

IMPACT OF RIOCIQUAT ON HEALTH-RELATED QUALITY OF LIFE (HRQOL) IN PATIENTS (PTS) WITH CHRONIC THROMBOEMBOLIC PULMONARY HYPERTENSION (CTEPH)

NH Kim,¹ HA Ghofrani,^{2,3} F Grimminger,² MM Hoeper,⁴ E Mayer,⁵ G Simonneau,⁶ A Fritsch,⁷ N Davie,⁷ B Luong,⁷ MR Wilkins.³

¹UCSD School of Medicine, USA; ²University of Giessen and Marburg Lung Center, Germany; ³Imperial College London, UK; ⁴Hannover Medical School, Germany; ⁵Kerckhoff Heart and Lung Center, Germany; ⁶University Paris-Sud, France; ⁷Bayer HealthCare, Germany.

Objective: The CHEST-1 study showed clinical efficacy of riociguat in pts with inoperable CTEPH or persistent/recurrent CTEPH after pulmonary endarterectomy. Here, we evaluate the impact of riociguat on HRQoL in pts with CTEPH.

Methods: CHEST-1 was a 16-week, double-blind, randomized, placebo (pbo)-controlled study. The pulmonary arterial hypertension (PAH) disease-specific (Living with Pulmonary Hypertension [LPH]) questionnaire, that has been validated for PAH but not CTEPH, and the generic EuroQoL 5-Dimension (EQ-5D) and EQ-5D-Visual Analog Scale (EQ-VAS) questionnaires were completed by pts at baseline and Week (Wk) 16. Change from baseline to Wk 16 for the total population and sub-scores were examined. Relationships between HRQoL and other clinical endpoints (6-minute walking distance and World Health Organization functional class) were also evaluated.

Results: A total of 173 pts received riociguat (individual dose adjustment up to 2.5 mg three times daily) and 88 pts received pbo. At Wk 16, riociguat significantly improved the EQ-5D score, with an increase of $+0.06 \pm 0.28$ (mean \pm standard deviation) vs a decrease of -0.08 ± 0.34 in pbo-treated pts (least-squares [LS] mean difference $+0.13$ [95% confidence interval (CI): 0.06 to 0.21]; $p < 0.0001$). The EQ-VAS score also improved at Wk 16 with riociguat treatment, with an increase of $+10.5 \pm 23.4$, but remained stable in pbo-treated pts (LS mean difference $+10.0$ [95% CI: 5.4 to 14.7]; $p < 0.0001$). At Wk 16, the LPH total score improved by -6.7 ± 18.6 in riociguat-treated pts and by -2.1 ± 19.3 in pbo-treated pts compared with baseline

(LS mean difference -5.8 [95% CI: -10.5 to -1.1]; $p=0.12$). Use of the LPH questionnaire in pts with CTEPH needs further validation.

Conclusions: Pts with CTEPH treated with riociguat reported significant improvements in HRQoL after 16 weeks of treatment compared with baseline, as measured by the generic EQ-5D and EQ-VAS scores. Smaller differences between riociguat and pbo were observed with the LPH questionnaire.