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Helicobacter pylori eradication by low-dose rifabutin triple therapy (RHB-105) is unaffected by body mass index

Helicobacter pylori (H. pylori) infection has a domestic prevalence of ~35% and a global prevalence of ~50% and may lead to peptic ulcer disease or gastric cancer if left untreated. Obesity is a significant risk factor for H. pylori antibiotic treatment failure (e.g., clarithromycin-based triple, quadruple therapy); however, little work has been done to understand the influence of high body mass index (BMI) on the success rates of H. pylori eradication regimens in adult patients. This work aimed to evaluate the association of subject obesity on overall H. pylori eradication rates for RHB-105 (50 mg rifabutin, 1000 mg amoxicillin, and 40 mg omeprazole; given Q8H, Talicia®) and its comparators using data from two Phase 3 clinical trials. Results Subjects receiving RHB-105 with 30 ≤ BMI < 40 or BMI ≥ 40 had pooled modified intent to treat (mITT) eradication rates of 88.1% (95% CI: 81.1-92.8) and 90.9% (95% CI: 72.2-97.5) [P = .707], respectively, compared to active comparator (1000 mg amoxicillin and 40 mg omeprazole; given Q8H; Talicia without rifabutin) rates of 62.9% (95% CI: 52.5-72.2) and 31.8% (95% CI: 16.4-52.7) [P = .008]. Obese subjects treated with RHB-105 were associated with efficacy rates comparable to the overall study population (89.4% by modified intent to treat and 90.3% by confirmed adherent analysis in the supportive and pivotal trials, respectively). Additionally, physiologically based pharmacokinetic (PBPK) modeling supports that the pharmacokinetic properties of rifabutin (e.g., at the site of infection) are largely uninfluenced by patient BMI. This work supports further evaluation of the efficacy of RHB-105 in obese populations, where H. pylori is prevalent.

Biography

Kely L Sheldon received his Ph.D in Molecular Microbiology and Immunology from Johns Hopkins University, where he was a GPP Fellow fully sponsored by the National Institutes of Health, National Institute of Child Health, and Human Development. His specialties include mitochondrial bioenergetics as it relates to disease progression, and more recently, infectious diseases, namely, Helicobacter pylori. He currently serves as the Associate Director of Medical Affairs at RedHill Biopharma, a specialty biopharmaceutical company primarily focused on gastrointestinal and infectious diseases.

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