Table. Mean change from baseline (SD) in total modified vdH-S score stratified by CDAL, DAPSA, PASDAS, MDA, and VLDA in PsA patients from GO-VIBRANT				
	Baseline to Wk24		Baseline to Wk52	
	PBO	GLM 2 mg/kg	PBO→GLM 2*	GLM 2 mg/kg
DAPSA				
Remission-low disease activity (≤14), n	10	107	105	119
Mean change (SD)	-0.05±2.14	-0.64±1.66	1.49±4.96	-0.88±2.34
p-value		0.4422		<0.001
Moderate disease activity (>14–28), n	37	59	66	64
Mean change (SD)	0.29±1.81	-0.32±1.54	1.38±4.16	-0.48±1.82
p-value		0.0268		0.0025
Active disease activity (>28), n	190	71	66	54
Mean change (SD)	1.77±3.56	0.21±1.97	1.27±4.36	0.41±3.30
p-value		0.0007		0.2598
PASDAS				
Inactive disease activity (≤3.2), n	12	101	114	118
Mean change (SD)	-0.17±2.136	-0.64±1.729	1.53±4.850	-1.01±2.384
p-value		0.4305		<0.0001
Moderate disease activity (>3.2 & ≤5.4), n	85	109	83	83
Mean change (SD)	0.73±1.926	-0.16±1.750	1.14±3.727	-0.20±1.965
p-value		0.0003		0.0003
High disease activity (≥5.4), n	125	22	19	17
Mean change (SD)	2.29±4.107	0.47±1.891	3.81±7.052	0.54±3.066
p-value		0.0290		0.1122
MDA				
Yes, n	11	78	80	101
Mean change (SD)	0.91±2.49	-0.83±1.78	1.19±3.86	-1.16±2.46
p-value		0.0232		<0.0001
No, n	226	159	157	136
Mean change (SD)	1.49±3.39	-0.05±1.70	1.50±4.90	0.03±2.44
p-value		<0.0001		0.0011
VLDA				
Yes, n	1	16	24	35
Mean change (SD)	0	-0.91±1.04	0.91±3.32	-1.49±2.22
p-value		0.3749		0.0041
No, n	236	221	213	202
Mean change (SD)	1.47±3.36	-0.26±1.80	1.45±4.69	-0.30±2.52
p-value		<0.0001		<0.0001
CDAL				
Remission (≤2.8), n	5	43	58	63
Mean change (SD)	-0.60±1.34	-0.80±1.76	1.52±5.55	-1.06±2.41
p-value		0.9170		0.0003
Low disease activity (>2.8 & ≤10), n	28	98	78	92
Mean change (SD)	0.77±2.01	-0.41±1.43	1.21±3.59	-0.81±2.12
p-value		0.0011		<0.0001
Moderate disease activity (>10 & ≤22), n	67	66	64	69
Mean change (SD)	0.88±2.73	-0.10±2.04	1.32±4.25	0.20±2.82
p-value		0.0429		0.0905
High disease activity (>22), n	137	30	37	13
Mean change (SD)	1.96±3.79	0.30±1.95	1.75±5.34	1.11±2.65
p-value		0.0079		0.8144

CDAL=Clinical Disease Activity Index; DAPSA=Disease Activity in Psoriatic Arthritis score; GLM=golimumab; MDA=Minimal Disease Activity; PBO=placebo; PASDAS=Psoriatic Arthritis Activity Score; PsA=active psoriatic arthritis; SD=standard deviation; vdH-S=van der Heijde-Sharp; VLDA=Very Low Disease Activity
 *PBO pts crossed over to IV GLM 2 mg/kg at Wk24.
 †P-value is based on ANOVA w/ Van der Waerden rank test

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SAT0390

GUSELKUMAB WAS MORE EFFECTIVE THAN SECUKINUMAB IN PATIENTS WITH PLAQUE PSORIASIS AND THE SUBSET OF PATIENTS WITH SELF-REPORTED PSORIATIC ARTHRITIS IN THE RANDOMIZED, DOUBLE-BLIND, HEAD-TO-HEAD COMPARISON STUDY ECLIPSE OVER 1 YEAR

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Background: Guselkumab (GUS, an antibody against IL-23) and secukinumab (SEC, an antibody against IL-17A) are both approved for the treatment of psoriasis (PsO). Up to 30% of patients with PsO may have psoriatic arthritis (PsA).

Objectives: The ECLIPSE study compared efficacy and safety of GUS vs SEC in patients with plaque PsO. Post hoc analyses examined outcomes in the subgroup of patients with self-reported psoriatic arthritis (PsA).

Methods: ECLIPSE was a randomized, double-blind trial of adults with moderate-to-severe plaque PsO who received GUS 100 mg at Weeks 0, 4, then every 8 weeks, or SEC 300 mg at Weeks 0, 1, 2, 3, and 4, then every 4 weeks, both through Week 44. The primary endpoint was

the proportion of patients achieving ≥90% improvement compared to baseline in the Psoriasis Area and Severity Index (PASI) score at Week 48. Cochran-Mantel Haenszel chi-square testing stratified by investigator was used to compare treatment-group responses.

Results: Overall, treatment groups [GUS (n=534), SEC (n=514)] were comparable at baseline: weight 89kg, 24% body surface area PsO, and Investigator Global Assessment (IGA) moderate (76%) or severe (24%). These characteristics were similar to those of subgroups with self-reported PsA [GUS (n=97), SEC (n=79)]. In the overall population, the primary endpoint of PASI 90 response at Week 48 was achieved by 84.5% of GUS vs 70.0% of SEC patients (treatment difference 14.2 [95% CI=9.6%,18.8%], P<0.001). Among patients with PsA, the primary endpoint of PASI 90 response at Week 48 was achieved by 82.5% of GUS vs 63.3% of SEC patients (treatment difference 19.2% [95% CI=5.0%, 33.4%]). Beyond week 20, in both the overall study population and the PsA subpopulation, GUS-treated patients maintained the PASI 90 response while SEC-treated patients had a reduction in response through week 48 (Figure). In the overall population, results of the first major secondary endpoint (proportion of patients with a PASI 75 response at both Week 12 and 48) showed non-inferiority of GUS vs SEC (GUS-84.6% vs SEC-80.2% of patients, p<0.001), but superiority was not demonstrated (p=0.062). Adverse events observed in the overall population and PsA subgroup were generally consistent with the established safety profiles for GUS and SEC.

Conclusion: In the subset of patients with self-reported PsA in the ECLIPSE study, GUS demonstrated better maintenance of response and higher efficacy at approximately one year compared with SEC in the treatment of moderate to severe plaque PsO. These findings were consistent with those for the overall study population of patients with plaque PsO. AEs observed were generally consistent with the established safety profiles for GUS and SEC.

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Figure. Proportion of Patients Achieving PASI 90 Response (95% CI)

Non-responder imputation was used for missing data.
 CI=Confidence interval, PASI 90=90% improvement in the Psoriasis Area and Severity Index (PASI).

Affairs, LLC, Abbott, BMS, Novartis, Susan Flavin Employee of: Janssen Research & Development, LLC, Bruce Randazzo Employee of: Janssen Research & Development, LLC, 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
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SAT0391

REMISSION AND DRUG RETENTION RATES OF SECUKINUMAB IN 1549 PATIENTS WITH PSORIATIC ARTHRITIS TREATED IN ROUTINE CARE – POOLED DATA FROM THE OBSERVATIONAL EUROSPA RESEARCH COLLABORATION NETWORK

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Background: There is a lack of data on exposure, treatment outcomes and retention rates of secukinumab in patients with psoriatic arthritis (PsA) treated in routine care.

Objectives: Primary objective: To assess the proportion of PsA patients in remission after 6 months of secukinumab treatment across Europe. Secondary objectives: To compare baseline clinical and demographic characteristics, 6-month crude and LUNDEX adjusted remission rates, 6-month retention rates and median time to secukinumab withdrawal (due to loss of efficacy/adverse events) between bDMARD naïve and non-naïve patients as well as across the participating European registries.

Methods: PsA patients starting secukinumab in routine care and followed for at least 6 months were included from 12 European registries within the European Spondyloarthritis Research Collaboration (EuroSpA). Independent t-test, Mann-Whitney U test, ANOVA, Kruskal-Wallis and Chi-square test were used for group comparisons as appropriate, and Kaplan-Meier plots with log rank test for comparison of secukinumab drug survival.

Results: A total of 1549 PsA patients starting secukinumab were included (Table). 6-month remission and retention rates were significantly different between the registries (Table). Biologic DMARD (bDMARD) naïve compared with non-naïve patients had significantly higher 6-month remission rates and a trend towards better 6-month retention rates (Table, Figure 1a-b).

Conclusion: This study of >1500 patients in 12 European countries provides real-world data on the effectiveness of secukinumab in patients with PsA, adding evidence to existing RCTs. A majority of the patients had long disease duration and was previous bDMARD users. DAS28CRP, SDAI and DAPSA28 remission at 6 months were achieved by 35%, 12% and 12%, respectively. The overall retention rate was 86%, with significant differences across the registries. bDMARD naïve compared with non-naïve patients had significantly better 6-month remission rates and a trend towards better secukinumab retention rates.

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Figure 1. a Overall 6-month secukinumab retention rate in EuroSpA as well as compared between bDMARD naïve and non-naïve patients (Kaplan-Meier, log rank test; $p=0.07$)

Figure 1. b 6-month secukinumab retention rates overall and compared across the different registries in the EuroSpA collaboration (Kaplan-Meier, log rank test; $p<0.001$)

Pooled data from all registries		All patients (n=1549)		bDMARD naïve patients (n=302)		Previous bDMARD users (n=1247)		p*					
Age (years), mean (SD)		52 (11)		50 (12)		52 (11)			0.005				
Male, n/total (%)		425		47		406			0.03				
Disease duration (years), mean (SD)		9 (8)		7 (7)		10 (8)			<0.001				
Current smokers, %		18%		18%		18%			0.97				
Baseline CRP (mg/L), median (IQR)		5 (2-13)		8 (2-22)		5 (2-11)			<0.001				
Baseline ESR (mm/h), median (IQR)		17 (7-33)		22 (10-42)		15 (7-30)			<0.001				
Baseline SJC (0-25), median (IQR)		2 (0-4)		2 (0-5)		1 (0-4)			0.002				
Baseline IJC (0-25), median (IQR)		4 (1-9)		5 (1-10)		4 (1-9)			0.41				
Baseline Pain (0-10), median (IQR)		7 (5-8)		6 (5-8)		7 (5-8)			0.14				
6-month DAS28 remission rate (<2.6, % (95%CI)		35% (32-38%)		52% (44-61%)		32% (28-35%)			<0.001				
6-month SDAI remission rate (<3.3, % (95%CI)		12% (9-15%)		23% (16-31%)		9% (6-11%)			<0.001				
6-month DAPSA28 remission rate (<4, % (95%CI)		12% (10-14%)		22% (14-30%)		11% (8-13%)			0.001				
6-month secukinumab retention rate, % (95%CI)		96% (94-97%)		89% (83-95%)		85% (83-87%)			0.07				
LUNDEX adj. 6-month DAS28 remission rate, % (95%CI)		25% (23-27%)		39% (32-46%)		22% (20-24%)			<0.001				
LUNDEX adj. 6-month SDAI remission rate, % (95%CI)		9% (6-11%)		17% (11-23%)		6% (4-8%)			<0.001				
LUNDEX adj. 6-month DAPSA28 remission rate, % (95%CI)		9% (7-10%)		17% (11-22%)		8% (6-9%)			0.004				
Time to secukinumab withdrawal due to loss of efficacy or adverse events before 6 months, median (IQR) weeks, n of events		17 (10-21), n=203		18 (14-23), n=31		16 (9-21), n=172			0.09				
Mean (95%CI) drug retention time, weeks (censored by 26 weeks)		24.5 (24.3-24.7)		25.0 (24.6-25.4)		24.4 (24.1-24.6)			0.07				
*Comparison between bDMARD naïve and non-naïve patients													
According to registry													
	ARTIS n=10	ATTR A n=14	BIOBA DASER n=113	BIOBa L n=19	DAN BIO n=242	ICE BIO n=32	NOR- DMARD n=97	REFUM A-PT n=55	ROB- FIN n=12	ERRR n=24	SCQM n=166	TURK BIO n=24	p*
Age (years) mean (SD)	53 (12)	51 (10)	50 (11)	54 (10)	51 (12)	55 (14)	54 (11)	51 (11)	52 (11)	51 (13)	52 (11)	49 (12)	0.07
Male, n/total (%)	39%	54%	42%	41%	42%	23%	32%	42%	58%	43%	82%	33%	0.04
Disease duration (years), mean (SD)	8 (7)	11 (8)	8 (7)	11 (8)	8 (8)	15 (11)	13 (10)	8 (9)	13 (9)	8 (7)	9 (7)	11 (10)	<0.001
Current smokers, %	15%	18%	25%	22%	26%	22%	28%	17%	15%	3%	10%	23%	0.04
BL CRP (mg/L), median (IQR)	5 (2-11)	4 (2-7)	5 (2-13)	4 (1-16)	5 (2-12)	1 (0-3)	5 (2-13)	5 (2-17)	1 (0-4)	18 (4-40)	18 (4-40)	18 (4-40)	<0.001
BL ESR (mm/h), median (IQR)	14 (7-28)	17 (8-34)	17 (8-34)	17 (8-34)	17 (8-34)	17 (8-34)	17 (8-34)	17 (8-34)	17 (8-34)	17 (8-34)	17 (8-34)	17 (8-34)	<0.001
BL SJC (0-25), median (IQR)	2 (0-4)	4 (1-7)	2 (0-3)	4 (0-7)	1 (0-4)	1 (0-3)	1 (0-3)	1 (0-3)	1 (0-3)	1 (0-3)	1 (0-3)	1 (0-3)	<0.001
BL IJC (0-25), median (IQR)	2 (0-4)	4 (1-7)	2 (0-4)	4 (0-7)	1 (0-4)	1 (0-3)	1 (0-3)	1 (0-3)	1 (0-3)	1 (0-3)	1 (0-3)	1 (0-3)	<0.001
BL Pain (0-10), median (IQR)	7 (5-9)	7 (5-14)	7 (5-9)	7 (5-9)	7 (5-9)	7 (5-9)	7 (5-9)	7 (5-9)	7 (5-9)	7 (5-9)	7 (5-9)	7 (5-9)	<0.001
6-month DAS28CRP <2.6, %	26%	40%	30%	47%	30%	25%	57%	40%	38%	50%	52%	**	0.001
6-month SDAI <3.3, %	7%	18%	-	15%	11%	0%	10%	15%	17%	**	23%	**	0.13
6-month DAPSA28 <4, %	8%	20%	-	12%	11%	0%	14%	13%	24%	-	38%	**	<0.001
6-month secukinumab retention rate, % (95%CI)	82%	92%	94%	92%	79%	91%	33%	91%	87%	93%	92%	97%	<0.001
LUNDEX adj. 6-month DAS28 <2.6, %	22%	38%	35%	47%	26%	23%	47%	42%	33%	47%	48%	**	<0.001
LUNDEX adj. 6-month SDAI <3.3, %	6%	17%	-	14%	9%	0%	8%	14%	15%	**	19%	**	0.11
LUNDEX adj. 6-month DAPSA28 <4, %	6%	19%	-	11%	9%	0%	12%	14%	21%	-	31%	**	<0.001
Median (IQR) weeks to secukinumab withdrawal, n events	18 (13-22), n=9	**	**	**	13 (6-19), n=9	**	**	**	**	**	17 (12-21), n=11	**	0.01
Abbreviations across the registries: ART as above 10 observations; BL baseline; - not available.													

*Comparison across the registries; **Less than 10 observations; BL, baseline; - not available

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SAT0392

IMPLEMENTING THE PSORIATIC ARTHRITIS DISEASE ACTIVITY SCORE (PASDAS) IN ROUTINE CLINICAL PRACTICE: (IM)POSSIBLE?

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Background: Psoriatic arthritis (PsA) is a heterogeneous disease, with involvement of at least five health domains: peripheral joint disease, enthesitis, dactylitis, axial involvement, and skin and nail psoriasis. Because of the heterogeneity of the disease, assessment of disease activity is challenging. One of the many single or composite outcome measures that has been developed is the Psoriatic Arthritis Disease Activity Score (PASDAS). The PASDAS is a comprehensive measure that takes arthritis (66/68 joint score), dactylitis, enthesitis, CRP, physician disease activity VAS score and patient-reported outcomes into account¹. Furthermore, it is a continuous outcome measure in contrast to the Minimal Disease Activity criteria (MDA), facilitating the longitudinal follow-up of disease activity. The PASDAS also has better parametric distribution and discriminative capacity compared to other outcome measures such as the Disease Activity for Psoriatic Arthritis score (DAPSA). However, feasibility of PASDAS use in routine clinical care has been questioned due to its complexity. It requires a CRP and filled-out SF36 form at time of assessment, does not include a formal skin assessment, is difficult to calculate and is time consuming for both patient and physician.

Objectives: To implement PASDAS measurements and skin assessments in routine clinical care for all 1300 PsA patients treated at our centre.

Methods: The implementation consisted of the following stages: 1) assessment of patients' acceptability of measurement burden; 2) implementation of mathematical calculations of the PASDAS in our electronic health record; 3) PASDAS and skin assessment training of rheumatology nurses and rheumatologists; and 4) (logistic) adjustments to the outpatient visit.

Results: Our patient partners preferred comprehensive clinical assessment of skin and joints above a limited assessment (such as the DAS28-CRP), although the latter would be less time consuming. For this reason, and to comply with international guidelines, we decided to also add assessment of skin disease, by using the Body Surface Area (BSA) and Physician Global Assessment score (PGA). Furthermore, research demonstrated that for the PASDAS calculation the physical component score (PCS) of the SF36 could be substituted by the SF12-PCS². As the SF12 is more concise, minimizing patient burden, we chose to implement the SF12 instead of the SF36. The SF12-PCS, together with the other separate component scores and corresponding mathematical calculation of the PASDAS, was implemented in our electronic health record. Lastly, we set-up a three phase consultation that consists of laboratory tests and consultation with a rheumatology nurse who performs the physical measurements before each visit with the physician.

Conclusion: Standardized and routine measurement of the PASDAS and skin involvement at each outpatient visit of all our PsA patients before consultation with the treating rheumatologist was successfully implemented, underscoring the feasibility of this approach. In addition to improving clinical care, routine outcome measurements can be used for a variety of clinical studies.

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