AB0301

SARILUMAB AS MONOTHERAPY OR IN COMBINATION WITH CONVENTIONAL SYNTHETIC DMARDS IN PATIENTS WITH RHEUMATOID ARTHRITIS: 12-WEEK TREATMENT RESULTS FROM A MULTICENTER, OPEN-LABEL, PROSPECTIVE, SINGLE-ARM OBSERVATIONAL STUDY

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Background: Due to strict inclusion/exclusion criteria, randomized controlled trials (RCTs) may not represent the heterogeneous rheumatoid arthritis (RA) population encountered in routine clinical practice; longitudinal observational studies are needed to complement learnings from RCTs. The PROspective sarilumab (preFILLed syringe/pen) multinational, observational Study (PROFILE) is collecting information on treatment strategies and sarilumab usage patterns and adherence in routine clinical practice for up to 52 weeks in patients with moderate-to-severe RA.

Objectives: In this planned interim analysis, we report baseline characteristics of patients prescribed sarilumab in routine clinical practice and the efficacy and safety of sarilumab after 12 weeks of treatment.

Methods: Adults with RA (2010 ACR/EULAR criteria) can enroll in this multinational, open-label, single-arm, Phase 4 study if, per their treating physicians' judgment, they are to initiate treatment with sarilumab as mono- or combination (with csDMARD) therapy, in accordance with local labeling/prescribing information, ≤ 4 weeks prior to or ≤ 8 weeks after study Visit 1 (signed informed consent and disease characteristics documented); 1000 patients are planned for enrollment. Concomitant use of biologic or targeted synthetic DMARDs (b/tsDMARDs) is not permitted. Primary endpoint is change from baseline in Clinical Disease Activity Index (CDAI) score at Weeks 24 and 52. Statistical analyses are descriptive.

Results: This analysis included 291 patients who reached, or discontinued before, the Week 12 visit, of whom 108 (37%) received sarilumab mono- and 183 (63%) received combination therapy. At baseline (BL), the monotherapy group had longer disease duration and a smaller proportion of b/tsDMARD-naïve patients than the combination therapy group (9.7 vs 8.7 years and 39% vs 53%). Baseline and week 12 CDAI values were available in 132 patients. Mean (SD) BL CDAI scores for the monotherapy and combination groups were 26.7 (13.1) and 27.0 (14.4). At Week 12, CDAI scores were improved by -9.1 (17.5) and -10.5 (13.9), and 37% (19/51) of patients receiving monotherapy and 48% (45/93) of those receiving combination therapy had achieved low disease activity (CDAI ≤ 10). Remission (CDAI ≤ 2.8) was achieved by 12% (6/51) of monotherapy and 20% (19/93) of combination-therapy patients. Overall, 55 (19%) discontinued sarilumab: 27 (9%) for an adverse event (AE), 19 (7%) for insufficient response, 4 (1%) for noncompliance, 5 (2%) for other reasons. Severe AEs leading to treatment discontinuation were leukopenia and neutropenia (n=1 patient), peripheral swelling (1), lung cancer (1), and fatigue (1). Ten patients (3%) had a treatment-emergent serious AE.

Conclusion: In this planned interim analysis, sarilumab mono- or combination therapy resulted in improved disease outcomes, assessed by CDAI, at Week 12, an important treat-to-target time point. Safety and efficacy were consistent with Phase 3 trial findings, with no new safety signals, although interim results must be interpreted with caution. Future analyses will evaluate efficacy and safety after 24 and 52 weeks of treatment in routine clinical practice.

Acknowledgments: Study funding and medical writing support (Laura George, Adelphi Communications Ltd, Macclesfield, UK) were provided by Sanofi Genzyme (Cambridge, USA) and Regeneron Pharmaceuticals, Inc. (Tarrytown, USA) in accordance with Good Publication Practice (GPP3) guidelines.

Disclosure of Interests: Alan Kivitz Shareholder of: AbbVie, Amgen, Gilead, GSK, Pfizer Inc, Sanofi, Consultant of: AbbVie, Boehringer Ingelheim, Flexion, Genzyme, Gilead, Janssen, Novartis, Pfizer Inc, Regeneron, Sanofi, SUN Pharma Advanced Research, UCB, Paid instructor for: Celgene, Genzyme, Horizon, Merck, Novartis, Pfizer, Regeneron, Sanofi, Speakers bureau: AbbVie, Celgene, Flexion, Genzyme, Horizon, Merck, Novartis, Pfizer Inc, Regeneron, Sanofi, Jacques-Eric Gottenberg Grant/research support from: Bristol-Myers Squibb, Pfizer, Roche, Consultant of: AbbVie, Bristol-Myers Squibb, Janssen, Lilly, MSD, Pfizer, Roche, UCB, Speakers bureau: AbbVie, Bristol-Myers Squibb, Gilead, Janssen, Lilly, MSD, Pfizer, Roche, UCB, Martin Bergman Shareholder of: Johnson & Johnson – stockholder, Consultant of: AbbVie, BMS, Celgene Corporation, Genentech, Janssen, Merck, Novartis, Pfizer, Sanofi – consultant, Speakers bureau: AbbVie, Celgene Corporation, Novartis, Pfizer,

Sanofi – speakers bureau, Melitta Iglesias-Rodriguez Shareholder of: Sanofi Genzyme, Employee of: Sanofi Genzyme, Gregory St John Shareholder of: Regeneron Pharmaceuticals, Inc., Employee of: Regeneron Pharmaceuticals, Inc., Chunfu Qiu Shareholder of: Sanofi Genzyme, Employee of: Sanofi Genzyme, Hubert van Hoogstraten Shareholder of: Sanofi, Employee of: Sanofi, Louis Bessette Grant/research support from: AbbVie, Amgen, Bristol-Myers Squibb, Celgene, Eli Lilly, Janssen, Merck, Novartis, Pfizer, Roche, Sanofi, UCB Pharma, Consultant of: AbbVie, Amgen, Bristol-Myers Squibb, Celgene, Eli Lilly, Janssen, Merck, Novartis, Pfizer, Roche, Sanofi, UCB Pharma, Speakers bureau: AbbVie, Amgen, Bristol-Myers Squibb, Celgene, Eli Lilly, Janssen, Merck, Novartis, Pfizer, Sanofi

DOI: 10.1136/annrheumdis-2020-eular.1972

AB0302

USE OF TNF-INHIBITORS BEFORE, DURING AND THE FIRST YEAR AFTER PREGNANCY AMONG WOMEN WITH RHEUMATOID ARTHRITIS

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Background: Treat to target is a goal, also in pregnant women with Rheumatoid arthritis (1). There is increasing evidence on safe use with TNF inhibitors during pregnancy. Adjusted use of TNF inhibitors preconception and throughout pregnancy may stabilize disease activity and prevent flares (2). Low disease activity is also beneficial for the fetus.

Objectives: To study the use of TNF-inhibitors among women with Rheumatic arthritis during and after pregnancy.

Methods: RevNatus is a Norwegian, nationwide quality register that monitors treatment of inflammatory rheumatic diseases before, during and after pregnancy. Data from RevNatus in the period October 2017 to October 2019 was used to map the use of all types of TNF inhibitors among 208 women with rheumatoid arthritis, diagnosed by the ACR/EULAR criteria. The use of medication was reported at the time of visit in outpatient clinic. The frequency of use of TNF inhibitors registered at seven timepoints from pre-pregnancy to twelve months after delivery.

Results: The use of medication was reported at each visit for all the women with rheumatoid arthritis. Most of the women were not using TNF inhibitors before and beyond conception. Most of the women continuing TNF inhibitors beyond conception used certolizumab or etanercept. Adalimumab and infliximab were used in pregnancy (tabell 1).

Tabell 1.

	certoliz- umab	etane- recept	adalim- umab	golim- umab	inflixi- mab	No TNF- inhibitor
Before pregnancy n=105	21% (22)	9% (10)	3% (3)		1% (1)	66% (69)
1.trimester n=81	19% (15)	10% (8)				71% (58)
2.trimester n=88	10% (9)	10% (9)				80% (70)
3.trimester n=91	11% (10)	5% (5)				83% (76)
6 weeks post partum n=96	22% (21)	13% (13)	1% (1)		1% (1)	63% (60)
6 months post partum n=88	24% (21)	18% (16)	4% (4)		1% (1)	53% (46)
12 months post partum n=84	21% (18)	17% (15)	7% (6)		2% (2)	53% (43)

Conclusion: Most of the women with rheumatic arthritis were not treated with TNF inhibitors before or in pregnancy. Women with rheumatic arthritis that continuing treatment with TNF inhibitors through pregnancy were using certolizumab and etanercept.

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Disclosure of Interests: None declared

DOI: 10.1136/annrheumdis-2020-eular.3622