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

Late Breaking Abstract - Clinical improvement with ralinepag in a contemporary pulmonary arterial hypertension population: Insights from the ADVANCE Outcomes study

M. Humbert (Le Kremlin-Bicêtre, France), D. Solum (Research Triangle Park, United States), A. Ataya (Gainesville, United States), J. Barbera (Barcelona, Spain), G. Bohns Meyer (Porto Alegre, Brazil), C. Botta (Sante Fe, Argentina), C. Church (Glasgow, United Kingdom), J. Elwing (Cincinnati, United States), J. Feenstra (Queensland, Australia), P. George (Denver, United States), S. Chang (Seoul, Republic of Korea), T. Low (Singapore, Singapore), Z. Safdar (Houston, United States), D. Cella (Research Triangle Park, United States), C. Deng (Research Triangle Park, United States), D. Yehle (Research Triangle Park, United States), V. Lacasse (Research Triangle Park, United States), L. Peterson (Research Triangle Park, United States), V. McLaughlin (Ann Arbor, United States)

Background

Pulmonary arterial hypertension (PAH) is a progressive disease leading to right ventricular failure and death. Treatment options have improved but the mortality rate remains high. Ralinepag is an oral, potent, once-daily prostacyclin (IP) receptor agonist to treat PAH.

Methods

ADVANCE Outcomes was a global, randomized, placebo-controlled, study to assess ralinepag in participants with PAH. The primary end point was the time to first clinical worsening event. Key secondary end points were change in N-terminal pro-B-type natriuretic peptide (NT-proBNP), 6MWD, and clinical improvement (an absence of clinical worsening and at least 2 of 3 criteria [increase in 6MWD by ≥10% or ≥30 m, improvement to or maintenance of WHO FC I or II, or decrease in NT-proBNP ≥30% from baseline]).

Results

687 participants were randomized (350 ralinepag; 337 placebo). Most (79.8%) were receiving dual background therapy and 70.5% were FC II with a mean (SD) 6MWD of 439 (105) m.

The study showed ralinepag reduced the risk of a clinical worsening event by 55% compared with placebo (hazard ratio 0.45, 95% CI [0.33-0.62]; P<0.001). At Week 28, participants had a 47% greater odds of achieving clinical improvement (P=0.015) and ralinepag treatment resulted in significant reductions in NT-proBNP (24.3% over placebo; 95% CI [-36.1%, -10.3%]; P=0.001) and an increase in 6MWD (20.4 m placebo-corrected difference; 95% CI [6.81, 34.02]; P=0.003).

Ralinepag treatment was generally well tolerated, and no new safety signals were observed.

Conclusions

Ralinepag resulted in a significant 55% reduction in the risk of clinical worsening and 47% greater odds of

achieving clinical improvement. The results underscore the durable efficacy of ralinepag in a lower risk, pretreated, and contemporary PAH population.
