis, UBC, Takeda, GSK, Boehringer, and Celgene, Hermine Brunner Grant/research support from: Bristol-Myers Squibb, Pfizer, Consultant for: Pfizer, Bristol-Myers Squibb, Janssen, Novartis, Lilly, Roche, GlaxoSmithKline, Sanofi, Speakers bureau: Novartis, Roche

DOI: 10.1136/annrheumdis-2019-eular.5824