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LB0006 SUBCUTANEOUS SECUKINUMAB 300MG AND 150MG PROVIDES SUSTAINED INHIBITION OF RADIOGRAPHIC PROGRESSION IN PSORIATIC ARTHRITIS OVER 2 YEARS: RESULTS FROM THE PHASE 3 FUTURE-5 TRIAL

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Background: Secukinumab (SEC) provided sustained clinical efficacy, and inhibition of radiographic progression over 52 Weeks (Wks) in patients (pts) with psoriatic arthritis (PsA) in the FUTURE 5 study[1].
Objectives: To report the effect of SEC on radiographic progression at Wk 104 (2 years) in PsA pts in the FUTURE 5 study.
Methods: Adults (N=996) with active PsA, stratified by prior anti-TNF therapy (naïve and inadequate response/intolerance [IR]) were randomised 2:2:2:3 to subcutaneous SEC 300mg with loading dose (LD; 300mg), 150mg LD (150mg), 150mg no LD, or placebo at baseline (BL), Wks 1, 2, 3, 4, and every 4 wks thereafter. Pts could have SEC dose escalated from 150 to 300 mg starting from Wk 52, based on physicians' judgement. Data are shown for pts originally randomised to SEC; 150mg groups include pts who had dose escalated to 300mg. Concomitant MTX (≤25 mg/week) was allowed. Radiographic progression (mean change in van der Heijde-modified total Sharp score [vdH-mTSS] and its components: erosion and joint space narrowing [JSN] scores, was based on hand/wrist/foot X-rays obtained at BL and Wk 104, and assessed by two blinded readers (plus an adjudicator if required). Other efficacy endpoints included ACR20/50, PASI90 and resolution of dactylitis and enthesitis.

Table. Summary of Efficacy Results

Mean change in vdH-mTSS scores from BL to Wk 104 (BL score)			
	300mg N=222 n=191	**150mg group* N=220 n=181**	**150mg no LD group* N=222 n=169**
vdH-mTSS	0.37 (12.07)	0.52 (11.47)	0.41 (13.99)
Erosion	0.27 (7.15)	0.27 (6.67)	0.38 (8.07)
JSN	0.11 (4.92)	0.24 (4.79)	0.03 (5.92)
Clinical responses at Wk 104 (% responders [n])			
	300 mg N = 222	**150 mg group* N = 220**	**150 mg no LD group* N = 222**
ACR20	77.0 (187)	79.4 (175)	78.0 (168)
ACR50	51.9 (187)	52.6 (175)	57.7 (168)
PASI90[1]	70.1 (97)	59.2 (103)	62.6 (91)
Resolution of enthesitis[2]	78.0 (118)	80.3 (117)	69.5 (95)
Resolution of dactylitis[3]	82.8 (64)	85.5 (62)	89.3 (75)

Observed data

*150mg and 150mg no load arms include 86 and 92 pts, respectively, who were dose escalated at Wk 52 or later.

N, number of pts randomised; n, number of pts with data at BL and Wk 104.

Data from pts with: [1]BL psoriasis ≥3% body surface area, [2]enthesitis at BL, [3]dactylitis at BL

Results: Overall, 84.7% (300mg), 82.3% (150mg) and 75.2% (150mg no LD) pts completed 2 years of treatment. A total of 86 (39%) and 92 (41%) pts had their dose escalated to 300mg in the 150mg and 150mg no LD groups, respectively. Inhibition of radiographic progression was sustained with SEC through 2 years (Table 1). Proportions of pts with no radiographic progression (change from BL in mTSS ≤0.5) with SEC were 89.5% (300 mg), 82.3% (150 mg), and 81.1% (150 mg no LD) at 2 years; corresponding proportion of pts for change from BL in mTSS ≤0.0 were: 81.2%, 69.1% and 73.4%, respectively. Clinical responses were also sustained through 2 years (Table 1).
Conclusion: Subcutaneous secukinumab provided sustained inhibition of radiographic progression and sustained clinical responses through 2 years of treatment in pts with active PsA.

REFERENCE

[1] Mease PJ *et al. Arthritis Rheumatol* 2018;70(suppl 10).

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LB0007 SUBCUTANEOUS TANEZUMAB FOR OSTEOARTHRITIS PAIN: A 24-WEEK PHASE 3 STUDY WITH A 24-WEEK FOLLOW UP

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Background: Tanezumab, a monoclonal antibody against nerve growth factor, is in development for treatment of osteoarthritis (OA) pain.
Objectives: To assess efficacy and safety of tanezumab in patients with moderate to severe OA pain who have not responded to or cannot tolerate standard of care analgesics.
Methods: A randomized, double-blind, placebo-controlled study (24 week treatment; 24 week follow-up) was conducted in patients in Europe and Japan with moderate to severe OA pain of the knee or hip and history of insufficient pain relief or intolerance to acetaminophen, oral nonsteroidal anti-inflammatory drug, and either tramadol or opioids (or unwilling to take opioids). Patients received subcutaneous tanezumab (2.5 or 5 mg) or placebo at baseline, week 8, and week 16. Co-primary endpoints were change from baseline in Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) Pain, WOMAC Physical Function, and Patient Global Assessment of OA (PGA-OA) scores at week 24. Safety, including independent adjudication of joint safety events, was assessed.
Results: Tanezumab 5 mg met all co-primary endpoints (Fig. 1). Tanezumab 2.5 mg met WOMAC Pain and Physical Function endpoints but not the PGA-OA endpoint; thus, this dose did not meet pre-specified efficacy criteria. The occurrence