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Late Breaking Abstract - Selective TRPA-1 antagonist in patients with chronic cough and idiopathic pulmonary fibrosis: A phase IIa/IIb randomized, double-blind, placebo-controlled study (BI 1839100)

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Introduction: Chronic cough is a burdensome and often refractory symptom in idiopathic pulmonary fibrosis (IPF) with limited therapeutic options. We evaluated BI1839100, a selective oral TRPA1 inhibitor, in IPF-related cough.

Methods: Adults with IPF-related cough were enrolled in a Phase IIa/IIb trial of 4 and 12-week duration, respectively. The primary endpoint was 24-hour (h) cough count (CC) at Week 4 and 12. Secondary and further endpoints included cough severity visual analogue scores (VAS), FVC, daytime and cough-bout analyses and safety.

Results: Of 85 randomized patients, 28 received high dose BI 1839100, 150 mg BID, and 29 placebo (PBO); 26 and 27 completed treatment, respectively. Median baseline cough burden was ~20 coughs/h. Relative CC/h change from baseline for the 150 mg BID dose at Week 4 was -5.7% (**Figure**). Following a prespecified interim analysis for Phase IIa, the trial was terminated for futility. At Week 12, the 150 mg BID dose showed a 45.5% 24-h CC reduction vs PBO. Daytime CC and cough bouts were also reduced vs PBO (–48.8% vs –18.6%, and –36.8% vs 17.9%, respectively; **Figure**). Cough severity VAS numerically improved over time (**Figure**). No effect on FVC was observed. BI1839100 showed acceptable safety.

Discussion: While the primary endpoint was not met at Week 4, BI1839100 showed clinically meaningful reductions in CC by Week 12. The slower onset of effect may reflect neuroplastic or fibro-inflammatory remodeling, supporting further study of TRPA1 inhibition in IPF-related cough.