AB0753

COMPARING COMPOSITE MEASURES OF DISEASE ACTIVITY IN PSORIATIC ARTHRITIS: RESULTS FROM A RANDOMIZED PHASE 2 TRIAL WITH GUSELKUMAB

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Methods: In this Phase-2 trial, patients with active PsA (≥3 tender, ≥3 swollen joints, C-reactive protein ≥3 mg/L, ≥3% body surface area) were randomized 2:1 to subcutaneous GUS 100mg (n=100) or placebo (PBO, n=50) at Wks 0, Wk4, and every 8 wks through Wk44. At Wk16, patients with <5% improvement in swollen plus tender joints could early-escape placebo, regardless of composite index employed (Figure). Changes in SF-36 PCS score were consistent with disease activity at Wk24 in each PsA composite index in guselkumab-treated patients. The SMD, ES and SRM indicated that guselkumab elicited a substantial effect in treating the diverse manifestations of PsA compared with placebo, regardless of composite index employed (Figure). PASDAS and GRACE indices appeared to be more sensitive than mCPDAI and DAPSA in detecting changes upon treatment and distinguishing guselkumab treatment effects relative to placebo. Residual disease activities among guselkumab-treated patients who achieved low disease activity at Week24 based on each PsA composite index are summarized in the Table.

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AB0754

CLINICALLY MEANINGFUL IMPROVEMENT IN SKIN AND NAIL PSORIASIS IN BIO-NAİVE ACTIVE PSORIATIC ARTHRITIS PATIENTS TREATED WITH INTRAVENOUS GOLIMUBAB: RESULTS THROUGH WEEK 52 FROM A PHASE-3 STUDY

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Background: GO-VIBRANT is a Phase 3 trial of intravenous (IV) golimumab (GLM) in adult patients (pts) with active psoriatic arthritis (PsA). Clinically meaningful improvements in skin and nail psoriasis (PsO) and in Dermatology Life Quality Index (DLQI) that were significantly greater than placebo, regardless of composite index employed (Figure). IV GLM 2mg/kg at wks 0/4 & every 8 wks thereafter or PBO at wks 0/ 4/12/20 with crossover to GLM at wk24. Pts with ≥3% body surface area (BSA) psoriasis at baseline (BL) were assessed using Psoriasis Area and Severity Index (PASI, 0-72) of 75/90:100% improvement scale,
modified Nail Psoriasis Severity Index (mNAPSI, 0-130) in pts with mNAPSI >0 at BL and DLQI (0-30) scale.

Results: 394 pts (PBO:n=198; GLM:n=196) had >=3% BSA psoriasis at BL; 76.5% had mNAPSI>0 at BL(mean 18.6). Pts on IV GLM achieved a greater PASI 75 response rate (RR) vs PBO at wk24 (64.8% vs 13.1%, p<0.001). At wk52, PASI 75 RR was maintained in pts who continued IV GLM treatment and increased numerically in those who crossed-over from PBO to IV GLM at wk24 (71.9% and 60.6%, respectively). At wk24, pts on IV GLM achieved significantly greater PASI 90/100 RR vs PBO. At wk52, PASI 90/100 RR was maintained among those continually on IV GLM and increased numerically in PBO to IV GLM pts(Table). At wk24, significantly greater proportions of pts on IV GLM ± BL methotrexate (MTX) achieved PASI 90/100 vs PBO. By wk52, both ± BL MTX, PASI 90/100 responses were maintained in those continually on IV GLM and increased numerically in PBO to IV GLM pts (Table). The mean decrease (improvement) from BL in the mNAPSI score was also greater with IV GLM vs PBO at wk24, overall and in groups ± BL MTX. At wk52, mNAPSI RR was maintained with continual IV GLM and increased numerically in PBO to IV GLM pts. At wk24, the mean decrease (improvement) from BL in DLQI was greater with IV GLM vs PBO at wk24, overall and in groups ± BL MTX. At wk52, mean DLQI improvement was maintained in pts continually on IV GLM and increased numerically in PBO to IV GLM pts (~7.8 vs ~5.8). Similar patterns were seen in subgroups ± BL MTX. In pts with DLQI improvement >1 at baseline, rate of simultaneous achievement of both PASI 50 response & improvement in DLQI was maintained from 24 to 52 weeks of treatment.

Conclusion: Clinically meaningful improvements in skin and nail psoriasis and psoriasis quality of life after IV GLM treatment of PsA pts were maintained from 24 to 52 weeks of treatment.

REFERENCES


AB0755

REGIONAL AND TEMPORAL VARIATION IN THE BASELINE PROFILE OF PSORIATIC ARTHRITIS PATIENTS INITIATING ADALIMUMAB FOLLOWING FAILURE OF NON-BIOLOGIC TREATMENT IN CANADIAN ROUTINE CARE

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Background: Treatment selection in routine clinical care is driven by treatment guidelines, physician judgment, patient preferences, and regional reimbursement policies, which may vary over time and among geographic regions.

Objectives: The objective of this analysis is to investigate the regional and temporal variability of the profile of anti-TNF naïve psoriatic arthritis (PsA) patients at initiation of adalimumab (ADA) treatment following failure of initial non-biologic treatment.

Methods: COMPLETE-PsA is an ongoing Canadian observational study of adalimumab-treated PsA adults with active PsA who require change in their current treatment as per the judgement of their treating physician. Patients are followed for up to 2 years. Regional variation was assessed for the following regions: British Columbia/Manitoba (BC/MB), Newfoundland/Nova Scotia (NL/NS), Ontario (ON), and Quebec (QC). Temporal variation was assessed for the following periods: 2012-2014 and 2015-2017. Multivariate linear regression was used to evaluate the independent impact of region and time period on disease activity (DAS28) and patient function (HAQ).

Results: A total of 278 patients were included, of whom 68 (24.5%), were from BC/MB, 25 (9%) from NL/NS, 104 (37.4%) from ON, and 81 (29.1%) from QC. One hundred fifty-three patients (55%) were enrolled in 2012-2014 and 125 (45%) in 2015-2017.

Using univariate analysis, significant regional variation at ADA initiation was observed for the following disease parameters: BSA-% (from 42.3% in ON to 76% in NL/NS; p=0.003), morning stiffness (from 60.9 min in QC to 119.7 in BC/MB; p=0.049), WLO productivity loss score (from 8.4% in BC/MB to 12.9% in NL/NS; p=0.028), and DLQI (from 3.5 in NL/NS to 7.9 in ON; p=0.007); and for the initiation of ADA monotherapy vs. ADA combination therapy (range from 9.9% in QC to 27.9% in ON; p=0.022). No differences were observed in demographics (other than race: Caucasian range from 85% to 100%; p=0.006), or other disease parameters (DAS28, HAQ, SJC, TJC, DAPSA, PIGA, BDI). A statistical trend towards lower DAS28 (2012-14 vs. 2015-17: 4.9 vs. 4.6; p=0.070), SJC (8.3 vs. 6.4; p=0.001), TJC (9.5 vs. 8.1; p=0.074), and DAPSA (10.8 vs. 27.8; p=0.080) at ADA initiation was observed in the more recent time period. Using multivariate analysis, to adjust for age, gender, BSA levels, and corticosteroid use, there was no regional or temporal variation in DAS28 and HAQ.

Conclusion: The results of this analysis demonstrate that there is significant regional and temporal variation in the profile of PsA patients initiated on ADA treatment in Canadian routine care. The impact of this profile variation on treatment outcomes requires further investigation.

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