AB0759

FOUR-YEAR EFFICACY AND SAFETY OF GUSELKUMAB IN PSORIASIS PATIENTS WITH AND WITHOUT PSORIATIC ARTHRITIS: A POOLED ANALYSIS FROM VOYAGE 1 AND VOYAGE 2

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Background: Guselkumab (GUS), a fully human monoclonal antibody, selectively binds and blocks interleukin-23. VOYAGE 1 and VOYAGE 2 are two ongoing Phase 3, randomized, double-blind, placebo (PBO)/active comparator-controlled clinical trials of GUS in patients (pts) with moderate-to-severe psoriasis (PsO).

Objectives: This post-hoc analysis reports pooled results through 4 years among a subgroup of moderate-to-severe PsO pts with self-reported psoriatic arthritis (PsA) at baseline.

Methods: 1829 pts were randomized to GUS 100mg at Weeks (Wks) 0, 4, and 12, then every 8 wks (q8wk); PBO at Wks 0, 4, and 12, GUS at Wks 16 and 20 then q8wk; or adalimumab (ADA) 80mg at Wk 0, 40mg at Wk 1, then 40mg q2wk until Wk 47 (VOYAGE 1) or Wk 23 (VOYAGE 2). In VOYAGE 1, all pts received open-label GUS 100mg q8wk during Wks 52-204. VOYAGE 2 incorporated a randomized withdrawal study design, followed by open-label GUS during Wks 76-204. Pooled subgroup analyses using the combined GUS group were conducted based on self-reported PsA status at baseline. Efficacy based on Investigator Global Assessment (IGA) score and Psoriasis Area and Severity Index (PASI) response was assessed using prespecified treatment failure rules (nonresponder status for all time points after discontinuing due to lack of efficacy, worsening of PsO, or use of a prohibited treatment).

Results: For pooled VOYAGE 1 and VOYAGE 2 pts (N=1721), combined GUS and ADA to GUS response rates at Wks 100, 156, and 204 were: PASI 90 80.6%, 80.0%, and 80.4%; PASI 100 50.1%, 49.9%, and 52.2%; IGA 0/1 83.6%, 83.3%, and 81.7%; and IGA 0 54.3%, 52.9%, and 53.9%, respectively. In the pooled subgroup analysis of pts with and without PsA, response rates were similar across the Wk 100, Wk 156, and Wk 204 evaluations (Table). Rates of adverse events through Wk 204 were comparable for pts with PsA vs those without PsA at baseline.

Conclusion: Among GUS-treated pts with moderate-to-severe PsO with and without self-reported PsA at baseline, stable, durable, and high levels of skin responses, as well as comparable safety outcomes, through 4 years were observed.

Table. Pooled GUS Response Rates

	Without PsA at Baseline			With PsA at Baseline		
	Wk 100	Wk 156	Wk 204	Wk 100	Wk 156	Wk 204
PASI 90	N=1301 1049 (80.6%)	N=1239 1001 (80.8%)	N=1191 964 (80.9%)	N=289 233 (80.6%)	N=276 211 (76.4%)	N=264 206 (78.0%)
PASI 100	648 (49.8%)	631 (50.9%)	635 (53.3%)	149 (51.6%)	125 (45.3%)	125 (47.3%)
IGA 0/1	N=1300 1086 (83.5%)	N=1235 1042 (84.4%)	N=1189 979 (82.3%)	N=288 241 (83.7%)	N=276 217 (78.6%)	N=264 208 (78.8%)
IGA 0	702 (54.0%)	664 (53.8%)	649 (54.6%)	160 (55.6%)	135 (48.9%)	134 (50.8%)

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SERIOUS INFECTIONS IN PATIENTS WITH RHEUMATOID ARTHRITIS AND PSORIATIC ARTHRITIS TREATED WITH TNFI: DATA FROM THE NOR-DMARD STUDY.

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Background: Infection is an important complication in patients with rheumatoid arthritis (RA), especially when exposed to therapy with tumor-necrosis-factor-inhibitors (TNFi) compared to conventional synthetic DMARDs. The majority of studies have been in RA populations and less is known about the risk of serious infections (SIs) in patients with psoriatic arthritis (PsA).

Objectives: To compare the incidence and risk of SI between RA and PsA patients treated with TNFi.

Methods: The NOR-DMARD is a prospective observational multi-centre study. Patients diagnosed with clinical RA or PsA, starting treatment with a TNFi between Jan 2009 to Dec 2018 were included. SI was identified through linkage to the Norwegian Cause of Death Registry and the Norwegian Patient Register and defined as an infection requiring hospital admission with at least one-night hospital stay and/or as an infection causing death. A predefined list of ICD10 diagnosis for infections was used. Time at risk was defined as time from baseline to the first SI, 30 days after discontinuation of TNFi therapy, emigration or end of study period. Crude incidence rates (IRs) of SIs for RA and PsA were presented as events per 100 patient years at risk (PYR) and hazard ratios (HRs) were adjusted for age and gender. The risk of SI in PsA vs RA patients was estimated in cox-regression models adjusted for age and gender, and corrected for multiple observations. The models were stratified by age < 50 vs ≥ 50 years, gender, DAS28-CRP remission (<2.6) vs non-remission at 3 months, and use of methotrexate as co-medication.

Results: A total of 3180 treatment courses on TNFi were identified (1780 RA and 1400 PsA) in 2368 patients (1356 RA and 1012 PsA) with 5697 person years at risk. The mean age in RA patients was 53.2 (SD 13.9), in PsA 48.2 (SD 11.9), p < 0.001. 1542 (65 %) were women. Mean disease duration in years in RA patients was 10.0 (SD 9.7) and 8.5 (SD 9.0) in PsA patients, with no significant difference in disease duration, p = < 0.001. There were 124 cases of SI in RA patients and 55 cases in PsA patients during treatment with a TNFi. The crude SI IRs were 4.00 (3.35, 4.76) in RA patients and 2.12 (1.63, 2.76) in PsA patients. Compared with RA patients, patients with PsA had a lower risk of SI (HR 0.64, 95 % CI 0.46-0.91) when adjusted for age and gender. The HR for females was (HR, p-value) (1.00, 0.97), age ≥ 50 was (1.80, 0.001), MTX co-medication (1.00, 0.99), DAS28-CRP >2.6 at 3 months was (1.20, <0.001) and for seropositives (0.95, 0.77).

Conclusion: In patients starting treatment with a TNFi, the risk of SI was significantly lower in patients with PsA, compared to patients with RA, when adjusted for age and gender. The incidence rate of SI was lower in patients aged < 50, and in patients in DAS28-CRP remission for both PsA and RA patients.

Table 1. IRs of SI in RA and PsA patients starting a TNFi Jan 2009 – Dec 2018. HRs for PsA compared to RA.

	RA (1780 treatment courses)			PsA (1400 treatment courses)		
	SI, n	PYR	IR (95 % CI)	SI, n	PYR	IR (95 % CI)
Overall SI	124	3105	4.00 (3.35, 4.76)	55	2592	2.12 (1.63, 2.76)
Female	91	2253	4.04 (3.29, 4.96)	27	1302	2.07 (1.42, 3.02)
Male	33	852	3.87 (2.75, 5.45)	28	1290	2.17 (1.50, 3.14)
Age, baseline	30	1122	2.67 (1.87, 3.82)	23	1497	1.54 (1.02, 2.31)
< 50	94	1983	4.74 (3.87, 5.80)	32	1095	2.92 (2.07, 4.13)
> = 50						
MTX comedication	94	2424	3.88 (3.17, 4.75)	38	1690	2.25 (1.64, 3.09)
Yes	30	681	4.40 (3.08, 6.30)	17	902	1.89 (1.17, 3.03)
No						
DAS28-CRP at 3 months	35	1234	2.84 (2.04, 3.95)	12	1174	1.02 (0.58, 1.80)
< 2.6	59	1193	4.94 (3.83, 6.38)	25	814	3.07 (2.07, 4.54)
> = 2.6						

Table 1. IRs of SI in RA and PsA patients starting a TNFi Jan 2009 – Dec 2018. HRs for PsA compared to RA.

	RA (1780 treatment courses)			PsA (1400 treatment courses)			HR (95% CI)
	SI, n	PYR	IR (95% CI)	SI, n	PYR	IR (95% CI)	
Serological status	64	1743	3.67	-	-	-	-
RA	60	1362	(2.87, 4.69)	-	-	-	-
Seropositive			4.40				
Seronegative			(3.42, 5.67)				

*DAS28-CRP < 2.6 = remission, PYR; Patient years at risk, MTX; Methotrexate, IR; Incidence rate

Figure 1. Age- and gender-adjusted risk of SI across RA and PsA

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AB0761

DEMOGRAPHIC AND CLINICAL FEATURES OF JUVENILE-ONSET PSORIATIC ARTHRITIS: RESULTS FROM PSART-ID REGISTRY

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Background: Although psoriatic arthritis (PsA) may be seen at any decades, juvenile onset PsA is relatively rare. Moreover, there were no more data about clinical features, treatments, and course in juvenile PsA when they reached to adult age.

Objectives: The objective of this study was to assess and compare demographic and clinical features for juvenile onset PsA and adult onset PsA.

Methods: PsART-ID is a multicenter, international database, investigating the disease characteristic in real life (1). Briefly, demographic data, PsA subtypes,

uveitis, enthesitis, dactylitis, Co-morbidities, disease activity scores (TJC, SJC, VAS-pain, VAS patients and physician global assessments, VAS-fatigue, BASDAI), and functional status (HAQ-DI, BASFI) were recorded. Psoriasis and PsA starting age were noted, as well. Patients were classified as juvenile PsA or juvenile PsO (under 18 years old). Results were compared regarding to juvenile versus adult onset age.

Results: Overall, 1644 PsA patients were included to study, 301/1644 (18.3%) patients had juvenile onset psoriasis. Of 39/1644 (2.4%) patients had juvenile onset PsA, as well. As expected, juvenile onset PsA patients were younger, however PsA disease duration were longer than adult onset PsA patients. There were no any difference between demographic and clinical data, except BMI and enthesitis were less frequently at the juvenile onset PsA groups. Although, ever csDMARD using were similar between two groups, however, juvenile onset PsA patients were used more frequently bDMARDs.

Table. Comparison of demographic and clinical characteristics of juvenile and adult-onset psoriatic arthritis

	Juvenile onset	Adult onset	p
N (%)	39 (2.4)	1605 (976)	
Female Sex n (%)	24 (61.5)	1006 (62.7)	0.884
PsA beginning age mean (SD)	13.3 ± 3.85	42.3 ± 12.9	<0.001
Current age mean (SD)	26.6 ± 10.7	47.3 ± 13.07	<0.001
Duration of psoriasis (years)	17.10 ± 11.26	14.75 ± 11.78	0.124
Duration of psoriatic arthritis (years)	13.5 ± 11	5.06 ± 6.7	<0.001
Cigarette smoking (ever) n (%)	15/38	641/1494	0.72
Education duration/year (mean,SD)	10.09 ± 3.67	9.52 ± 4.81	0.464
BMI (kg/m2) (mean, SD)	24.5 ± 5.1	28.3 ± 5.21	<0.001
Family history of PsO/PsA n (%)	15 (38.5)	559 (34.9)	0.642
Nail involvement n (%)	18 (46.2)	762 (47.5)	0.864
Dactylitis n (%)	9 (23.7)	367 (24)	0.958
Entesitis n (%)	3 (7.9)	384 (25.7)	0.013
Uveitis n (%)	-	13 (4.3)	0.713
Axial involvement (%)	15 (38.5)	464 (29)	0.199
Methotrexate	36 (92.3)	1348 (84)	0.162
Sulfasalazine	17 (43.6)	612 (38.1)	0.488
Leflunomide	14 (35.9)	379 (23.6)	0.076
Biologic DMARDs	102 (33.9)	358 (26.8)	0.013

Conclusion: Although psoriasis may be seen frequently in the juvenile age, juvenile onset PsA was not so frequent in our PsA cohort. Although, ever csDMARD using were similar between two groups, however, juvenile onset PsA patients were used bDMARDs more frequently.

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AB0762

METABOLIC SYNDROME IN EGYPTIAN PSORIATIC ARTHRITIS PATIENTS.

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Background: Psoriatic arthritis (PsA) is a chronic inflammatory arthritis affecting 20:30% of patients with skin Psoriasis (PsO). It is strongly associated with obesity, particularly excess visceral adiposity, which leads to insulin resistance, hyperglycemia, dyslipidemia, and hypertension (HTN).

All the previous findings are grouped in Metabolic Syndrome (MetS) which increase the risk of development of Type 2 diabetes mellitus (T2DM) by five folds and cardiovascular disease (CVD) by two folds.

Objectives: The aim of this work was to define those who fulfill MetS criteria in PsA patients thus of greater risk to develop CVD and T2DM.

Methods: Fifty PsA patients diagnosed according to the CASPAR criteria and 50 matched healthy controls were included in this study.