PERFECT-USE PREGNANCY RATES WITH PHEXXI®, A NON-HORMONAL VAGINAL CONTRACEPTIVE: Efficacy Results from AMPower

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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 infections1,2

• 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 gel3

• 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 semen3,4

The vaginal pH modulator (VPM; Phexxi®) is designed to form a barrier layer over the vaginal and cervical surfaces

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

METHODS

• AMPower (NCT03243305) was a single-arm, open-label, confirmatory trial conducted at 112 US sites (Figure 2)1

• Women were instructed to administer a single prefilled applicator of study drug intravaginally before each episode of intercourse

RESULTS

• AMPower 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)

Figure 3. Patient Disposition

Table 2. 7-cycle Cumulative Pregnancy Percentages and Perfect-use Analysis Representing “Real-world” Use

<table>
<thead>
<tr>
<th>Analyses</th>
<th>Population</th>
<th>Pregnancy (%)</th>
<th>Cumulative pregnancy percentage, %</th>
<th>95% CI for pregnancy percentage, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Typical-use</td>
<td>mITT</td>
<td>100</td>
<td>11.31</td>
<td>8.92, 13.70</td>
</tr>
<tr>
<td>Perfect-use</td>
<td>mITT</td>
<td>56</td>
<td>6.68</td>
<td>4.87, 8.49</td>
</tr>
</tbody>
</table>

Note: cycles with backup contraception, i.e., intercourse, and cycle lengths between 21-42 days.

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 efficacy rate is 6.68% with VPM

REFERENCES


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DISCLOSURE

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

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