Characterizing Women in the U.S. with Acute and Recurrent Vulvovaginal Candidiasis and their Unmet Needs

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INTRODUCTION

• Three-quarters of all women have an episode of acute VVC in their lives with the majority of infections occurring in women of childbearing age⁴
• Women in the U.S. seek treatment from a physician for VVC approximately 2-4 times in total per year. Supporting novel needs are significant due to a combination of resistance, recurrence, cure rates, and lack of new therapeutic options.
• No novel therapy has been introduced for VVC in over 20 years.
• CD101, a novel topical antifungal, is the first antifungal agent to be developed for VVC.

This research was designed to identify differences in characteristics, attitudes and unmet needs of women with acute and recurrent VVC (RVVC) and recurrent VVC (RVVC) in alignment with the development of CD101 Topical and improved VVC therapies in general.

METHODS

Study Design

• 30-minute online survey conducted in June 2015 of 478 women in the U.S. 18+ years of age. All women had visited their physician for VVC and taken 1 or more medications for VVC in the past year.
• Women were screened to meet one of three cohort definitions below and were grouped by descriptive symptoms of VVC severity from which to self-classify. All results were self-reported.

• Where substantial difference between cohorts was achieved it is noted as ‘significant’ throughout.

Distribution of Women By VVC/RVC Criteria

<table>
<thead>
<tr>
<th>Cohort</th>
<th>Abbr.</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recurrent VVC (1+ infections/year) and any severity</td>
<td>R</td>
<td>n=152</td>
</tr>
<tr>
<td>Mild VVC and &lt;3 infections/year</td>
<td>M</td>
<td>n=152</td>
</tr>
<tr>
<td>Moderate/Severe VVC and ≥3 infections/year</td>
<td>Mo/S</td>
<td>n=174</td>
</tr>
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</table>

RESULTS

• The frequency of mild, moderate and severe infections was evenly distributed among the R cohort.

• All cohorts reported infections of each severity, despite screening for culture.

• CD101 Topical, being developed as the first topical echinocandin antifungal for the treatment of VVC and prevention of RVVC. Preclinical VVC models performed at oral and vaginal sites have demonstrated intravaginal CD101 to be effective against azole- and quinolone-resistant Candida.⁵

1. Materials/methods: 478 U.S. women (18-65 y) participated in a 30-min online survey in June 2015. Screening used standard VVC/RVC definitions with one exception: RVVC was defined as ≥3 more VVC episodes in the last year, v 4 episodes as defined by the FDA. VVC (R): n=152; M: Mild acute VVC; Mo/S: Moderate/Severe acute VVC n=174

2. Results: R self-reported sexually more VVC (4.0) and bacterial vaginosis episodes (1.0) per year. Self-reported floconazole resistance was higher in R (16%) and Mo/S (32%) than in M (3%), 75% of women visited a doctor for a VVC Rx, higher among M and Mo/S, vs 26% for Rx, higher among R. VVC evaluations were conducted by an OB/GYN (56%), a pharmacist (30%), 14% Mo/S reported visiting the doctor 2.8, 1.2 times per year. R and Mo/S scored statistically greater than M on taking active role in healing VVC and willingness to try new medications: 36% of women are actively seeking new treatments. The most desired treatment features were women across all groups ‘less resistant to killer,’ and ‘starts to work faster,’ followed by ‘getting rid of vaginal yeast’ and ‘keeping my yeast from coming back.’

• Conclusions: Regardless of acute or recurrent VVC, women prioritize rapid symptom relief in an acute VVC episode over decreasing symptom severity.

• These patterns of all women have an episode of acute VVC in their lives with the majority of infections occurring in women of childbearing age⁴

• Women in the U.S. seek treatment from a physician for VVC approximately 2-4 times in total per year. Supporting novel needs are significant due to a combination of resistance, recurrence, cure rates, and lack of new therapeutic options.

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