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 I邢 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.


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**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**

**E. Feist**1, P. M. Aries2, S. Zinke3, H. Burkhardt1, I. Albrecht1, O. Bley2, M. Obermeier2, P. Sternal2, M. Welcker1, C. Kühne1, A. D. Holst3, N. T. Baerlecken1, H. P. Tony1

1Helios Department of Rheumatology, Vogelsang-Gommern, Germany; 2Rheumatologie im Struenseehaus, Hamburg, Germany; 3Outpatient Rheumatology Center Berlin-Lichtenberg, Berlin, Germany; 4University Hospital, Division of Rheumatology, Frankfurt am Main, Germany; 5Sanofi Aventis, Berlin, Germany; 6GKM Gesellschaft für Therapieforschung, Munich, Germany; 7MVZ fuer Rheumatologie Dr. M. Welcker, Planegg, Germany; 8Outpatient practice, Haldensleben, Germany; 9Outpatient practice, Ludwigslust, Germany; 10Private Practice Rheumatology, Cologn, Germany; 11Rheumatology/Clinical Immunology, Department of Internal Medicine II, Würzburg, 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 (SARILL08661) 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:** Of 348 patients included in the study; of which 265 patients had post-baseline data. The mean age of the patients analyzed was 56.8 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 naive. Most common pretreatment with b/ts DMARDs included TNF-inhibitors (TNFi, 56.2%), non-TNF biologics (29.1%) or JAK-inhibitors (JAKi, 17.4%). At baseline, 49% received sarilumab as monotherapy and 29% in combination with conventional DMARDs (not specified for 22%). After 12 weeks of treatment with sarilumab, the mean DAS28-ESR decreased from 5.0±1.46 to 3.0±1.44 and CDAI from 26.7±13.79 to 13.6±11.4, respectively. DAS28-ESR remission/ low disease activity was achieved in 42.8% [n=77/180] patients with valid data on this parameter/ 59.4% [n=107/180] of patients; 13.6% [n=28/206] and 49% [n=101/206] of patients reached CDAI remission and low disease activity. Boolean remission was observed in 9.5% [n=19/201] of patients at week 12. HAQ-DI improved from 1.3 at baseline to 1.1 at week 12 (n=195). The mean CDAI improvement was similar for autoantibody-positive (RF and/or ACPA) CDAI -12.5 at week 12) compared to -negative patients (CDAI -15.4 at week 12). Patients switching from JAKi to sarilumab (n=32), were more severely affected, had longer disease duration and received more prior treatments than patients switched from another compound. 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, CDAI, TJC, SJC and global assessments improved consistently (Figure 1).

**Safety:** Was consistent with the anticipated profile of IL-6-R-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 Aries Consultant of: Sanofi, Speakers bureau: Sanofi, Ilse Zinke: None declared, Harald Burkhardt Grant/research support from: Pfizer, Roche, Abbvie, Consultant of: Sanofi, Pfizer, Roche, Boehringer Ingelheim, UCB, Eli Lilly, Chugai, Bristol Myer Scripps, Janssen, and Novartis, Speakers bureau: Sanofi, Pfizer, Roche, Abbvie, Boehringer Ingelheim, UCB, Eli Lilly, Chugai, Bristol Myer Scripps, Janssen, and Novartis, Inka Albrecht Employee of: Sanofi, Oliver Bley Employee of: Sanofi, Michaela Scherwinka: None declared, Patrizia Sternal: 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, UCB, Cornelia Kühne Grant/research support from: Novartis, Amgen, Roche/Chugai, Pfizer, Celgene, Abbvie, Sanofi, Ann-Dörthe Holst: None declared, Niklas Thomas Baerlecken: None declared, Hans-Peter Tony Consultant of: AbbVie, Astra-Zeneca, BMS, Chugai, Janssen, Lilly, Novartis, Pfizer, Roche, Sanofi.

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**THU0166**

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

R. Freitas1, N. Madeira2, B. M. Fernandes3, F. Costa4, M. Santiago4, A. Neto5, S. Azvedo5, J. Madurga Dias5, M. Couto5, M. Bernardes6, L. Cunha Miranda7, J. Polido-Pereira8, J. E. Fonseca9, M. J. Santos10.1. Hospital Garcia Orta, Rheumatology, Almada, Portugal; 2Hospital Português de Radiologia, Lisboa, Portugal; 3Hospital São João, Rheumatology, Porto, Portugal; 4Hospital Coimbra, Rheumatology, Coimbra, Portugal; 5Hospital Egas Moniz, Rheumatology, Lisboa, Portugal; 6ULSAM, Rheumatology, Ponte Lima, Portugal; 7Centro Hospitalar Médio Tejo, Torres Novas, Portugal; 8Hospital São Teotónio, Viseu, Portugal; 9Hospital Santa Maria, Lisboa, Portugal; 10Instituto de Medicina Molecular, Lisboa, Portugal

**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 Anti-Rheumatic Drugs (bDMARD) in elderly and very elderly RA patients.