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Disclosure of Interests: MARIA MARTIN LOPEZ: None declared, Beatriz Joven-Ibáñez Speakers bureau: Abbvie, Celgene, Janssen, Merck Sharp & Dohme, Novartis, Pfizer, José Luis Pablos: None declared

DOI: 10.1136/annrheumdis-2020-eular.6579

SAT0429

SECUKINUMAB IMPROVES CLINICAL AND PATIENT-REPORTED OUTCOMES AT 6 MONTHS AMONG PATIENTS WITH PSORIATIC ARTHRITIS IN THE US-BASED CORRONA PSORIATIC ARTHRITIS/SPONDYLOARTHRITIS (PSA/SPA) REGISTRY

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Background: Secukinumab, an interleukin-17 antagonist approved for the treatment of PsA, improves all PsA manifestations in the GRAPPA-OMERACT core domain set.¹ Few US-based studies have evaluated the real-world effectiveness of secukinumab in patients with PsA.

Objectives: To examine clinical and patient-reported outcomes (PROs) in patients with PsA enrolled in the Corrona PsA/SpA registry initiating secukinumab with ≥ 1 follow-up visit.

Methods: Included were adult patients with PsA in the Corrona registry who initiated secukinumab after April 1, 2017 and remained on secukinumab at their 6-month (window, 5-8 months) follow-up visit. The primary outcome was achievement of minimal disease activity (MDA) at 6 months among patients not in MDA at secukinumab initiation. MDA was defined as meeting 5 of the 7 following criteria: tender joint count (TJC) ≤ 1, swollen joint count (SJC) ≤ 1, psoriasis affected body surface area (BSA) < 3%, patient assessment of pain on visual analog scale (VAS) ≤ 15, patient global assessment VAS ≤ 20, HAQ-DI ≤ 0.5, and tender entheses points ≤ 1 using the Leeds Enthesitis Index (LEI). Secondary outcomes included the proportion of patients who achieved resolution (0 sites) of TJC, SJC, enthesitis (using the LEI), and dactylitis among those with ≥ 1 site at initiation and improvement from baseline in clinical outcomes (BSA, nail psoriasis, physician global assessment, TJC, SJC, and DAPSA) and PROs (patient-reported pain, patient global assessment, HAQ-DI, and Work Productivity and Activity Impairment questionnaire) at 6 months. Outcomes were evaluated in the overall population and in potentially recalcitrant patients with failure of or intolerance to ≥ 3 previous biologics to examine if the later line biologic could be adequately effective.

Results: A total of 100 patients with PsA who initiated and maintained secukinumab after 6 months were included. The mean (SD) age was 51.6 (11.6) years, 54.3% were male, and 96.8% were white. The mean (SD) symptom and disease duration were 10.8 (9.7) and 7.0 (7.0) years, respectively. Thirty patients (30.0%) initiated secukinumab 150mg and 70 (70.0%) initiated secukinumab 300mg. Most (83.0%) were biologic experienced; 17 patients initiated secukinumab as a 1st biologic, 34 as 2nd, 26 as 3rd, and 23 as ≥ 4th. At initiation, 75/90 patients (83.3%) were not in MDA; 26/71 (36.6%) of those with follow-up data available achieved MDA at 6 months (Figure 1). In the overall population, 28 patients (41.2%) with TJC ≥ 1, 24 (44.4%) with SJC ≥ 1, 17 (60.7%) with enthesitis, and 9 (75.0%) with dactylitis at initiation achieved resolution at 6 months (Table 1). Improvement was observed at 6 months in clinical outcomes and PROs in the overall population (Figures 1 and 2) and in patients who initiated secukinumab as a ≥ 4th-line biologic.

Table 1. Resolution of Peripheral Arthritis, Enthesitis, and Dactylitis at 6 Months Among Patients With ≥ 1 Site at Initiation

Secondary Outcomes	Initiation, Mean (SD) [n]	6-Month Follow-Up, Resolution (Count = 0), n (%)
TJC (1-68)	9.0 (9.7) [68]	28 (41.2)
SJC (1-66)	4.7 (4.2) [54]	24 (44.4)
Enthesitis (1-6)	1.9 (1.1) [28]	17 (60.7)
Dactylitis (1-20)	2.1 (1.3) [12]	9 (75.0)

Figure 1. Achievement of MDA and Change From Initiation in Clinical Outcomes at the 6-Month Follow-Up for Patients With PsA Who Initiated and Maintained Secukinumab

Figure 2. Change From Initiation in Patient-Reported Outcomes at the 6-Month Follow-Up for Patients With PsA Who Initiated and Maintained Secukinumab

Conclusion: In the Corrona registry, most secukinumab initiators with PsA were biologic experienced and were not in MDA at time of initiation. Consistent with clinical trials, real-world patients treated with secukinumab achieved MDA as well as improvement in clinical manifestations, PROs, and work productivity.

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Disclosure of Interests: Philip J Mease Grant/research support from: Abbott, Amgen, Biogen Idec, BMS, Celgene Corporation, Eli Lilly, Novartis, Pfizer, Sun Pharmaceutical, UCB – grant/research support, Consultant of: Abbott, Amgen, Biogen Idec, BMS, Celgene Corporation, Eli Lilly, Novartis, Pfizer, Sun Pharmaceutical, UCB – consultant, Speakers bureau: Abbott, Amgen, Biogen Idec, BMS, Eli Lilly, Genentech, Janssen, Pfizer, UCB – speakers bureau, Taylor Blachley Employee of: Corrona, LLC, Meghan Glynn Shareholder of: Corrona, LLC – shareholder, Grant/research support from: Pfizer – grant/research support, Employee of: Corrona, LLC – employment, Blessing Dube Employee of: Corrona, LLC, Robert McLean Employee of: Corrona, LLC, Nina Kim Employee of: Postdoctoral fellow at the University of Texas at Austin and Baylor Scott and White Health, providing services to Novartis Pharmaceuticals Corporation, Peter Hur Employee of: Novartis Pharmaceuticals Corporation, Alexis Ogdie Grant/research support from: Pfizer to Penn, Novartis to Penn, Amgen to Forward/NDB, Consultant of: Abbvie, Amgen, Bristol-Myers Squibb, Celgene, Corrona, Janssen, Eli Lilly, Novartis, Pfizer

DOI: 10.1136/annrheumdis-2020-eular.1014

SAT0430

SECUKINUMAB EFFECTIVENESS IN 1543 PATIENTS WITH PSORIATIC ARTHRITIS TREATED IN ROUTINE CLINICAL PRACTICE IN 13 EUROPEAN COUNTRIES IN THE EUROSPA RESEARCH COLLABORATION NETWORK

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Background: There is a lack of real-life evidence on secukinumab effectiveness in psoriatic arthritis (PsA) patients.

Objectives: To assess the real-life 6- and 12-month secukinumab retention rates and proportions of patients in remission/low disease activity (LDA) overall, and by prior biologic disease-modifying anti-rheumatic drug (bDMARD)/targeted synthetic (ts)DMARD use.

Methods: Data from PsA patients treated with secukinumab in routine care from 13 countries in the European Spondyloarthritis (EuroSpA) Research Collaboration Network were pooled. Patients started secukinumab ≥ 12 months before date of datacut. Crude and LUNDEX adjusted (crude value adjusted for drug retention) 28-joint Disease Activity index for Psoriatic Arthritis (DAPSA28) and 28-joint Disease Activity Score with CRP (DAS28CRP) remission and LDA rates were calculated. Group comparisons between b/tsDMARD naïve, 1 prior and ≥ 2 prior b/tsDMARD users were done with ANOVA, Kruskal-Wallis, Chi-square or Kaplan-Meier analyses with log-rank test, as appropriate.

Results: A total of 1543 PsA patients were included (Table 1). b/tsDMARD naïve patients had shorter time since diagnosis, higher baseline disease activity, a higher proportion were men and a higher proportion achieved remission. Overall 6/12-month secukinumab retention rates were 86%/74% and significantly higher in b/tsDMARD naïve patients at 12, but not 6 months (Table 2, Figure). Overall, crude 6- and 12-month DAPSA28 ≤ 4 /DAS28CRP < 2.6 were achieved by 13%/34% and 11%/39% of the patients, respectively.

Table 1.

	All patients (n=1543)	b/tsDMARD naïve (n=287)	1 prior b/tsD- MARD (n=333)	≥ 2 prior b/ tsDMARDs (n=923)	p *
Age (years), mean (SD)	52 (11)	49 (12.3)	51 (11)	53 (11)	<0.001
Male, %	42%	49%	46%	39%	0.003
Years since diagnosis, mean (SD)	9 (8)	7 (8)	8 (7)	10 (8)	<0.001
Current smokers, %	19%	21%	22%	18%	0.23
CRP (mg/L), median (IQR)	5 (2-12)	7 (2-19)	4 (2-8)	5 (2-11)	<0.001
DAPSA28, median (IQR)	26 (18-37)	28 (19-38)	22 (13-32)	27 (19-38)	<0.001
DAS28CRP, median (IQR)	4.2 (3.3-5.0)	4.4 (3.5-5.2)	3.8 (2.6-4.5)	4.2 (3.4-5.0)	<0.001

*Comparisons across number of prior b/tsDMARD were done with ANOVA, Kruskal-Wallis or Chi-square test, as appropriate

Table 2.

	Months	All patients (n=1543)	b/tsDMARD naïve (n=287)	1 prior b/ tsDMARD (n=333)	≥ 2 prior b/ tsDMARDs (n=923)	p *
Secukinumab retention rate, % (95%CI)	6	86% (84-87%)	89% (86-93%)	85% (81-89%)	85% (82-87%)	0.11
	12	74% (72-76%)	81% (76-86%)	76% (71-80%)	72% (69-75%)	0.006
DAPSA28 ≤ 4						
Crude	6	13%	25%	11%	11%	<0.001
LUNDEX	6	11%	22%	9%	9%	<0.001
Crude	12	11%	22%	11%	8%	<0.001
LUNDEX	12	7%	17%	7%	5%	0.001
DAS28CRP < 2.6						
Crude	6	34%	51%	33%	30%	<0.001
LUNDEX	6	29%	45%	27%	24%	<0.001
Crude	12	39%	55%	41%	34%	<0.001
LUNDEX	12	26%	41%	27%	21%	<0.001
DAPSA28 > 4 and ≤ 14						
Crude	6	33%	42%	32%	30%	0.04
LUNDEX	6	27%	37%	27%	25%	0.02
Crude	12	35%	48%	36%	32%	0.009
LUNDEX	12	24%	36%	24%	20%	0.004
DAS28CRP ≤ 3.2						
Crude	6	52%	69%	53%	47%	<0.001
LUNDEX	6	43%	61%	45%	38%	<0.001
Crude	12	55%	72%	55%	50%	<0.001
LUNDEX	12	37%	54%	37%	32%	<0.001

*Comparisons across number of prior b/tsDMARDs were done with Kaplan-Meier with log-rank test or Chi-Square test, as appropriate

Conclusion: In this real-life study of 1543 patients with PsA in 13 European countries 12-month secukinumab retention was high, and significantly higher for b/tsDMARD naïve patients. Overall, a higher proportion of bionative than previous b/tsDMARD users achieved remission, regardless of remission criteria.

Acknowledgments: Novartis and IQVIA for supporting the EuroSpA RCN

Disclosure of Interests: Brigitte Michelsen Grant/research support from:

Research support from Novartis, Consultant of: Consulting fees Novartis, Stylianos Georgiadis Grant/research support from: Novartis, Daniela Di Giuseppe: None declared, Anne Gille Loft Grant/research support from: Novartis, Consultant of: AbbVie, MSD, Novartis, Pfizer and UCB, Speakers bureau: AbbVie, MSD, Novartis, Pfizer and UCB, Michael Nissen Grant/research support from: AbbVie, Consultant of: Novartis, Lilly, Abbvie, Celgene and Pfizer, Speakers bureau: Novartis, Lilly, Abbvie, Celgene and Pfizer, Florenzo Iannone Consultant of: Speaker and consulting fees from AbbVie, Eli Lilly, Novartis, Pfizer, Roche, Sanofi, UCB, MSD, Speakers bureau: Speaker and consulting fees from AbbVie, Eli Lilly, Novartis, Pfizer, Roche, Sanofi, UCB, MSD, Manuel Pombo-Suarez Consultant of: Janssen, Lilly, MSD and Sanofi., Speakers bureau: Janssen, Lilly, MSD and Sanofi., Heiman Mann: None declared, Ziga Rotar Consultant of: Speaker and consulting fees from Abbvie, Amgen, Biogen, Eli Lilly, Medis, MSD, Novartis, Pfizer, Roche, Sanofi., Speakers bureau: Speaker and consulting fees from Abbvie, Amgen, Biogen, Eli Lilly, Medis, MSD, Novartis, Pfizer, Roche, Sanofi., Kari Eklund Consultant of: Celgene, Lilly, Speakers bureau: Pfizer, Roche, Tore K. Kvien Grant/research support from: Received grants from Abbvie, Hospira/Pfizer, MSD and Roche (not relevant for this abstract), Consultant of: Have received personal fees from Abbvie, Biogen, BMS, Celltrion, Eli Lilly, Hospira/Pfizer, MSD, Novartis, Orion Pharma, Roche, Sandoz, UCB, Sanofi and Mylan (not relevant for this abstract), Paid instructor for: Have received personal fees from Abbvie, Biogen, BMS, Celltrion, Eli Lilly, Hospira/Pfizer, MSD, Novartis, Orion Pharma, Roche, Sandoz, UCB, Sanofi and Mylan (not relevant for this abstract), Speakers bureau: Have received personal fees from Abbvie, Biogen, BMS, Celltrion, Eli Lilly, Hospira/Pfizer, MSD, Novartis, Orion Pharma, Roche, Sandoz, UCB, Sanofi and Mylan (not relevant for this abstract), Maria Jose Santos Speakers bureau: Novartis and Pfizer, Björn Gudbjörnsson Speakers bureau: Novartis and Amgen, Catalin Codreanu Consultant of: Speaker and consulting fees from AbbVie, Accord Healthcare, Alfasigma, Egis, Eli Lilly, Ewopharma, Genesis, Mylan, Novartis, Pfizer, Roche, Sandoz, UCB, Speakers bureau: Speaker and consulting fees from AbbVie, Accord Healthcare, Alfasigma, Egis, Eli Lilly, Ewopharma, Genesis, Mylan, Novartis, Pfizer, Roche, Sandoz, UCB, Sema Yilmaz: None declared, Johan K Wallman Consultant of: AbbVie, Celgene, Eli Lilly, Novartis and UCB Pharma, Cecilie Heegaard Brahe Grant/research support from: Novartis, Burkhard Moeller: None declared, Ennio Giulio Favalli Consultant of: Consultant and/or speaker for BMS, Eli-Lilly, MSD, UCB, Pfizer, Sanofi-Genzyme, Novartis, and Abbvie, Speakers bureau: Consultant and/or speaker for BMS, Eli-Lilly, MSD, UCB, Pfizer, Sanofi-Genzyme, Novartis, and Abbvie, Carlos Sánchez-Piedra: None declared, Lucie Nekvindova: None declared, Matija Tomšic: None declared, Nina Trokovic: None declared, Eirik kristianslund: None declared, Helena Santos Speakers bureau: AbbVie, Eli-Lilly, Janssen, Pfizer, Novartis, Thorvardur Love: None declared, Ruxandra Ionescu Consultant of: Consulting fees from Abbvie, Eli-Lilly, Novartis, Pfizer, Roche, Sandoz, Speakers bureau: Consulting and speaker fees from Abbvie, Eli-Lilly, Novartis, Pfizer, Roche, Sandoz, Yavuz Pehlivan: None declared, Gareth T. Jones Grant/research support from: Pfizer, AbbVie, UCB, Celgene and GSK., Irene van der Horst-Bruinsma Grant/research support from: AbbVie, Novartis, Eli Lilly, Bristol-Myers Squibb, MSD, Pfizer, UCB Pharma, Consultant of: AbbVie, Novartis, Eli Lilly, Bristol-Myers Squibb, MSD, Pfizer, UCB Pharma, Lykke Midtbøll Ørnbjerg Grant/research support from: Novartis, Mikkel Østergaard Grant/research support from: AbbVie, Bristol-Myers Squibb, Celgene, Merck, and Novartis, Consultant of: AbbVie, Bristol-Myers Squibb, Boehringer Ingelheim, Celgene, Eli Lilly, Hospira, Janssen,

Merck, Novartis, Novo Nordisk, Orion, Pfizer, Regeneron, Roche, Sandoz, Sanofi, and UCB, Speakers bureau: AbbVie, Bristol-Myers Squibb, Boehringer Ingelheim, Celgene, Eli Lilly, Hospira, Janssen, Merck, Novartis, Novo Nordisk, Orion, Pfizer, Regeneron, Roche, Sandoz, Sanofi, and UCB, Merete L. Hetland Grant/research support from: BMS, MSD, AbbVie, Roche, Novartis, Biogen and Pfizer, Consultant of: Eli Lilly, Speakers bureau: Orion Pharma, Biogen, Pfizer, CellTrion, Merck and Samsung Bioepis
DOI: 10.1136/annrheumdis-2020-eular.1413

SAT0431

PROPORTIONS OF PATIENTS ACHIEVING A MINIMAL DISEASE ACTIVITY STATE UPON TREATMENT WITH TILDRAKIZUMAB IN A PSORIATIC ARTHRITIS PHASE 2B STUDY

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Background: Tildrakizumab (TIL) is a high-affinity anti-interleukin-23p19 monoclonal antibody approved in the US, EU, and Australia to treat moderate to severe plaque psoriasis. A randomised, double-blind, placebo-controlled, multiple-dose, phase 2b study evaluating the efficacy and safety of TIL was recently completed (NCT02980692).

Objectives: To characterise and evaluate the rate of minimal disease activity (MDA) up to week (W)52 from the phase 2b study.

Methods: Patients (pts) ≥18 years old with active psoriatic arthritis (PsA)² and ≥3 tender and ≥3 swollen joints were randomised 1:1:1:1:1 to receive TIL 200mg every 4 weeks (Q4W) to W52, TIL 200mg Q12W to W52, TIL 100mg Q12W to W52, TIL 20mg Q12W to W24→TIL 200mg Q12W to W52, or placebo (PBO) Q4W to W24→TIL 200mg Q12W to W52. MDA was assessed throughout the study; an MDA response was achieved when 5 of 7 criteria were met.³ Safety was assessed throughout the study and included treatment-emergent adverse event (TEAE) monitoring.

Results: Of 500 pts screened, 391 were randomised and received ≥1 dose of study drug. At baseline (BL), mean age was 48.8 years, 55% were female, 97% were White, mean body mass index was 29.7 kg/m², and pts had PsA for a median (range) of 4.4 (0–42.8) years since diagnosis. Baseline disease characteristics related to MDA varied little between study arms (Table).

By W24, MDA state was achieved in significantly more pts receiving TIL vs PBO (24%–39% vs 7%; p<0.02 for all groups); the proportion further increased with continued TIL treatment to W52 (45%–64%), including pts who switched from PBO to TIL (47%) (Figure).

Among the overall pt population from BL→W24/W25→W52, 50.4%/39.9% and 2.3%/1.0% experienced a TEAE and serious TEAE, respectively. From BL→W24, 1 serious infection (chronic tonsillitis) was reported for TIL 20 mg→200 mg Q12W arm. From W25→W52, there was 1 malignancy (TIL 20→200 mg Q12W). There were no reports of candidiasis, uveitis, inflammatory bowel disease, major adverse cardiac events, or deaths from BL→W24 or W25→W52.

Table. Baseline disease characteristics related to minimal disease activity

	TIL 200mg Q4W n = 78	TIL 200mg Q12W n = 79	TIL 100mg Q12W n = 77	TIL 20→200mg Q12W n = 78	PBO→TIL 200mg Q12W n = 79
Swollen joint count	10.4	10.0	11.0	9.4	11.8
Tender joint count	16.6	19.5	21.3	19.0	19.7
Patient GADA score	57.8	61.1	60.3	61.9	65.2
Patient pain assessment	55.4	59.6	59.2	60.9	64.2
Enthesitis (LEI) score*	1.9	1.5	2.2	2.2	1.5
PASI†	7.6	6.2	8.8	6.6	5.0
HAQ-DI score	1.0	1.0	1.0	1.1	1.2

Data are reported as mean.

*Total patients analysed (n) = 76, 79, 76, 78, 78, respectively.

†Total patients analysed (n) = 75, 79, 76, 75, 75, respectively.

GADA, global assessment of disease activity; HAQ-DI, Health Assessment Questionnaire Disability Index; LEI, Leeds Enthesitis Index; PASI, Psoriasis Area and Severity Index; PBO, placebo; Q4W, every 4 hours; Q12W, every 12 hours; TIL, tildrakizumab.

Figure. Minimal disease activity response rates from baseline to week 52 in PsA patients across treatments and time points

Conclusion: TIL produced clinically meaningful improvement in pts with PsA, resulting in a large proportion of pts achieving MDA by W52, and was well tolerated through W52.

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Disclosure of Interests: Peter Nash Grant/research support from: AbbVie, Bristol-Myers Squibb, Celgene, Eli Lilly and Company, Gilead, Janssen, MSD, Novartis, Pfizer Inc, Roche, Sanofi, UCB, Consultant of: AbbVie, Bristol-Myers Squibb, Celgene, Eli Lilly, Gilead, Janssen, MSD, Novartis, Pfizer Inc, Roche, Sanofi, UCB, Speakers bureau: AbbVie, Bristol-Myers Squibb, Celgene, Eli Lilly, Gilead, Janssen, MSD, Novartis, Pfizer Inc, Roche, Sanofi, UCB, Michael E Luggen Grant/research support from: AbbVie; Amgen; Eli Lilly; Genentech; Nichi-Iko; Novartis; Pfizer; R-Pharm; and Sun Pharmaceutical Industries, Inc., Consultant of: AbbVie; Amgen; Eli Lilly; Genentech; Nichi-Iko; Novartis; Pfizer; R-Pharm; and Sun Pharmaceutical Industries, Inc., Speakers bureau: AbbVie; Amgen; Eli Lilly; Genentech; Nichi-Iko; Novartis; Pfizer; R-Pharm; and Sun Pharmaceutical Industries, Inc., Luis Espinoza: None declared, Ferran J García Fructuoso Grant/research support from: AbbVie, Eli Lilly, Gedeon Richter, MedImmune, Nichi-Iko, Pfizer, Sanofi-Aventis, Takeda, and UCB, Consultant of: AbbVie, Eli Lilly, Gedeon Richter, MedImmune, Nichi-Iko, Pfizer, Sanofi-Aventis, Takeda, and UCB, Speakers bureau: AbbVie, Eli Lilly, Gedeon Richter, MedImmune, Nichi-Iko, Pfizer, Sanofi-Aventis, Takeda, and UCB, Richard C Chou Consultant of: Sun Pharmaceutical Industries, Inc, Alan M Mendelsohn Shareholder of: Johnson and Johnson, Employee of: Sun Pharmaceutical Industries, Inc, Stephen Rozzo Employee of: Sun Pharmaceutical Industries, Inc, Iain McInnes Grant/research support from: Bristol-Myers Squibb, Celgene, Eli Lilly and Company, Janssen, and UCB, Consultant of: AbbVie, Bristol-Myers Squibb, Celgene, Eli Lilly and Company, Gilead, Janssen, Novartis, Pfizer, and UCB
DOI: 10.1136/annrheumdis-2020-eular.3947

SAT0432

EFFECT OF SEX ON DISEASE CHARACTERISTICS AND DISEASE IMPACT IN PATIENTS WITH PSORIATIC ARTHRITIS (PSA): INSIGHTS FROM THE REAL-WORLD, OBSERVATIONAL MULTINATIONAL PSABIO COHORT

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