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LB0001

DUAL NEUTRALISATION OF IL-17A AND IL-17F WITH BIMEKIZUMAB IN PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS (AS): 12-WEEK RESULTS FROM A PHASE 2B, RANDOMISED, DOUBLE-BLIND, PLACEBO-CONTROLLED, DOSE-RANGING STUDY

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Background: Dual neutralisation of IL-17F, in addition to IL-17A, reduces inflammation¹ to a greater extent than inhibition of IL-17A alone in disease-relevant cell models. Bimekizumab, a monoclonal antibody that potently and selectively neutralises both IL-17A and IL-17F, provided rapid and substantial clinical improvements in studies evaluating patients with psoriasis² and psoriatic arthritis.¹

Objectives: Assess 12 week efficacy and safety of bimekizumab in patients with active AS; the primary objective was to assess the ASAS40 dose-response relationship at Week 12.

*p<0.05, **p<0.001; calculated from a logistic regression model including fixed effects for treatment, geographic region and prior anti-TNF exposure
A: non-responder imputation, full analysis set; B: observed data, full analysis set

Abstract LB0001 – Figure 1 A) non-responder imputation, full analysis set; B) observed data, full analysis set

Methods: In this ongoing 48 week study (NCT02963506: double blind to Week 12 then dose blind to Week 48), 303 patients with active (BASDAI ≥ 4 ; spinal pain ≥ 4 [0–10 numerical rating scale]) AS, fulfilling the modified New York criteria, were randomised 1:1:1:1:1 to receive subcutaneous bimekizumab 16 mg, 64 mg, 160 mg, 320 mg or placebo Q4W, for 12 weeks. Prior exposure to 1 anti-TNF therapy was permitted. The primary endpoint was ASAS40 response rate at Week 12. Secondary endpoints (ASAS20 and ASAS5/6 response rate and change from baseline in BASDAI and ASDAS-CRP at Week 12) and safety were also assessed.

Results: Overall, 297 (98.0%) patients completed the 12 week double-blind period. The majority of patients were male (84.5%) with a mean (SD) age of 42.2 (11.8) and median (min, max) symptom duration of 13.3 (0.3, 48.2) years; baseline characteristics were similar among treatment groups (median [min, max] hs-CRP: 12.1 [0.3, 130.6] mg/L; mean [SD] BASDAI: 6.5 [1.4]; ASDAS-CRP: 3.9 [0.8]; prior anti-TNF exposure: 11.2%). At Week 12, there was a significant (p<0.001) dose-response for ASAS40. A greater percentage of bimekizumab-treated patients achieved ASAS40 (primary endpoint) than placebo (Figure: p<0.05, all doses). More patients receiving bimekizumab than placebo also achieved ASAS20 (figure 1; p<0.05, 64 mg–320 mg doses) and ASAS5/6 (16mg: 29.5%; 64 mg: 39.3%; 160 mg: 50.0%; 320 mg: 52.5%; placebo: 5.0%; p<0.05, all comparisons). Compared with placebo, greater reductions from baseline were achieved with bimekizumab for both BASDAI (figure 1) and ASDAS-CRP (LS mean [SE] change from baseline: 16 mg: –1.0 [0.15]; 64 mg: –1.6 [0.15]; 160 mg: –1.4 [0.16]; 320 mg: –1.5 [0.16]; placebo: –0.4 [0.16]; p<0.001, all doses). The overall incidence of TEAEs was 86/243 (35.4%) for bimekizumab-treated patients versus 22/60 (36.7%) for placebo. No unexpected safety risks were observed; the most frequently reported events were nasopharyngitis and headache.

Conclusions: The primary and key secondary objectives were achieved; dual neutralisation of IL-17A and IL-17F with bimekizumab provided clinically meaningful improvements in disease outcome measures. No new safety signals were observed versus previous studies.^{1,2}

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WEDNESDAY, 13 JUNE 2018

Doctor, how bad will my rheumatoid become? RA – prognosis, predictors and outcomes

OP0038

DOSE TAPERING AND DISCONTINUATION OF BIOLOGICAL THERAPY IN RHEUMATOID ARTHRITIS PATIENTS IN REMISSION IN ROUTINE CARE – 2-YEAR OUTCOMES AND IDENTIFICATION OF PREDICTORS

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Background: A cohort of routine care rheumatoid arthritis (RA) patients in sustained remission had biological disease-modifying anti-rheumatic drugs (bDMARDs) tapered according to a treatment guideline. Little is known about predictors of successful tapering and discontinuation of bDMARDs.

Objectives: We studied: 1) the proportion of patients whose bDMARD could be successfully tapered or discontinued; 2) unwanted consequences of tapering/discontinuation; 3) potential baseline predictors of successful tapering and discontinuation.