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OP0308

EFFICACY AND SAFETY RESULTS OF GUSELKUMAB IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS OVER 56 WEEKS FROM A PHASE 2A, RANDOMISED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY

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Objectives: Evaluate efficacy and safety of guselkumab (GUS) in patients (pts) with active psoriatic arthritis (PsA) over 56 weeks (wks).

Methods: Pts w/active PsA (defined as ≥ 3 tender and ≥ 3 swollen joints, C-reactive protein ≥ 3 mg/L) and $\geq 3\%$ body surface area (BSA) of plaque psoriasis despite current or previous treatment w/standard-of-care therapies, including previous TNF inhibitor therapy, were eligible to participate and were randomised 2:1 to receive GUS 100 mg subcutaneously or placebo (PBO) at wk 0, 4, and every 8 wks thereafter through wk44. At wk16, pts from either group with $<5\%$ improvement from baseline in both swollen and tender joint counts were eligible for early escape (EE) to open-label ustekinumab. All remaining PBO pts crossed-over to receive GUS 100 mg at wks24, 28, 36, and 44. At wk56, a post-treatment follow-up visit was conducted. Efficacy post wk24 through wk44 and wk56 was evaluated in pts who did not EE and continued treatment at wk24 (post wk24 efficacy analysis set) based on observed data. The wk24 data in this population were included as a reference.

Results: 149 pts were randomised to receive study agent (PBO: 49, GUS: 100). The study met its primary and all secondary endpoints through wk24. At wk24, 29 pts in the PBO group crossed over to receive GUS, of which 28 completed treatment through wk44. 86 pts in the GUS group continued treatment at wk24 and 84 pts completed treatment through wk44. Post wk24, ACR 20/50/70 and PASI 75/90/100 responses improved in PBO to GUS crossover pts and were well-maintained in GUS pts through wk44 (last efficacy assessments while on drug) and wk56 (final follow-up visit) (table 1). The efficacy results from wk24 through wk44 and wk56 are summarised in table 1.

Through wk56, 17.2% of PBO—GUS, 46.0% of GUS, and 39.5% of the combined GUS pts had ≥ 1 AEs, of which infections and infestations were the most commonly reported (3.4%, 27.0%, and 21.7%, respectively). Post wk24, there was no disproportional increase in overall AE frequency, or infections and infestations among GUS pts with longer exposure. Through wk56, among 129 pts who received GUS, there was 1 pt with malignancy (basal cell carcinoma), 1 pt with 2 serious infections (both pneumonia), 6 pts reported ≥ 1 SAEs (myocardial infarction, osteoarthritis, pupils unequal, radius fracture, pneumonia, ulcerative keratitis), 2 pts discontinued treatment due to AEs, 1 pt had neutropenia meeting NCI-

CTCAE toxicity grade 3, and 6 pts were positive for antibodies to GUS. No deaths occurred through wk56.

Abstract OP0308 – Table 1 Efficacy results from Wk24 through Wk44 and Wk56 in post Wk24 efficacy analysis set based on the observed data

Efficacy Endpoints	PBO→GUS			GUS		
	Week 24*	Week 44	Week 56	Week 24	Week 44	Week 56
ACR 20	9/29 (31.0%)	21/28 (75.0%)	22/27 (81.5%)	57/86 (66.3%)	65/84 (77.4%)	61/83 (73.5%)
ACR 50	5/29 (17.2%)	13/28 (46.4%)	18/27 (66.7%)	34/86 (39.5%)	39/84 (46.4%)	44/83 (53.0%)
ACR 70	1/29 (3.4%)	7/28 (25.0%)	8/28 (28.6%)	14/86 (16.3%)	22/84 (26.2%)	27/83 (32.5%)
PASI 75	6/29 (20.7%)	23/28 (82.1%)	22/27 (81.5%)	71/86 (82.6%)	75/83 (90.4%)	70/82 (85.4%)
PASI 90	3/29 (10.3%)	21/28 (75.0%)	20/27 (74.1%)	61/86 (70.9%)	68/83 (81.9%)	64/82 (78.0%)
PASI 100	3/29 (10.3%)	19/28 (67.9%)	15/27 (55.6%)	38/86 (44.2%)	53/83 (63.9%)	47/82 (57.3%)
Mean (SD) change from baseline in HAQ-DI score	-0.19 (0.581)	-0.63 (0.612)	-0.67 (0.558)	-0.46 (0.530)	-0.54 (0.598)	-0.55 (0.621)
Median (IQR) percent change from baseline in Enthesis Scores	-50.0 (-100.0, 0.0)	-100.0 (-100.0, -60.0)	-100.0 (-100.0, -35.0)	-100.0 (-100.0, -50.0)	-100.0 (-100.0, -50.0)	-100.0 (-100.0, -50.0)
% of patients with unresolved enthesitis	12/18 (66.7%)	8/17 (47.1%)	6/16 (37.5%)	26/67 (38.8%)	25/66 (37.9%)	19/65 (29.2%)
Median (IQR) percent change from baseline in dactylitis	-46.0 (-100.0, 0.0)	-100.0 (-100.0, -100.0)	-100.0 (-100.0, -80.0)	-100.0 (-100.0, -100.0)	-100.0 (-100.0, -100.0)	-100.0 (-100.0, -95.0)
% of patients with unresolved dactylitis	13/16 (81.3%)	2/16 (12.5%)	1/16 (6.3%)	20/50 (40.0%)	10/49 (20.4%)	12/48 (25.0%)
Mean (SD) change from baseline in SF-36 physical component summary (PCS) score	2.13 (7.365)	8.02 (8.647)	N/A	7.40 (7.448)	8.34 (8.783)	N/A
Mean (SD) change from baseline in SF-36 mental component summary (MCS) score	0.51 (6.770)	5.53 (9.013)	N/A	5.45 (9.081)	4.56 (9.548)	N/A
% of patients achieving Minimal Disease Activity (MDA)	1/29 (3.4%)	8/28 (28.6%)	N/A	23/86 (26.7%)	29/84 (34.5%)	N/A

*Among the patients with enthesitis at baseline

*Among the patients with dactylitis at baseline

*Measured prior to receiving guselkumab

Conclusions: In pts with active PsA and $\geq 3\%$ BSA of psoriasis, GUS demonstrated substantial benefits on joint symptoms, physical function, psoriasis, enthesitis, dactylitis, and quality of life, and efficacy was well-maintained through wk56. GUS was well-tolerated with no unexpected safety findings in this population after ~1 year of exposure.

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OP0309

CHARACTERISATION OF CLINICAL BENEFITS IN SUBJECTS CLASSIFIED AS ACR20 NON-RESPONDERS AT WEEK 104 OF APREMILAST TREATMENT: SUBANALYSIS OF 3 LONG-TERM, PHASE III TRIALS

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Background: The PALACE 1, 2, and 3 trials evaluated the efficacy and safety of apremilast (APR) in subjects with active psoriatic arthritis (PsA) despite prior conventional disease-modifying anti-rheumatic drugs and/or biologics.

Objectives: The aim of this analysis is to further characterise the clinical benefits associated with long-term APR exposure in subjects who failed to achieve an ACR20 response at Week 104.

Methods: Subjects were randomised (1:1:1) to receive placebo (PBO), APR 30 mg BID (APR30), or APR 20 mg BID at baseline. Subjects who were randomised to APR30 at baseline and classified as ACR20 non-responders (ACR20NRs) at Week 104 were considered for this analysis. At Weeks 24, 52, and 104, ACR core components were examined as well as the proportions of

subjects achieving PASI-75/PASI-50 among those with psoriasis involvement $\geq 3\%$ of the body surface area at baseline, and dactylitis count and MASES of 0 among those with dactylitis or enthesitis at baseline. Safety is described for the overall PALACE 1–3 population.

Results: A total of 109 subjects randomised to APR30 treatment at baseline were ACR20NRs at Week 104. Baseline ACR core components were similar for ACR20NRs and ACR20 responders at Week 104. Among these ACR20NRs, several core components of ACR response, including swollen/tender joint counts and Physician's Global Assessment of Disease Activity (visual analogue scale) scores, showed sustained improvements from baseline through Week 104 (table 1). Importantly, of the 109 ACR20NRs at Week 104, 50.0% achieved a PASI-50 response after continued treatment with APR30 through Week 104 (table 1). Among ACR20NRs with baseline dactylitis ($n=44$) or enthesitis ($n=74$), 68.2% achieved a dactylitis count of 0 and 33.8% achieved a MASES of 0 at Week 104. More limited improvements in Subject's Global Assessment of Disease Activity, Subject's Assessment of Pain, Health Assessment Questionnaire-Disability Index, and C-reactive protein outcomes most commonly had an impact on subjects' ability to achieve an ACR20 response. In the overall subject population, no new safety concerns were identified through 104 weeks.

Abstract OP0309 – Table 1

	ACR20NRs at Week 104 With APR30 From Baseline ($n=109$)		
	Week 24	Week 52	Week 104
Swollen joint count (0–76), mean and median % change	-52.2, -71.4	-62.8, -73.3	-58.0, -75.0
Tender joint count (0–78), mean and median % change	-32.5, -47.4	-45.8, -53.5	-41.7, -51.7
PhGA (VAS 0–100 mm), mean and median % change	-37.9, -43.6	-49.8, -54.2	-44.3, -48.7
Dactylitis=0, n/m (%) ^a	23/44 (52.3)	29/44 (65.9)	30/44 (68.2)
MASES=0, n/m (%) ^b	20/74 (27.0)	27/74 (36.5)	25/74 (33.8)
PASI-75, n/m (%) ^c	17/50 (34.0)	22/50 (44.0)	18/50 (36.0)
PASI-50, n/m (%) ^d	31/50 (62.0)	33/50 (66.0)	25/50 (50.0)

Data are as observed at Week 24, Week 52, and Week 104 for all subjects who were randomized to APR30 at baseline and were ACR20NRs at Week 104 and with a value at the time point indicated.
^aExamined among subjects with dactylitis at baseline. ^bExamined among subjects with enthesitis at baseline. ^cExamined among subjects with $\geq 3\%$ psoriasis involvement of the body surface area at baseline. PhGA=Physician's Global Assessment of Disease Activity; VAS=visual analog scale; n/m=number of subjects achieving response/number of subjects with evaluable data at the time point; MASES=Maastricht Ankylosing Spondylitis Enthesitis Score; PASI-75/50= $\geq 75\%/ \geq 50\%$ reduction from baseline Psoriasis Area and Severity Index score.

Conclusions: ACR20NRs receiving APR30 demonstrated significant improvements in core PsA domains. The data may explain why subjects who failed to achieve an ACR20 response remained on long-term APR treatment. These findings suggest that some subjects with PsA may experience meaningful clinical improvement that is not completely captured by the assessment of ACR20 response criteria. Outcome measures specifically designed for PsA subjects, may be more suitable to evaluate treatment response in PsA subjects.

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OP0310 PREVALENCE OF RISK FACTORS AND CARDIOVASCULAR EVENTS ACROSS PSORIATIC ARTHRITIS PATIENTS TREATED WITH BIOLOGICAL THERAPY

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Background: Psoriasis and psoriatic arthritis (PsA) are described as associated with more frequency of risk factors and cardiovascular events.

Objectives: To determine the prevalence of risk factors and cardiovascular events in a cohort of patients with PsA treated with biological therapy and its correlation with gender.

Methods: We included all PsA patients (met CASPAR criteria) following treatment with bDMARDs (reference population 2.055.000). We obtained data of high

blood pressure, hyperlipidemia, hyperuricemia, type 2 diabetes mellitus, obesity (BMI ≥ 30), non-infectious liver disease, ischaemic cardiopathy, myocardial infarction, ischaemic stroke or transient ischaemic attack. For this analysis included gender, age, disease duration, current bDMARDs with or without current co-medication with csDMARDs and HLA-B27 status. Continuous variables were reported as mean $\pm$ standard deviation. Categorical variables were reported as percentages and frequencies. All analyses were performed using SPSS software. Differences were considered statistically significant if $p < 0.05$ (two-tailed).

Results: Data were obtained from 598 PsA patients who have been treated with bDMARDs. Three-hundred and twenty-five (54.3%) patients were men, mean age was 53.3 ± 12.6 years (men 53.3 ± 12.9 and women 53.2 ± 12.3 , $p=0.943$) and disease duration of PsA was 12.4 ± 8.7 years. No differences were seen for disease duration of PsA, nail disease, dactylitis, uveitis or HLA-B27. The prevalence of high blood pressure, hyperlipidemia, hyperuricemia, type 2 diabetes mellitus, obesity, non-infectious liver disease, ischaemic cardiopathy, myocardial infarction (MI) and ischaemic stroke/transient ischaemic attack (IS) was 36.0%, 43.6%, 16.0%, 12.5%, 26.3%, 12.5%, 5.5%, 3.8% and 1.3%, respectively. Men had most prevalence of type 2 diabetes mellitus, hyperuricemia, non-infectious liver disease, ischaemic cardiopathy, myocardial infarction and brain stroke event (see table 1). Patients with MI or IS had more prevalence of CV risk factors.

Abstract OP0310 – Table 1

	Female (273)	Male (325)	P
High blood pressure, n(%)	98 (35.9)	117 (36.0)	0.979
Hyperlipidemia, n(%)	111 (40.7)	150 (46.2)	0.177
Hyperuricemia, n(%)	13 (4.8)	82 (25.3)	<0.001
Diabetes mellitus, n(%)	21 (7.7)	54 (16.6)	0.001
Liver disease, n(%)	19 (7.6)	49 (16.7)	0.002
Ischaemic cardiopathy, n (%)	8 (2.9)	25 (7.7)	0.011
Myocardial infarction, n (%)	5 (1.8)	18 (5.5)	0.019
Brain stroke event, n (%)	1 (0.2)	7 (2.2)	0.058

Conclusions: Type 2 diabetes mellitus, hyperuricemia, non-infectious liver disease, ischaemic cardiopathy, myocardial infarction and brain stroke event were more prevalent in men than in women with PsA. Male gender had correlation with the prevalence of cardiovascular events or their risk factors.

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OP0311 NOTABLE EVOLUTIONS IN THE CHARACTERISTICS OF PSORIATIC ARTHRITIS CLINICAL TRIALS POPULATIONS IN THE ERA OF BIOLOGICAL TREATMENTS

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Background: Psoriatic arthritis is a chronic inflammatory disease that affects the musculoskeletal system. It can include arthritis, spondylitis, dactylitis and enthesitis, and is strongly associated with the presence of psoriasis. The introduction of biological therapies as a treatment option has brought a significant improvement in disease control for these patients.

Objectives: In this study, we wanted to detect emerging differences in demographic and clinical characteristics of the PsA-patient study population since the introduction of biologicals.

Methods: We selected 12 phase II- and phase III-trials and divided them into 3 treatment periods based on different time windows and working mechanisms of the particular biologicals or targeted DMARDs. Published tables with the baseline demographic and clinical characteristics of study population from the individual studies were used. For inclusion of a specific parameter, it had to be present in at least one study of each period. An exception to this rule was made for the 'number of patients with prior anti-TNF therapy', only present in studies from the second and third period. Parameters were defined in different categories: patient characteristics (gender, age, race, weight), disease characteristics (duration of PsA, presence of dactylitis, presence of enthesitis, psoriasis body surface area), disease activity parameters (swollen joint count, tender joint count, C-reactive protein