Late Breaking Abstract - A phase 2, dose-finding study of inhaled itraconazole in ABPA-complicating asthma (ERS 2025)

R. Agarwal (Chandigarh, India), D. Chaudhry (Rohtak, India), S. Gupta (Lucknow., India), R. Dhar (Kolkata., India), P. Ranganadin (Puducherry, India), R. Kumar (New Delhi, India), A. Mohan (New Delhi, India), J. Bajpai (Lucknow, India), R. Davis (Thrissur, India), S. Jadhav (Mumbai, India), A. Vaidya (Mumbai, India), S. Chhowala (Mumbai, India), S. Sawant (Mumbai, India), J. Gogtay (Mumbai, India)

Background: Oral itraconazole use in allergic bronchopulmonary aspergillosis (ABPA) is limited by suboptimal pharmacokinetics, drug interactions, and adverse effects (AEs). PUR1900, a novel dry powder inhaled formulation of itraconazole, enables targeted lung delivery. Herein, we evaluated the efficacy and safety of PUR1900.

Methods: We conducted a phase 2, randomized, double-blind, placebo-controlled trial including subjects with ABPA-complicating asthma. Participants received PUR1900 (20 or 40 mg) or placebo (2:2:1) once daily for 16 weeks. Efficacy endpoints included FEV1, asthma control (ACQ-7), serum total IgE, and quality of life (AQLQ).

Results: Forty-three subjects (mean age 40.2 years) received PUR1900 20 mg (n=18), 40 mg (n=16), or placebo (n=9). Baseline pre-dose FEV1% was 63.5±10.2 predicted; serum total IgE was 4469±55 kU/L. At week 16, PUR1900 40 mg significantly improved FEV1, reduced IgE, and achieved clinically meaningful improvement in ACQ-7 (Table). AQLQ improvement was not statistically significant. The frequency and severity of AEs were comparable across groups.

	Placebo-adjusted effect at week 16	
	PUR1900 20 mg	**PUR 1900 40 mg**
Predose FEV1 (L)	0.17 (-0.07, 0.40) p=0.15	0.28 (0.02, 0.53) p=0.03
IgE (KU/L)	431.27 (-250.14, 2112.68) p=0.88	-2010.42 (-3633.23, -387.61) p=0.05
ACQ-7	-0.24 (-0.68, 0.20), p=0.2790	-0.51 (-0.97, -0.06), p=0.0295
AQLQ	0.17 (-0.28, 0.61), p=0.45	0.06 (-0.41, 0.52), p=0.79
Data presented as least square mean, 95% confidence intervals; p value vs placebo.		

Conclusions: PUR1900 (40 mg) significantly improved lung function, asthma control, and IgE levels in adults with ABPA, with a favourable safety profile.