FRI0436

ACHIEVING THE TREATMENT TARGETS OF REMISSION OR LOW DISEASE ACTIVITY (LDA) IN PSORIATIC ARTHRITIS (PSA) IS ASSOCIATED WITH SIGNIFICANTLY IMPROVED QUALITY OF LIFE, FUNCTION AND PAIN

Laure Gossec^{1,2}, Paul Bergmans³, Kurt de Vlam⁴, Elisa Gremese⁵, Beatriz Joven-Ibáñez⁶, Tatiana Korotaeva⁷, Wim Noel⁸, M.T. Nurmohamed^{9,10}, Petros Sfikakis¹¹, Stefan Siebert¹², Pavel Smirnov¹³, Elke Theander¹⁴, Josef S. Smolen¹⁵. ¹Paris-Sorbonne University, Paris, France; ²Hôpital Pitié-Salpêtrière, Paris, France; ³Janssen-Cilag B.V., Tilburg, Netherlands; ⁴University Hospitals Leuven, Leuven, Belgium; ⁵Fondazione Policlinico Gemelli-IRCCS-Università Cattolica del Sacro Cuore, Rome, Italy; ⁶Hospital 12 De Octubre, Madrid, Spain; ⁷Nasonova Research Institute of Rheumatology, Moscow, Russian Federation; ⁸Janssen-Cilag B.V., Brussels, Belgium; ⁹Amsterdam Rheumatology and Immunology Center | Reade, Amsterdam, Netherlands; ¹⁰Amsterdam Rheumatology and Immunology Center | VU Medical Center, Amsterdam, Netherlands; ¹¹University of Athens, First Department of Propædæutic Internal Medicine and Rheumatology, Athens, Greece; ¹²Institute of Infection, Immunity and Inflammation, University of Glasgow, Glasgow, United Kingdom; ¹³Janssen-Cilag B.V., Moscow, Russian Federation; ¹⁴Janssen-Cilag B.V., Lund, Sweden; ¹⁵Medical University of Vienna, Vienna, Austria

Background: The link between reaching a state of remission or LDA^{1,2} and patient-reported outcomes in PsA has been little explored in an observational setting.

Objectives: This analysis investigates the potential effect of reaching remission or LDA according to cDAPSA and achievement of VLDA/MDA on patient-reported outcomes such as HRQoL, functioning and pain in an observational cohort of PsA patients.

Methods: PsABio (NCT02627768) is an ongoing real-world observational study in 8 European countries where PsA patients receive 1st, 2nd- or 3rd-line biologics (starting either ustekinumab [UST] or a TNFi. Of 563 UST- or TNFi-treated patients enrolled Dec 2015 – Aug 2017, 303 had data available from their 6-month follow-up. Disease states were defined using cDAPSA ≤4 for remission and ≤13 for LDA (data available for 250 patients) and VLDA 7/7 and MDA 5/7 criteria (data available for 206 and 260 patients, respectively). HRQoL was assessed by the generic instrument EQ5D and the PsA specific tool PsAID-12. Physical functioning was measured by the HAQ-DI and pain with a Pain VAS (0–100). Assessment of Psoriasis Skin Disease (68/299=22.7%) was the most frequently missed MDA component, while enthesitis was the least frequently missed (6/299=2.0%). The other 5 components were all missed with equal frequency (8–9%). Available observed data on univariate associations are presented, with no imputation of missing data or adjustment for baseline imbalances.

Figure 2.

cDAPSA, clinical Disease Activity Index for psoriatic arthritis; CI, confidence interval; EQ-5D, EuroQoL 5-dimension questionnaire; HAQ-DI, Health Assessment Questionnaire – Disability Index; LDA, low disease activity; MDA, minimal disease activity; PsAID-12, Psoriatic Arthritis Impact of Disease 12-item questionnaire; VAS, visual analogue scale; VLDA, very low disease activity

Results: For the 303 patients, mean age was 49.7 (standard deviation [SD] 12.8) years, mean disease duration was 7.2 (SD, 8.2) years, and

50.5% were women. Figure 1 shows data at 6 months for cDAPSA remission, cDAPSA LDA, VLDA, and MDA in UST- and TNFi-treated patients. Start of treatment with either UST or TNFi did not significantly influence the rates of these outcomes at 6 months. cDAPSA remission/LDA and VLDA/MDA achievement (Yes vs No) was associated with better general and disease-specific HRQoL assessments, (EQ5D VAS, PsAID-12) physical function (HAQ-DI) and Pain (VAS) shown by non-overlapping confidence intervals in Figure 2.

Conclusion: In real-life, treatment with either UST or a TNFi leads to considerable and comparable numbers of patients reaching LDA or remission. Reaching such LDA is associated with clinically important improvements exceeding minimal clinically important differences for QoL, functioning and pain experience. Our data therefore strongly support a treat-to-target strategy in routine care for PsA.

REFERENCES:

- Gossec L, et al. Ann Rheum Dis. 2016;75:499–510; 2. Smolen JS, et al. Ann Rheum Dis. 2018;77:3–17.

Acknowledgement: This study was sponsored by Janssen

Disclosure of Interests: Laure Gossec Grant/research support from: AbbVie, BMS, Celgene, Janssen, Lilly, MSD, Novartis-Sandoz, Pfizer, Sanofi, and UCB, Consultant for: AbbVie, Biogen, BMS, Celgene, Janssen, Lilly, MSD, Nordic Pharma, Novartis-Sandoz, Pfizer, Roche, Sanofi, and UCB, Consultant for: L Gossec has received honoraria from Celgene as investigator for this study, Paul Bergmans Shareholder of: Johnson & Johnson, Employee of: Janssen, Kurt de Vlam Consultant for: Pfizer Inc, Consultant for: Johnson & Johnson, Elisa Gremese Consultant for: AbbVie, BMS, Celgene, Janssen, Lilly, MSD, Novartis, Sanofi, UCB, Roche, and Pfizer, Speakers bureau: BMS, Speakers bureau: Roche, Speakers bureau: AbbVie, BMS, Celgene, Janssen, Lilly, MSD, Novartis, Sanofi, UCB, Roche, and Pfizer, Beatriz Joven-Ibáñez Speakers bureau: Celgene, Novartis, MSD, Pfizer, AbbVie, and Janssen, Tatiana Korotaeva Consultant for: Pfizer, MSD, Novartis, AbbVie, Celgene, Biocad, Janssen, UCB, Lilly and Novartis-Sandoz, Speakers bureau: Pfizer, MSD, Novartis, AbbVie, Celgene, Biocad, Janssen, UCB, Lilly and Novartis-Sandoz, Wim Noel Employee of: Janssen, M.T. Nurmohamed Grant/research support from: Pfizer, AbbVie, Roche, BMS, MSD, Mundipharma, UCB, Janssen, Menarini, Lilly, Sanofi, and Celgene., Grant/research support from: Pfizer, AbbVie, Roche, BMS, MSD, Mundipharma, UCB, Janssen, Menarini, Eli Lilly, Celgene & Sanofi, Consultant for: Pfizer, AbbVie, Roche, BMS, MSD, Mundipharma, UCB, Janssen, Menarini, Lilly, Sanofi, and Celgene., Speakers bureau: Pfizer, AbbVie, Roche, BMS, MSD, Mundipharma, UCB, Janssen, Menarini, Lilly, Sanofi, and Celgene., Speakers bureau: Pfizer, AbbVie, Roche, BMS, MSD, Mundipharma, UCB, Janssen, Menarini, Eli Lilly, Celgene & Sanofi, Petros Sfikakis: None declared, Stefan Siebert Grant/research support from: AbbVie, Novartis, Pfizer, Janssen, BMS, Celgene, UCB, and Boehringer Ingelheim, Consultant for: AbbVie, UCB, Pfizer, Janssen, Boehringer Ingelheim, Celgene, and Novartis, Speakers bureau: AbbVie, UCB, Pfizer, Janssen, Boehringer Ingelheim, Celgene, and Novartis, Pavel Smirnov Employee of: Janssen, Elke Theander Employee of: Janssen, Josef S. Smolen Grant/research support from: AbbVie, Amgen, AstraZeneca, Astro, Celgene, Celtrion, Eli Lilly, GlaxoSmithKline, ILTOO, Janssen, Medimmune, MSD, Novartis-Sandoz, Pfizer Inc, Roche, Samsung, Sanofi, UCB, Speakers bureau: AbbVie, Amgen, AstraZeneca, Astro, Celgene, Celtrion, Eli Lilly, GlaxoSmithKline, ILTOO, Janssen, Medimmune, MSD, Novartis-Sandoz, Pfizer Inc, Roche, Samsung, Sanofi, UCB

DOI: 10.1136/annrheumdis-2019-eular.2379

FRI0437

PATIENT-DEFINED FLARES IN IN PSORIATIC ARTHRITIS: WHAT DO THEY MEAN? AN ANALYSIS OF CHANGE BETWEEN 2 VISITS IN 222 PATIENTS

Laure Gossec, Clemence Gorlier, Maarten de Wit, Laura C. Coates, Umut Kalyoncu, Adeline Ruyssen-Witrand, Ying Ying Leung, Rossana Scrivo, Juan D. Cañete, Penelope Palominos, Sandra Tälli, Andra Balanescu, Uta Kiltz, Sibel Aydin, Inna Gaydukova, Emmanuelle Derris, Ana-Maria Orbai, Ennio Lubrano, Josef S. Smolen. *ReFlap study group, PARIS, France*

Background: In psoriatic arthritis (PsA), disease fluctuations lead to periods of flares which impact patients' lives and treatment retention, these flares have been little studied.

Objectives: To explore the frequency of flares in patients with PsA, and to assess the validity of patient-defined flares against PsA disease activity.

Methods: ReFlap (NCT03119805, ref) was a longitudinal study in 14 countries of consecutive adult patients with definite PsA and more than 2 years of disease duration. Patients were seen twice in the context of usual care, around 4 months apart. The proportion of flares was computed at the second visit according to a patient-reported question: "At this time, are you having a flare of your psoriatic arthritis, if this means the symptoms are worse than usual?" and a symmetrical physician question. These definitions were compared with a change in disease activity defined as transition to a more active disease category based on the Disease Activity in Psoriatic Arthritis (DAPSA) categories. Agreement was calculated using prevalence-adjusted kappas. Validity of patient-reported flares was assessed by comparing patients who flared with patients who did not flare at the second visit using clinical and patient-reported variables. Finally, for patients flaring, effect sizes corresponding to a patient transition to flare state were calculated by standardized response means (SRMs) for continuous outcomes, with p values based on McNemar test or rank signed test. There was no imputation of missing data.

Results: Overall, 222 patients were analysed: 127 (58.8%) were male, mean age was 53.5±12.3 years, mean disease duration was 10.8±8.3 years; 66.3% received a biologic and 13.8% oral glucocorticoids. Disease activity was moderate: 35.9% had no current psoriasis skin lesions, mean tender joint count (TJC, 0-68) was 3.0±7.5, mean swollen joint count (SJC, 0-66) was 1.6±6.6, and mean DAPSA was 11.5±14.0. At 4.5±2.2 months follow-up, the proportion of patient-reported flares was 27.0% (n=60), compared to 17.6% (n=39) physician-reported flares; there was a worsening in DAPSA category in 40.1% (n=89) patients. Agreements between definitions were moderate (range of kappas, 0.32-0.59). Patients in flare had significantly more active disease than patients not in flare using all outcomes (all p<0.001 except skin lesions, p=0.01, perhaps due to the fact that the majority of patients were included in rheumatology departments and had mild skin involvement at visit 1). Finally, among patients self-describing as in flare (N=60), all outcomes were worse than at the first visit; changes from the first visit were most notable for patient global (SRM 1.22), pain (0.92), physician global (0.85), DAPSA (0.83) and PsAID12 (0.80).

Conclusion: Patient-reported flares occurred in 27% of these PsA patients at 4 months follow-up, which was more than the proportion of physician-reported flares but less than the proportion of patients showing worsening of DAPSA category. Patient flares were associated with more active disease for all PsA manifestations; and at the patient-level, to a clear worsening in disease activity. A single question for flares is feasible, easy to understand for patients and not time consuming. These findings provide preliminary validation of the notion of patient-reported flares.

REFERENCES:

- [1] Gorlier C, et al. Ann Rheum Dis. 2019;78(2):201-208.

Acknowledgement: This study was funded by Pfizer through an investigator-initiated grant.

Disclosure of Interests: Laure Gossec Grant/research support from: AbbVie, BMS, Celgene, Janssen, Lilly, MSD, Novartis-Sandoz, Pfizer, Sanofi, and UCB, Consultant for: AbbVie, Biogen, BMS, Celgene, Janssen, Lilly, MSD, Nordic Pharma, Novartis-Sandoz, Pfizer, Roche, Sanofi, and UCB, Consultant for: L Gossec has received honoraria from Celgene as investigator for this study, Clemence Gorlier: None declared, Maarten de Wit: None declared, Laura C Coates Grant/research support from: AbbVie, Celgene, Lilly, Novartis and Pfizer, Consultant for: AbbVie, Amgen, BMS, Celgene, Galapagos, Gilead Sciences Inc., Janssen, Lilly, Novartis, Pfizer, Prothena Corp and UCB, Umut Kalyoncu Grant/research support from: MSD, Roche, UCB, Novartis and Pfizer, Consultant for: MSD, AbbVie, Roche, UCB, Novartis, Pfizer and Abdi Ibrahim, Speakers bureau: MSD, AbbVie, Roche, UCB, Novartis, Pfizer and Abdi Ibrahim, Adeline Ruyssen-Witrand: None declared, Ying Ying Leung Grant/research support from: AbbVie, Novartis, Speakers bureau: AbbVie and Novartis, Speakers bureau: Novartis, Rossana Scivo: None declared, Juan D. Cañete: None declared, Penelope Palominos: None declared, Sandra Tälli: None declared, Andra Balanescu Speakers bureau: multiple, Uta Kiltz Grant/research support from: AbbVie, Chugai, Eli Lilly, Grünenthal, Janssen, MSD, Novartis, Pfizer, Roche, and UCB., Consultant for: AbbVie, Chugai, Eli Lilly, Grünenthal, Janssen, MSD, Novartis, Pfizer, Roche, and UCB., Sibel Aydin Consultant for: AbbVie, Celgene, UCB, Novartis, Janssen, Sanofi, Inna Gaydukova Grant/research support from: JSC BIOCAD, Speakers bureau: payment from Pfizer, Novartis, AbbVie, Biocad, Selgene, MSD, Sanofi does not exceed 10 000 euros, Emmanuelle Dernis: None declared, Ana-Maria Orbai Grant/research support from: AbbVie, Celgene,

Horizon Pharma, Janssen, Lilly, and Novartis, Consultant for: Lilly, Janssen, Novartis, Pfizer, and UCB, Ennio Lubrano Consultant for: Consultancy fees as speaker from AbbVie, Celgene, Novartis and Pfizer, Josef S. Smolen Grant/research support from: AbbVie, Eli Lilly, Janssen, MSD, Pfizer Inc, Roche, Consultant for: AbbVie, Amgen, AstraZeneca, Astro, Celgene, Celtrion, Eli Lilly, GlaxoSmithKline, ILTOO, Janssen, Medimmune, MSD, Novartis-Sandoz, Pfizer Inc, Roche, Samsung, Sanofi, UCB, Speakers bureau: AbbVie, Amgen, AstraZeneca, Astro, Celgene, Celtrion, Eli Lilly, GlaxoSmithKline, ILTOO, Janssen, Medimmune, MSD, Novartis-Sandoz, Pfizer Inc, Roche, Samsung, Sanofi, UCB

DOI: 10.1136/annrheumdis-2019-eular.2161

FRI0438

TREATMENT UTILISATION PATTERNS OF ADVANCED THERAPIES IN PSORIATIC ARTHRITIS

Leslie Harrold^{1,2}, Pankaj Patel³, Patrick Zueger³, Jacqueline O'Brien¹, Heather J. Litman¹, Hua Feng¹, Robert Mclean¹. ¹Corrona LLC, Waltham, United States of America; ²University of Massachusetts Medical School, Worcester, MA, United States of America; ³AbbVie, North Chicago, United States of America

Background: Psoriatic arthritis (PsA) is a chronic inflammatory arthropathy typically associated with psoriasis. Little is known regarding the pattern of advanced therapy use, such as biologics and targeted synthetic disease-modifying antirheumatic drugs (tsDMARDs), and how the characteristics of patients with PsA initiating these therapies differ by line of therapy.

Objectives: To characterise the prescribing frequency of medication classes and compare characteristics across line of therapy groups among patients with PsA who initiated a biologic/tsDMARD.

Methods: This observational study included patients with PsA in the US Corrona PsA/SpA Registry who initiated a biologic/tsDMARD between 31 March 2013 and 31 October 2018. Patients were grouped by line of therapy at time of drug initiation: 1st, 2nd, 3rd, or 4th-or-higher. For each group, frequencies of medication classes were calculated, and proportions (categorical variables) and means with standard deviations (continuous variables) were determined for patient demographic, clinical and disease activity characteristics, patient-reported outcome measures, history of medication use, and concomitant medication use at the time of therapy initiation. Comparisons across groups were made with chi-square tests and one-way analysis of variance.

Results: Data from 1516 initiators (396 (26%), 453 (30%), 333 (22%), 334 (22%) in the 1st, 2nd, 3rd, or 4th-or-higher line groups, respectively) were examined. Mean age was 53.1 years, mean time since PsA diagnosis was 8.1 years and mean time from PsA diagnosis to 1st line therapy initiation was 5.2 years. TNFi therapy was commonly initiated earlier, while initiation of the other classes as a proportion of total line-specific initiations increased in later lines of therapy (TNFi: 77%, 61%, 41%, and 30%; tsDMARDs: 16%, 18%, 19%, and 22%; IL-17: 4%, 12%, 25%, and 34%; non-TNFi/non-IL-17: 3%, 8%, 14%, and 14% for the 1st, 2nd, 3rd, and 4th-or-higher lines of therapy, respectively). Among all initiators, 72% had a history of methotrexate (MTX) use and 35% had concomitant MTX use at drug initiation. Most patients had moderate to high disease activity at therapy initiation based on the proportion of patients reporting minimal disease activity (20%) (Table); 30% had enthesitis and 15% had dactylitis. Across therapy lines, statistically significant differences in minimal disease activity, HAQ, fatigue, pain and morning stiffness (P<0.05) were seen. Generally, scores were lower for those receiving 1st line therapy relative to the 4th-or-higher line group; fatigue scores ranged from 45.1 to 56.8, pain scores ranged from 46.6 to 58.2, and the percentage of patients with morning stiffness ≥30 minutes ranged from 72% to 80%.

Conclusion: Patients with PsA who initiated biologic/tsDMARD therapies in a large, national US based registry frequently exhibited significant disease activity, as demonstrated by patient-reported outcome measures and validated disease activity measures. On average, disease activity was worse in later lines of therapy. Enthesitis and dactylitis were highly prevalent in this population. TNFi was the most common 1st line therapy while newer agents such as IL-17 inhibitors were most commonly initiated as 4th line therapy or higher. In light of the newly published guidelines, it appears that rheumatologists are treating in a manner aligned with the guidelines based on the characteristics of patients observed across the different lines of therapy.

Acknowledgement: This study was sponsored by Corrona, LLC. Corrona is supported through contracted subscriptions with multiple pharmaceutical companies. The abstract was a collaborative effort between Corrona and AbbVie with financial support provided by AbbVie.

Disclosure of Interests: Leslie Harrold Shareholder of: Corrona, Grant/research support from: Pfizer, Consultant for: AbbVie, BMS, and Genentech, Employee of: Corrona, Pankaj Patel Shareholder of: AbbVie,