# Oral Ibrexafungerp: An Investigational Agent for the Treatment of Acute and Recurrent Vulvovaginal Candidiasis


Barbara Dehn, MS, NP, FAANP, NCMP

El Camino Women's Medical Group

Mountain View, CA

Additional Authors: Nkechi Azie, MD, David Angulo, MD, Jack Sobel, MD


**Objectives:**

1. State the current treatment options for both acute and recurrent vulvovaginal candidiasis (VVC)
2. State the impact on women's quality of life from VVC
3. Describe the fungicidal mechanism of action of Ibrexafungerp

**Poster I270**

# Purpose: Vulvovaginal Candidiasis Affects Many Women in USA

- 75% of all women affected by one episode of VVC during their lifetime
  - 40-45% of women will have 2-3 episodes of VVC
- 10 million office visits per year for vaginal symptoms-
  - 40% for Candida infections
- Currently, azoles are the only treatments indicated for VVC
  - Majority of women prefer oral therapy to topical
- Recurrent VVC impacts quality of life, self-esteem and sexual activity in addition to causing bothersome and irritating symptoms

# Summary: Ibrexafungerp: 1st Non-azole Antifungal Class (Triterpenoid) Being Investigated for Vaginal Yeast Infections

**NOVEL Mode of Action**
**Targets β- (1,3)- glucan synthase**
**Not found in human cells**
Minimal risk of off-target effects
Proven MOA against Candida (echinocandins)

**Broad Spectrum**
*Candida,* including *non-albicans Candida spp.*

**No Safety Signals**
No Fetal Toxicity observed in pre-clinical models

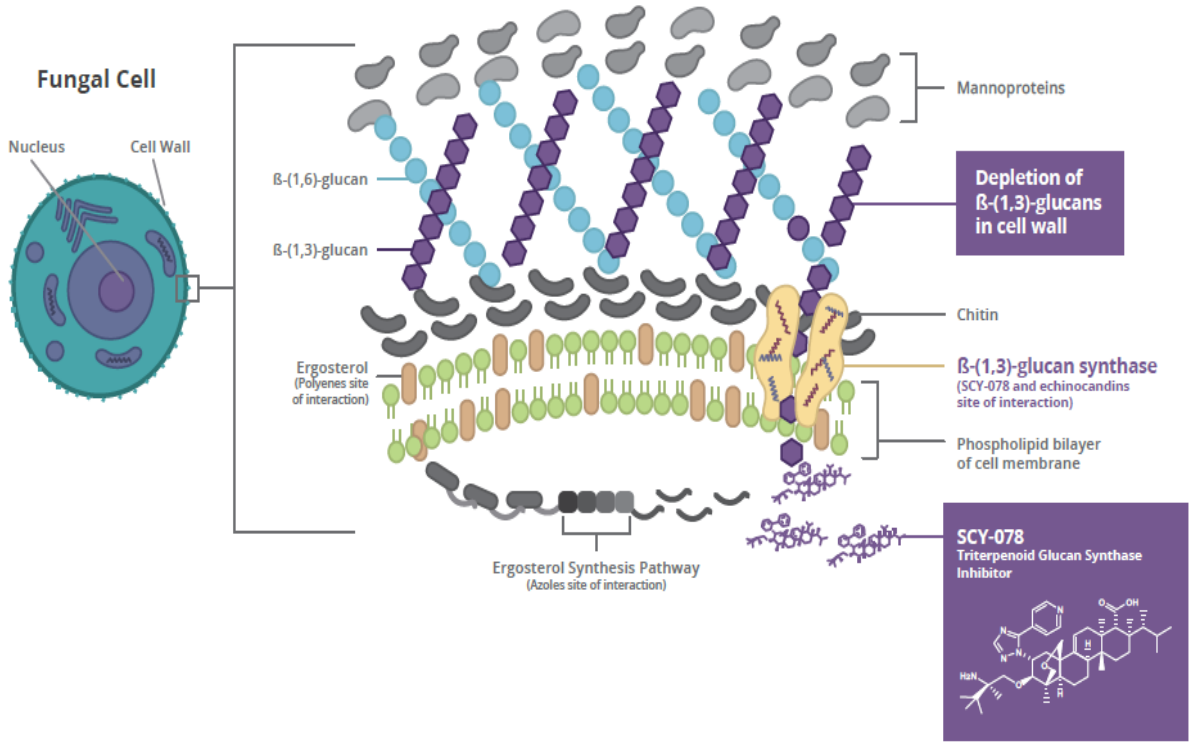
**Oral Formulation**
One day dose for VVC

**Activity vs. Fluconazole-resistant Strains**
Potency not affected by low pH environments

**Fungicidal vs. *Candida***
Benefits over fungistatic agents

**20-hour Half-Life**
**High Tissue Penetration**
**Low Risk of DDIs**

**Fungal Cell Membrane and Cell Wall**



# Outcomes: Ibrexafungerp Acute VVC Phase 3 Study (VANISH-303)

- Randomized, double-blind, placebo-controlled study in women with acute VVC
- Enrolled 376 women in a 2:1 ratio, with Vaginal Sign and symptoms (S&S)* ≥4
- Primary Endpoint was Clinical Cure Vaginal Signs and Symptoms (S&S) = 0 at Test of Cure Visit (TOC) on Day 11

| mITT | IBX 300mg BID (N=188) n (%) | PLACEBO (N=98) n (%) | OR (95 % CI) P value |
|---|---|---|---|
| Clinical Cure (S&S=0) at TOC (Day 11) | 95 (50.5) | 28 (28.6) | 1.71 (1.20, 2.43) 0.001 |
| Mycological eradication at TOC | 93 (49.5) | 19 (19.4) | 2.87 (1.80, 4.57) <0.001 |
| Clinical Improvement (S&S≤1) at TOC | 121 (64.4) | 36 (36.7) | 1.77 (1.31, 2.38) <0.001 |
| Symptom Resolution at FU (Day 25) | 112(59.6) | 44(44.9) | 1.41 (1.07, 1.85) 0.009 |

- Primary endpoint was achieved in the study
  - Superiority in clinical cure at TOC
- Key secondary endpoints were achieved
  - Superiority in mycological eradication at TOC
  - Superiority in clinical improvement at TOC and symptom resolution at FU
- Ibrexafungerp was generally safe and well-tolerated
  - Most of GI adverse events were deemed related to study drug and were mild to moderate in intensity
- Ongoing Phase 3 study of Ibrexafungerp for the prevention of recurrent VVC

**Implications for Women's Health**

VVC occurs in the majority of women at least once in a lifetime. For over 20 years, the standard of care for treatment is a topical or oral azole antifungal drug. There has not been a non-azole therapy approved for the treatment of VVC. As Women's Health Nurse Practitioners, we care for women with VVC and need to be aware of all treatment options including this novel orally active fungicidal medication.