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PROMIS ASSESSMENT OF RESPONSE TO TREATMENT WITH GOLIMUMAB IV OR INFLIXIMAB IN RHEUMATOID ARTHRITIS PATIENTS: RESULTS FROM THE PHASE-4 AWARE STUDY

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Background: AWARE is a phase-4 observational study designed to provide real-world assessment of Golimumab (GLM) IV & infliximab (IFX) in patients (pts) with rheumatoid arthritis (RA).

Objectives: To assess patient-reported aspects of social, mental, & physical health through the 8th infusion (~1 year of treatment) using Patient Reported Outcomes Measurement Information System (PROMIS), a validated, disease-agnostic set of health assessment instruments.

Methods: AWARE enrolled 1270 RA pts initiating treatment with GLM/IFX. The 52 week analysis set included pts with ≥1-year treatment or those discontinued and, while enrolled, completed PROMIS-29 or PROMIS short form (SF) questionnaires. PROMIS instruments were administered at baseline & prior to infusions 2, 5, & 8. The raw score was converted into a standardized T-score with a mean of 50 and SD of 10.

Results: At baseline, treatment groups were balanced on demographics & medical characteristics. Most pts were white (87.0% GLM, 86.2% IFX)

& female (83.4% GLM, 82.4% IFX). Mean ages were 58.5 ±12.96 years for GLM & 59.6 ±13.24 years for IFX. Overall, 35.3% GLM & 42.9% IFX pts were bio-naïve. The proportion of GLM & IFX pts with prior exposure to 1 or 2 biologics was similar; however, 20.1% GLM pts vs 10.8% IFX pts had exposure to ≥3 biologics. Methotrexate use was similar between GLM (76.4%) & IFX pts (75.0%). Based on mean PROMIS T-scores at baseline (Table 1), Fatigue, Pain Interference, & Physical Function domains approached or exceeded 1 SD worse than those of general US population. Through the 8th infusion, GLM- & IFX-treated pts achieved meaningful improvement based on mean changes from baseline in most PROMIS-29 domains & respective SFs with no significant difference between GLM and IFX. The percentage of GLM or IFX pts with improvements of ≥3, ≥5, or ≥10 units change in T-scores increased from infusion 2 through infusion 8.

Conclusion: RA pts treated with GLM or IFX achieved comparable improvements across PROMIS-assessed social, mental, & physical health. PROMIS-29 was able to detect change to subsequent anti-tumor necrosis factor-α therapies.

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Table 1. Mean (SD) Change from Baseline PROMIS-29 Domain and Short Form T-Scores: 52 Week Analysis Set

	GLM	IFX	LSM difference (95% CI)*
Anxiety (4-item)	N=6	N=570	
Baseline	53.4 (10.13)	54.6 (10.53)	
Change from baseline at infusion 8	N=223 -2.6 (8.10)	N=286 -3.7 (7.86)	-0.29 (-1.54, 0.97)
Depression (4-item)	N=674	N=574	
Baseline	51.9 (9.83)	52.5 (10.21)	
Change from baseline at infusion 8	N=225 -2.1 (7.56)	N=287 -2.3 (7.89)	0.49 (-0.72, 1.70)
Fatigue (4-item)	N=671	N=574	
Baseline	58.4 (9.91)	59.4 (9.99)	
Change from baseline at infusion 8	N=225 -3.4 (8.72)	N=281 -3.1 (7.77)	0.69 (-0.64, 2.03)
Short form Fatigue 7a	N=681	N=576	
Baseline	59.1 (8.51)	59.7 (8.25)	
Change from baseline at infusion 8	N=228 -3.2 (7.40)	N=287 -2.4 (6.35)	1.01 (-0.11, 2.14)
Pain interference (4-item)	N=679	N=574	
Baseline	63.0 (7.56)	63.9 (7.80)	
Change from baseline at infusion 8	N=227 -4.2 (8.23)	N=284 -3.1 (7.77)	1.84 (0.55, 3.13)
Short form Pain interference 6b	N=680	N=576	
Baseline	61.9 (7.45)	62.8 (7.54)	
Change from baseline at infusion 8	N=228 -3.8 (7.88)	N=287 -3.2 (6.67)	1.31 (0.15, 2.48)
Physical function (4-item)	N=678	N=571	
Baseline	38.2 (6.79)	38.0 (6.90)	
Change from baseline at infusion 8	N=224 2.2 (5.64)	N=283 1.9 (5.85)	-0.76 (-1.73, 0.21)
Sleep disturbance (4-item)	N=671	N=569	
Baseline	54.6 (8.72)	N=55.5 (8.61)	
Change from baseline at infusion 8	N=221 -1.4 (7.45)	N=281 -1.7 (7.61)	0.23 (-0.96, 1.42)
Social participation (4-item)	N=673	N=574	
Baseline	43.7 (8.40)	42.9 (8.77)	
Change from baseline at infusion 8	N=225 3.2 (8.15)	N=283 3.4 (7.48)	-0.10 (-1.36, 1.16)

*Least squares mean (LSM) difference & confidence interval (CI) are based on analysis of covariance controlling for baseline PROMIS score using inverse probability of treatment weighted propensity score.