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A phase Ib/IIa study of the anti-ST2 monoclonal antibody 9MW1911 in former smokers with moderate-to-severe COPD

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Background: 9MW1911 targets ST2 (the IL-33 receptor) and is designed to inhibit the inflammatory cascade associated with the IL-33/ST2 pathway. Its potential to reduce acute exacerbations in COPD remains to be evaluated.

Aims: This phase Ib/IIa randomized, double-blind, placebo-controlled study evaluated the pharmacokinetics, safety, tolerability, and preliminary efficacy of 9MW1911 in former smokers with moderate-to-severe COPD.

Methods: Subjects were randomized 3:1 to receive intravenous 9MW1911 or matching placebo. In the multiple-ascending-dose phase, subjects received 9MW1911 100, 300, 600, and 900 mg every 4 weeks, with 8 subjects per cohort (6 active:2 placebo). In the subsequent dose-cohort expansion phase, an additional 24 subjects were enrolled into each of the 300 mg and 600 mg cohorts under the same 3:1 randomization (18 active:6 placebo). The study comprised a 24-week treatment period followed by a 12-week safety follow-up.

Results: 80 subjects were included in the safety analysis (9MW1911, n=60; placebo, n=20). TEAEs were reported in 70.0% (42/60) of subjects receiving 9MW1911 and 85.0% (17/20) receiving placebo. The most common TEAE was upper respiratory tract infection (18.3% in 9MW1911 vs. 25.0% in placebo). No ADA was detected. C_{max} and AUC increased more than dose-proportionally across the 100–900 mg dose range, but were approximately dose-proportional within 300–900 mg. Compared with placebo, moderate-to-severe AECOPD events were numerically lower in subjects receiving 9MW1911 600 mg and 900 mg.

Conclusions: 9MW1911 was generally well tolerated, demonstrated approximately dose-proportional exposure across 300–900 mg, and showed preliminary efficacy signals versus placebo, supporting further clinical evaluation.