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Title: Impact of riociguat on health-related quality of life (HRQoL) in patients with chronic thromboembolic pulmonary hypertension (CTEPH)

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Body: Introduction The CHEST-1 study showed clinical efficacy of riociguat in patients with inoperable CTEPH or persistent/recurrent PH post-surgery. Objective To evaluate the impact of riociguat on HRQoL in patients with CTEPH. Methods CHEST-1 was a 16-week, double-blind, randomized, placebo-controlled study. Disease-specific (Living with PH [LPH]) and generic EQ-5D and EQ-Visual Analog Scale (EQ-VAS) questionnaires were administered at baseline and Week 16. Change from baseline to Week 16 for the total population and sub-scores were examined. Relationships between HRQoL and other clinical endpoints (6-min walking distance and WHO functional class) were also evaluated. Results 173 patients received riociguat (individual dose titration up to 2.5 mg tid) and 88 patients received placebo. Riociguat significantly improved the EQ-5D score, with an increase of 0.06±0.28 vs a decrease of 0.08±0.34 for placebo patients (treatment difference +0.13 [95% CI: 0.06 to 0.21]; p<0.0001). The EQ-VAS score also improved with riociguat, with an increase of 10.5±23.4 in the riociguat group, but remained stable in placebo patients (treatment difference +10.0 [95% CI: 5.4 to 14.7]; p<0.0001). The LPH total score improved by –6.7±18.6 in riociguat patients and by –2.1±19.3 in placebo patients (treatment difference –5.8 [95% CI: –10.5 to –1.1]; p=0.12). Use of the LPH questionnaire in patients with CTEPH needs further validation. Conclusions CTEPH patients treated with riociguat reported significant improvements in HRQoL after 16 weeks, as

measured by the generic EQ-5D and EQ-VAS scores. Smaller differences were observed with the LPH questionnaire.