



SAT0366 IMPROVEMENT IN PSORIATIC ARTHRITIS, INCLUDING ARTHRITIS SYMPTOMS AND PHYSICAL FUNCTION WITH ETANERCEPT IN PATIENTS WITH PSORIASIS AND PSORIATIC ARTHRITIS (PRESTA TRIAL)

S. Schewe^{*1}, J. Prinz¹, L. Puig², R. Burgos-Vargas³, R. Boggs⁴, D. Robertson⁴, R. Pedersen⁴, **C. Molta⁴**, B. Freundlich⁴

¹Abteilung Rheumatology, Ludwig-Maximilian-Universitaet, Munchen, Germany, ²Dermatology, Universitat Autònoma de Barcelona, Barcelona, Spain, ³Rheumatology Department, Universidad Nacional Autónoma de México, Mexico City, Mexico, ⁴Global Medical Affairs, Wyeth, Collegeville, United States

Background: Etanercept (ETN) 25 mg twice wkly (BIW) (or 50 mg once-wkly [QW]) has demonstrated significant benefit in psoriasis (PsO) and both skin and joint manifestations of psoriatic arthritis (PsA) subjects. Although ETN at an induction dose of 50 mg BIW is more effective than 50 mg QW in treating PsO, it has not been previously evaluated in PsA subjects.

Objectives: Assess the efficacy of 2 ETN regimens on the PsA response criteria (PsARC), arthritic symptoms, and physical function of subjects with PsO and PsA over 24 wks.

Methods: A 12-wk randomised double-blind study, followed by a 12-wk open-label extension; subjects received ETN 50 mg BIW or 50 mg QW during the double-blind period followed by 50 mg QW during the open-label period. Eligibility criteria included: age >18 y; stable, moderate-to-severe plaque Pso and PsA, with >=10% body surface area (BSA) affected; Physician Global Assessment (PGA) of PsO status of moderate or worse (>=3 on a scale of 0-5); and >=2 swollen/painful joints. Arthritis endpoints assessed were change from baseline in PGA of arthritis and subject global assessments (SGA) of joint pain, arthritis activity, and stiffness at wks 12 and 24; physical function was assessed using the Health Assessment Questionnaire (HAQ). Last-observation-carried-forward (LOCF) was used for imputation of missing values.

Results: At baseline, subjects (n=752) had a mean age 47 y, were 63% male, 89% white and had a mean BMI of 28. Mean duration of PsO and PsA was 19 and 7 years, respectively; mean PGA of PsO was 3.6 (median=4.0), and BSA 30.8%. Baseline arthritis PGA, HAQ and SGA of joint pain, arthritis activity, and stiffness were not different between the 2 groups (Table). The % of PsO PGA responders (clear or almost clear) at Wk 12, was 46% for the ETN 50 mg BIW group vs 32% for the 50 mg QW group (P<0.001); at Wk 24 they were 56% vs 50%, respectively (P=0.104). For PGA of arthritis, HAQ and SGA of joint pain, arthritis activity, and stiffness, within-group improvements from baseline for the 2 regimens were significant (p<0.001) at 12 and 24 wks; between-group differences were not (table). In the ETN 50 mg BIW group, 76.6% were PsARC responders at week 12 vs. 76.0% in the ETN 50 mg QW group (p=0.264). At wk 24 PsARC responders were 81.5% and 80.4% respectively (p=0.722).

Table:

Key Arthritis and Physical Function Assessments at Weeks 12 and 24

Endpoint	ETN 50 mg BIW/ N=379			ETN 50 mg QW N=373		
	Wk 0	Wk 12 Mean score (% Improvement)	Wk 24	Wk 0	Wk 12 Mean score (% Improvement)	Wk 24
PGA of arthritis	50.6	18.7 (63.0)	13.5 (73.3)	49.9	19.0 (62.0)	13.2 (73.7)
HAQ	0.9	0.5 (46.7)	0.44 (51.1)	0.93	0.49 (47.3)	0.43 (53.8)
SGA						
Joint pain	63.2	27.9 (55.7)	27.0 (57.1)	61.9	30.5 (50.8)	25.4 (59.0)
Arthritis activity	63.9	27.9 (56.4)	26.9 (58.0)	61.7	28.5 (53.8)	25.1 (59.3)
Stiffness	143.5	53.6 (62.8)	51.8 (64.0)	141.0	49.1 (65.3)	44.2 (68.7)

Conclusion: Etanercept 50 mg BIW for 12 wks followed by 50 mg QW for 12 wks was associated with similar improvements when compared with etanercept 50 mg QW for 24 weeks as assessed by the PsARC and assessments of arthritis symptoms in subjects with both PsO and PsA. Each regimen effectively improved the arthritis symptoms in these subjects. If rapid skin clearing is required, then initial treatment with etanercept 50 mg BIW may offer additional benefit.

Disclosure of Interest: SS: None declared; JP: Ad board Wyeth, Biogen-Idec, Novartis, Merk-Serono, Essex-Pharma, Galderma, Centocor, Abbott; LP: Consultant, speaker, Wyeth; RB-V: Ad board Wyeth, Roche, BMS, Schering-Plough, Pfizer, Abbott; RB, DR, RP, CM, BF: Wyeth employees