7 reported SAEs are unrelated to SB2: prostate and breast carcinoma in the RA cohort; alcohol poisoning, nephrotoxicity, epistaxis, cutaneous lesion and malleolar fracture in the AS cohort.

Conclusion: This interim analysis indicates that patients with RA, AS or PsA can be successfully transitioned from originator or biosimilar IFX to SB2, without loss of disease control and with no safety concerns. The majority of transitioned patients continued SB2 treatment at M12 post-initiation. The PERFUSE study will provide ongoing, pertinent information about outcomes in these populations, helping to inform evidence-based treatment decisions.


DOI: 10.1136/annrheumdis-2020-eular.5682

THU0165

PROSARA - A PROSPECTIVE, MULTICENTER, NON-INTERVENTIONAL STUDY TO EVALUATE THE SAFETY AND EFFECTIVENESS OF SARILUMAB FOR THE TREATMENT OF ACTIVE RHEUMATOID ARTHRITIS IN REGULAR CARE IN GERMANY


Background: Blockade of IL-6 signaling by sarilumab has been demonstrated to be an effective treatment approach for rheumatoid arthritis. Due to strict inclusion and exclusion criteria, randomized controlled trials may not represent the heterogeneous RA patient population encountered in regular care.

Objectives: The current study investigated the safety and effectiveness of sarilumab in the treatment of RA in regular care in Germany.

Methods: The prospective, observational, single-arm 24-months PROSARA study (SARILL06661) is currently running in Germany at 79 sites, aiming to include up to 750 RA patients treated with sarilumab. RA patients are selected at physician discretion and treated according to the label. Study objectives include the documentation of safety and various effectiveness outcomes. This interim analysis included patients with data available up to 12 weeks. All analyses are descriptive only.

Results: A total of 348 patients were included in the study; of which 265 patients had post-baseline data. The mean age of the patients analyzed was 58.6 years (24-83); 76.3% are female. The mean disease duration was 10.3 years; comorbidities were present in 80.7% of patients. At baseline, 32.5% were biologic naïve. Most common pretreatment with b/ts DMARDs included a 1st bDMARD. Treatment persistence, EULAR response at 6 and 12 months, treatment-related adverse events, and SAEs were reported. Of the 2401 patients included, of which 379 were elderly and 83 very elderly. Elderly and very elderly RA patients is scarce.

Background: The proportion of elderly patients is increasing in the rheumatoid arthritis (RA) population. However, data on drug effectiveness and safety in these patients is scarce.

Objectives: To assess effectiveness and safety of biologic Disease MODIFYING ANTIRHEUMATIC DRUGS in elderly and very elderly patients with RHEUMATOID ARTHRITIS?

R Freitas1, N. Madeira2, B. M. Fernandes3, F. Costa4, M. Santiago4, A. Neto5, S. Azévedo6, J. Madruga Dias7, M. Couto8, M. Bernardes9, L. Cunha Miranda9, J. Polido-Pereira10, J. E. Fonseca11, M. J. Santos1.1. Hospital Garcia Orta, 2Rheumatology, Armação de Pêra, Portimão, Portugal, 3Hospital São João, Porto, Portugal, 4Hospital de Águeda, Aveiro, Portugal, 5Hospital Egas Moniz, Lisboa, Portugal, 6Casa de Saúde, Lisboa, Portugal, 7European Federation of Medical Specialties, Lisboa, Portugal

Background: The background of elderly patients is increasing in the rheumatoid arthritis (RA) population. However, data on drug effectiveness and safety in these patients is scarce.

Objectives: To assess effectiveness and safety of biologic Disease MODIFYING ANTI-RHEUMATIC DRUGS in elderly and very elderly RA patients.

Methods: Prospective cohort-study of RA patients registered at Reuma.pt starting a 1st bDMARD. Treatment persistence, EULAR response at 6 and 12 months, and adverse events (AE) were compared between adults (>65 years-old), elderly (65-74 years-old) and very elderly (≥ 75 years-old).

Results: 2401 patients were included, of which 379 were elderly and 83 very elderly. Elderly and very elderly had higher disease activity at baseline and more comorbidities. Elderly patients started bDMARD later in the course of note, similar efficacy was observed among patients that switched from JAKi to sarilumab vs patients switched from other DMARDs; disease activity outcome measures including DAS28, CDAL, TJC and global assessments improved consistently (Figure 1).

Safety was consistent with the anticipated profile of IL-6-inhibition and no new safety signals occurred. Adverse events and serious adverse events were described in 33.9% and 6.3% of patients, respectively.

Conclusion: Sarilumab administered in regular care demonstrated rapid and clinically meaningful improvement in a general RA patient population including patients switching from JAKi. The safety profile was consistent with data reported from controlled clinical trials.

Disclosure of Interests: Eugen Feist Consultant of: Novartis, Roche, Sohi, Lilly, Pfizer, Abbvie, BMS, MSD, Sanofi, Speakers bureau: Novartis, Roche, Sohi, Lilly, Pfizer, Abbvie, BMS, MSD, Sanofi, Peer-Malte Ariës Consultant of: Sanofi, Speakers bureau: Sanofi, Silke Zinke: None declared, Harald Burkhart Grant/research support from: Pfizer, Roche, Abbvie, Consultant of: Sanofi, Pfizer, Roche, Boehringer Ingelheim, UCB, Eli Lilly, Chugai, Bristol Myer Scrpps, Janssen, and Novartis, Speakers bureau: Sanofi, Pfizer, Roche, Abbvie, Boehringer Ingelheim, UCB, Eli Lilly, Chugai, Bristol Myer Scrpps, Janssen, and Novartis, Inka Albrecht Employee of: Sanofi, Oliver Bley Employee of: Sanofi, Michael Obermeier: None declared, Patricia Sterndt: None declared, Martin Welcker Grant/research support from: Abbvie, Novartis, UCB, Hexal, BMS, Lilly, Roche, Celgene, Sanofi, Consultant of: Abbvie, Actelion, Aescu, Amgen, Celgene, Hexal, Janssen, Medac, Novartis, Pfizer, Sanofi, UCB, Speakers bureau: Abbvie, Aescu, Amgen, Biogen, Berlin Chemie, Celgene, GSK, Hexal, Mylan, Novartis, Pfizer, UCB, Cornellia Kühne Grant/research support from: Novartis, Amgen, Roche/Chugai, Pfizer, Celgene, Abbvie, Sanofi, Arn-Dörthe Holst: None declared, Niklas Thomas Baerleckena: None declared, Hans-Peter Tony Consultant of: Abbvie, Astra-Zeneca, BMS, Chugai, Janssen, Lilly, MSD, Novar- tis, Pfizer, Roche, Sanofi.

DOI: 10.1136/annrheumdis-2020-eular.1528

THU0166

HOW EFFECTIVE AND SAFE ARE BIOLOGIC DISEASE-MODIFYING ANTIRHEUMATIC DRUGS IN ELDERLY AND VERY ELDERLY PATIENTS WITH RHEUMATOID ARTHRITIS?


1Hospital Garcia Orta, Ormediana, Portugal, 2Instituto Português Reumatologia, Lisboa, Portugal, 3Hospital São João, Porto, Portugal, 4Hospital de Águeda, Aveiro, Portugal, 5Hospital Egas Moniz, Lisboa, Portugal, 6ULSAM, Rheumatology, Ponte Lima, Portugal, 7Centro Hospitalar Médico Tejo, Torres Novas, Portugal, 8Hospital São Teotónio, Viseu, Portugal, 9Hospital Santa Maria, Lisboa, Portugal, 10Instituto de Medicina Molecular, Lisboa, Portugal

Background: The background of elderly patients is increasing in the rheumatoid arthritis (RA) population. However, data on drug effectiveness and safety in these patients is scarce.

Objectives: To assess effectiveness and safety of biologic Disease MODIFYING ANTI-RHEUMATIC DRUGS in elderly and very elderly RA patients.

Methods: Prospective cohort-study of RA patients registered at Reuma.pt starting a 1st bDMARD. Treatment persistence, EULAR response at 6 and 12 months, and adverse events (AE) were compared between adults (>65 years-old), elderly (65-74 years-old) and very elderly (≥ 75 years-old).

Results: 2401 patients were included, of which 379 were elderly and 83 very elderly. Elderly and very elderly had higher disease activity at baseline and more comorbidities. Elderly patients started bDMARD later in the course of
RA (Table 1). Crude and adjusted bDMARD treatment persistence was similar in the 3 groups (p=0.07, Graph). At 6/12 months, EULAR response was achieved by 81.6%/83.3%, 75.2%/88.5% and 82.6%/84.2% of adults, elderly and very elderly, respectively (Table 2). Except for a lower response rate at 12 months in the elderly group, the EULAR response was comparable in the 3 groups. The same results were observed after adjustment for baseline characteristics, namely the chance of achieving EULAR response was not different in adults and very elderly (OR 0.78, 95% CI 0.19 to 3.2). Also, the variation of DAS, CDAI and SDAI at 6 months and 12 months were comparable in the 3 groups. AE were reported in 21%/22.5%/22.9% of adult/elderly/very elderly patients, respectively. The rate of AE per 100 patient-years was lower in adults when compared to elderly and very elderly (6.4, 13.5 and 14.7, respectively) (Table 2). Also the rate of severe AE (SAE) was higher in very elderly (4.29 per 100 patient-years) when comparing to adults and elderly (1.03 and 1.94 respectively).

Table 1. Baseline characteristics. no:number; IQR:interquartile range; SD:standard deviation; DAS28-disease activity score 28 joints ESR; CV: cardiovascular; RF:Rheumatoid Factor; ACPA:anti-citrullinated protein antibodies

<table>
<thead>
<tr>
<th></th>
<th>Adults</th>
<th>Elderly</th>
<th>Very elderly</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension – no (%)</td>
<td>373 (26.7)</td>
<td>108 (42.4)</td>
<td>29 (47.5)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Diabetes – no (%)</td>
<td>95 (6.8)</td>
<td>40 (15.7)</td>
<td>10 (16.6)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>CV disease – no (%)</td>
<td>93 (6.7)</td>
<td>24 (9.4)</td>
<td>10 (16.6)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>RF and/or ACPA positive – no (%)</td>
<td>1642 (73)</td>
<td>252 (72.8)</td>
<td>60 (74)</td>
<td>0.97</td>
</tr>
<tr>
<td>Years since diagnosis to 1st bDMARD -median (IQR)</td>
<td>7.4 (3.7-14.9)</td>
<td>9.9 (5-18)</td>
<td>5.2 (3-12.6)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Baseline DAS28 mean ± SD</td>
<td>5.5 ± 1.3</td>
<td>5.7 ± 1.3</td>
<td>6 ± 1.4</td>
<td>0.02</td>
</tr>
</tbody>
</table>

Table 2. Efficacy of biologics at 6 (T6) and 12 month (T12) and safety

<table>
<thead>
<tr>
<th></th>
<th>Adults</th>
<th>Elderly</th>
<th>Very elderly</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>DAS T6 mean ± SD</td>
<td>-2 ± 1.4</td>
<td>-2 ± 1.9</td>
<td>-2.1 ± 1.4</td>
<td>0.9</td>
</tr>
<tr>
<td>EULAR responders T6 %</td>
<td>618 (816)</td>
<td>108 (75.2)</td>
<td>81 (81.8)</td>
<td>0.19</td>
</tr>
<tr>
<td>DAS T12 mean ± SD</td>
<td>-2.1 ± 1.5</td>
<td>-1.8 ± 1.6</td>
<td>-2.6 ± 1.9</td>
<td>0.1</td>
</tr>
<tr>
<td>EULAR responders T12 %</td>
<td>538 (83.3)</td>
<td>84 (8.63)</td>
<td>16 (84.2)</td>
<td>0.01</td>
</tr>
<tr>
<td>Patients with AE – no (%)</td>
<td>396 (21)</td>
<td>80 (22.5)</td>
<td>19 (22.9)</td>
<td>0.76</td>
</tr>
<tr>
<td>AE/ 100 patient-years</td>
<td>6.4</td>
<td>13.5</td>
<td>14.7</td>
<td></td>
</tr>
</tbody>
</table>

Conclusion: The persistence on 1st bDMARD was similar in adults, elderly and very elderly RA patients. Though older patients have more comorbidities and more active disease at baseline, treatment with biologics was effective and with an acceptable safety profile. However, it is important to take into account the higher risk of AE and SAE in older patients. In conclusion, this study supports the use of bDMARD treatment in elderly and very elderly RA patients.

Graph – Persistence in bDMARD

Disclosure of Interests: Raquel Freitas: None declared, Nathalie Madeira: None declared, Bruno Miguel Fernandes: None declared, Flavio Costa: None declared, Mariana Santiago: None declared, Agna Neto: None declared, Soraia Azevedo: None declared, João Madruga Dias: None declared, Maura Couto: None declared, Miguel Bernardes Speakers bureau: Abbvie, Amgen, Biogen, Eli-Lilly, Glaxo-Smith-Kline, Pfizer, Janssen, Novartis, Luis Cunha Miranda: None declared, Joaquim Polido-Pereira: None declared, Joao Eunico Fonseca: None declared, Maria Jose Santos Speakers bureau: Novartis and Pfizer

DOI: 10.1136/annrheumdis-2020-eular.2386

THU0167 ASSOCIATIONS BETWEEN RHEUMATOID ARTHRITIS DISEASE ACTIVITY AND PATIENT-REPORTED OUTCOMES IN SARILUMAB CLINICAL TRIALS

1Stanford University, Palo Alto, United States of America; 2Charité – University Medicine Berlin, Berlin, Germany; 3Sorbonne Université et Pitié Salpetrière Hospital, Paris, France; 4Sanofi, Bridgewater, United States of America; 5Sanofi, Cambridge, United States of America; 6Regeneron Pharmaceuticals, Inc., Tarrytown, United States of America; 7Leiden University, Leiden, Netherlands; 8Medical University of Vienna, Vienna, Austria; 9Metropolex Clinical Research Center and University of Texas Southwestern Medical Center, Dallas, United States of America

Background: Sarilumab is a human interleukin (IL)-6 receptor inhibitor approved for the treatment of adults with moderately to severely active rheumatoid arthritis (RA). The relationship between disease activity (DA), sarilumab treatment, and improvements in patient-reported outcomes (PROs) has not been well-studied.

Objectives: Assess the association between DA and PROs in three sarilumab Phase 3 trials.

Methods: This post hoc analysis included patients from three trials: two placebo-controlled trials (MOBILITY; NCT01061736 and TARGET; NCT01709578) with sarilumab dose groups 150 mg and 200 mg q2w that were combined for this analysis; and MONARCH (NCT02332590) with sarilumab 200 mg versus adalimumab 40 mg q2w. Associations between PROs and DA were tested at Week 24. All statistics are descriptive.

Results: Sarilumab was generally associated with larger PRO improvement than placebo both in patients who did and patients who did not achieve DA thresholds (Table). Improvement was less pronounced in patients who did not achieve DA thresholds. In the active-comparator trial, PROs improved in both treatment groups, across all DA levels. There was no clear difference between sarilumab and adalimumab in PRO response. There was a consistent trend of positive but reduced PRO responses with increased DA level using multiple cut-points (data not shown).

Conclusion: Achieving lower DA was associated with increased PRO improvements. In patients who did not achieve DA thresholds, the improvements were more favorable with sarilumab than placebo. This may support the emerging concept that mechanisms other than inflammation may contribute to improvements in PROs, potentially mediated via IL-6 signaling.

Acknowledgments: Study funding and medical writing support (Matt Lewis, Adelphi Communications Ltd) were provided by Sanofi and Regeneron Pharmaceuticals, Inc.

Disclosure of Interests: Mark C. Genovese Grant/research support from: Abbvie, Eli Lilly and Company, EMD Merck Serono, Galapagos, Genentech/Roche, Gilead Sciences, Inc., GSK, Novartis, Pfizer Inc., RPharm, Sanofi Genzyme, Consultant of: Abbvie, Eli Lilly and Company, EMD Merck Serono, Genentech/Roche, Gilead Sciences, Inc., GSK, Novartis, RPharm, Sanofi Genzyme, Gerd Rüdiger Burmester Consultant of: AbbVie Inc, Eli Lilly, Gilead, Janssen, Merck, Roche, Pfizer, and UCB Pharma, Speakers bureau: AbbVie Inc, Eli Lilly, Gilead, Janssen, Merck, Roche, Pfizer, and UCB Pharma, Laura Gossec Grant/research support from: Lilly, Mylan, Pfizer, Sanzod, Consultant of: AbbVie, Amgen, Biogen, Celgene, Janssen, Lilly, Novartis, Pfizer, Sanzod, Sanofi-Aventis, UCB, Hubert van Hoogstraten Shareholder of: Sanofi, Employee of: Sanofi, Amy Praestgaard Employee of: Sanofi Genzyme, Gregory St John Shareholder of: Regeneron Pharmaceuticals, Inc., Employee of: Regeneron Pharmaceuticals, Inc., Thomas Huizinga Grant/research support from: Ablynx, Bristol-Myers Squibb, Roche, Sanofi, Consultant of: Ablynx, Bristol-Myers Squibb, Roche, Sanofi, Daniel Aletaha Grant/research support from: AbbVie, Novartis, Roche, Consultant of: AbbVie, Amgen, Celgene, Lilly, Medac, Merck, Novartis, Pfizer, Roche, Sanodz, Sanofi Genzyme, Speakers bureau: AbbVie, Celgene, Lilly, Merck, Novartis, Pfizer, Sanofi Genzyme, UCB, Roy Fleischmann Grant/research support from: AbbVie, Akros, Amgen, AstraZeneca, Bristol-Myers Squibb, Boehringer, Ingelheim Centrexion, Eli Lilly, EMD Serono, Genentech, Gilead, Janssen, Merck, Nextran, Novartis, Pfizer, Regeneron Pharmaceuticals, Inc, Roche, Samsung, Sanofi Genzyme, Selecta, Taiho, UCB, Consultant of: AbbVie, ACEA, Amgen, Bristol-Myers Squibb, Eli Lilly, Gilead, GlaxoSmithKline, Novartis, Pfizer, Sanofi Genzyme, UCB

DOI: 10.1136/annrheumdis-2020-eular.1977

DOI: 10.1136/annrheumdis-2020-eular.2386