PERFECT-USE PREGNANCY RATES WITH PHEXXI®, A NON-HORMONAL VAGINAL CONTRACEPTIVE: EFFICACY RESULTS FROM AMPPOWER

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INTRODUCTION

- Current guidelines recommend women who have been diagnosed with or are receiving treatment for cancer to avoid hormonal contraceptive methods due to the possibility of hormone-related risks and sensitivities, and to seek reversible and/or hormone-free methods1
- The vaginal pH modulator (VPM; Phexxi®) was developed as a novel, non-hormonal, woman-controlled, water-based, surfactant-free vaginal gel for the prevention of pregnancy and sexually transmitted infections2
- Compared with other vaginally administered products such as spermicides and vaginal rings that may contain surfactants, VPM is a surfactant-free, water-based, non-hormonal, non-systemic vaginal gel
- VPM has acid buffering properties and is able to maintain the acidic vaginal environment (pH 3.5-4.5) even in the presence of alkaline semen3
- VPM is designed to form a barrier layer over the vaginal and cervical surfaces

AIM

- To present the efficacy results in the efficacy evaluable (EE; “perfect-use”) study population with VPM

METHODS

- AMPPOWER (NCT03243305) was a single-arm, open-label, confirmatory trial conducted at 112 US sites4 (Figure 2)
- Women were instructed to administer a single prefilled applicator of study drug intravaginally every 40 to 48 hours between 14 to 30 days after the woman’s next menstrual period
- Any woman who missed ≥1 cycle without any backup or emergency contraception
- Expanding cycle lengths to include 21-42 day cycles
- ≥1 recorded act of vaginal intercourse
- 1,182 were included in the mITT population (had at least one cycle that was considered evaluable)
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RESULTS

- AMPPOWER enrolled a total of 1,384 women (Figure 3):
  - 1,182 were included in the mITT population (had at least one cycle that was considered evaluable for the mITT analysis)
  - 1,003 were included in the EE population (had at least one cycle that was considered evaluable for the EE analysis)

CONCLUSIONS/IMPLICATIONS

- There are multiple ways that efficacy can be measured
- Contraception clinical trials for FDA approval are not designed to accurately evaluate “real-world” use of the method due to stringent criteria for defining “evaluable” cycles
- Using multiple sensitivity analyses to determine perfect-use efficacy, women’s 7-cycle cumulative pregnancy percentage ranged from 6.67% to 9.99% with VPM
- When allowing analyses parameters with fewer restrictions to represent “real-world” contraceptive use, the perfect-use pregnancy percentage is 6.68% with VPM

REFERENCES


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DISCLOSURE

PTC: Research, Evofem Biosciences, Inc.
KC: Employee, Evofem Biosciences, Inc.
CB: Employee, Health Decisions, which received funding from Evofem Biosciences, Inc. to help conduct this study.
BH: Employee, Evofem Biosciences, Inc.

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