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

Methods: In this ongoing 48 week study (NCT02963506; double blind to Week 12; single blind to Week 48), 303 patients with active AS (moderate or severe back pain (>4/10 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 (10.1) years 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<0.005, 64 mg–320 mg doses) and ASAS30 (16 mg: 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 22/90 (24.4%) 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

REFERENCES:

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