Efficacy and Safety of a Novel Vaginal pH Modulator for Prevention of Chlamydia and Gonorrhea

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INTRODUCTION
• In 2017, the United States Centers for Disease Control and Prevention reported that Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (GC) were the first and second most common notifiable conditions in the United States, respectively.
• Increasing incidence of CT and GC infection rates suggest that there is an urgent need for new prevention strategies.
• It is thought that the naturally acidic vaginal environment can inhibit acquisition of common sexually transmitted infections such as CT and GC.
• EVO100 is being developed as a woman-controlled, antimicrobial, pH-modulating investigational vaginal gel for the prevention of sexually transmitted infections.
• EVO100 contains 3 active ingredients: L-lactic acid (1.7%), citric acid (1%), and potassium bitartrate (0.4%), has acid-buffering properties, and is able to maintain the acidic vaginal environment (pH 3.5–4.5) even in the presence of alkaline semen (Figure 1).

AIM
• To determine if EVO100 reduces the risk of unreported CT and GC infection in healthy, sexually active women.

METHODS
• AMPREVENT (NCT03107375) was a double-blinded, placebo-controlled, randomized phase 2b/3 trial conducted at 55 US sites with a 16-week intervention period (Figure 2). Sexually active, healthy women aged 18–45 with documented CT or GC infection within 16 weeks preceding the Enrollment Visit (Visit 1) and found to be positive at the visit and completed standard of care treatment with subsequent negative test prior to enrollment.
• Women were instructed to administer a single prefilled applicator of study drug intravaginally before each episode of intercourse.
• Women used diaries to record timing of product administration, cotral information, and side effects.
• The primary efficacy outcome was the incidence of CT during the intervention period.
• The secondary outcome was the incidence of GC during the intervention period.
• Study visits were scheduled every 4 weeks (Visits 2 to 5) to obtain repeat CT/GC vaginal acid amplification test (NAAT), to review diaries, and to collect adverse event (AE) and concomitant medication information.
• A follow-up visit (Visit 6) 4 weeks after the last intervention visit was scheduled for post-intervention assessment.

RESULTS
• In total, 860 women were randomized 1:1 to receive EVO100 (n=426) or Placebo (n=290).
• There were 164 women (EVO100: n=376, placebo: n=388) who used the study drug at least once and were included in the safety analysis.
• Baseline characteristics were similar between treatment arms (Table 1).

CONCLUSIONS
• AMPREVENT met its primary and secondary efficacy endpoints, with significantly lower CT and GC infection rates in women receiving EVO100 than placebo users. There was a 50% reduction of risk in CT infection and 78% reduction of risk in GC infection following 16 weeks of EVO100 use compared with placebo.

REFERENCES

DISCLOSURES
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