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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