A Phase 3 Randomized, Double-blind, Placebo-controlled Study to Confirm the Efficacy and Safety of a Single, Oral Dose of SYM-1219, a Granule Formulation Containing 2 Grams of Secnidazole, for the Treatment of Bacterial Vaginosis

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Objectives: SYM-1219, a granule formulation of secnidazole, is being developed as a single oral dose therapy for bacterial vaginosis (BV). A previous study of SYM-1219 for the treatment of BV demonstrated efficacy of 1 g and 2 g of secnidazole compared to placebo, with exceptional safety and tolerability. The objective of this study was to confirm the efficacy and safety of SYM-1219 granules containing 2 g of secnidazole compared to placebo for the treatment of BV.

Methods: 189 women who met the 4 Amsel criteria for BV (discharge characteristic of BV, pH ≥4.7, ≥20% clue cells, positive whiff test) were randomized 2:1 at 22 US sites and received single oral doses of 2g of secnidazole as SYM-1219 granules or placebo. The randomization was stratified by number of reported prior episodes of BV (<3 versus ≥4 episodes within 12 months) and by race (Black versus others). Nugent score ≥4 was required for inclusion in the efficacy analyses. Patients were evaluated for efficacy between days 7-14 (interim visit) and between days 21-30 (EOS). The primary endpoint was clinical response (CR) at EOS defined as a normal vaginal discharge, negative whiff test, and clue cells <20%. Microbiological cure was a Nugent score of <4. The modified Intention-to-Treat (mITT) population was used for the efficacy analyses. Statistical comparisons used a stratified Cochran-Mantel-Haenszel (CMH) test performed at a 0.05 level of significance (2-sided).

Results: The mITT population included 164 women. Median age was 30 years. 23% reported ≥4 BV episodes in the previous year; 54% self-identified as Black. CR for SYM-1219 was superior to placebo at EOS (53% vs. 19%, p<0.001) and at the interim visit (58% vs. 25%, p<0.001). Microbiological cure for SYM-1219 was superior to placebo at EOS (44% vs. 5.3%, p<0.001) and at the interim visit (46% vs. 3.5%, p<0.001). Similar efficacy results were observed for the analyses by BV and race strata. The overall rate of AEs was low including minimal systemic AEs. Those reported above 4% (vs placebo) were as follows: vulvovaginal mycotic infection (7.2% vs 3.1%), vulvovaginal candidiasis (6.4% vs 1.6%), nausea (4.8% vs 1.6%), diarrhea (4.0% vs 1.6%), and headache (4.8% vs 3.1%).

Conclusions: These data confirm the efficacy and safety of SYM-1219 for the treatment of BV. As a single-dose, well tolerated, oral therapy, SYM-1219 could improve adherence and be an important new option for the treatment of BV.

Character and space count: 2447 (maximum allowed is 2500)

Learning Objective: At the end of this presentation, participants will be able to describe the efficacy and safety of SYM-1219 for the treatment of bacterial vaginosis.