ERS CONGRESS | 2026
5-9 September | Barcelona, Spain

Late Breaking Abstract - A Dose-Ranging Study of the Novel PDE3/4 Inhibitor HSK39004 in Patients with COPD Receiving Maintenance Single or Dual Bronchodilators

F. Luo (Chengdu, China), Z. Luo (Chengdu, China), L. He (Chengdu, China), L. Yang (Chengdu, China)

Background

HSK39004 dry powder inhalation (DPI) is a novel PDE3/4 inhibitor DPI and designated a breakthrough therapy for chronic obstructive pulmonary disease (COPD) by the Center for Drug Evaluation of China.

Methods

This phase 2 study is the first clinical investigation of the novel PDE3/4 DPI combined with single/dual bronchodilators, evaluating HSK39004 in Chinese COPD patients (NCT07108699). The primary endpoint was ΔFEV_1 $AUC_{0-12}h$ (area under the curve of change from baseline in $FEV_1$from 0 to 12 hours post-dose) at Week 4.

Results

A total of 195 patients (90 on single bronchodilator, 105 on dual bronchodilators) were randomized 1:1:1 to HSK39004 0.75 mg or HSK39004 1.5 mg or placebo for 4 weeks. At Week 4, both doses significantly improved ΔFEV_1 $AUC_{0-12}h$ versus placebo; differences were 116 mL (0.75 mg) and 127 mL (1.5 mg), respectively.

Subgroup analysis revealed significant improvements with both doses in patients on single bronchodilators (164 mL, 189 mL) and, importantly, also in those on dual bronchodilators (74 mL, 75 mL).

No treatment-related adverse events (TRAEs) occurred in the 0.75 mg group. The TRAE rate was 6.1% in the 1.5 mg group, lower than that of placebo (7.9%).

Interpretation

HSK39004 DPI showed consistent efficacy and favorable safety, with efficacy demonstrated in a broad patient population. These results support further clinical development of HSK39004 for COPD. It is expected to become the first marketed PDE3/4 DPI, offering a new therapeutic option for a wider population of patients.