



## Phase 2b Results of Viamet's Oral VT-1161 for the Treatment of Recurrent Vulvovaginal Candidiasis Presented at IDSOG Annual Meeting

- Presentation detailed the Company's REVIVE study data demonstrating unprecedented results in the treatment of RVVC -

RESEARCH TRIANGLE PARK, N.C., August 11, 2017, – [Viamet Pharmaceuticals, Inc.](#) today announced the presentation of results from REVIVE, a Phase 2b clinical trial of VT-1161 in the treatment of patients with recurrent vulvovaginal candidiasis (RVVC), at the Infectious Diseases Society for Obstetrics and Gynecology (IDSOG) Annual Meeting in Park City, Utah. VT-1161 is a highly potent and selective, orally-administered inhibitor of fungal CYP51 that has demonstrated broad-spectrum activity against yeast, dermatophyte, endemic and multi-drug resistant fungal pathogens. The REVIVE study, presented by Jack Sobel, M.D., during an oral presentation on Thursday, August 10, demonstrated unprecedented efficacy and safety in patients with RVVC, a condition associated with a very high burden of disease and for which there are no approved therapies.

"Recurrent yeast infections are a pervasive problem, affecting approximately 5% to 8% of women. While the physical symptoms of infection are distressing, the emotional and psychological consequences of RVVC have a significant impact on the quality of life for those affected," stated Robert Schotzinger, M.D., Ph.D., CEO of Viamet. "VT-1161 is highly potent against a broad spectrum of *Candida* species, the primary fungal pathogens responsible for RVVC, and has clinically demonstrated a durable response against re-infection. We believe that VT-1161 has the potential to be a best-in-class treatment option for patients suffering from RVVC and the first FDA approved treatment for this very common disease."

"The current treatment approach for patients with RVVC is typically treatment of the acute infection each time one occurs. In some cases, this is followed by long term suppressive therapy with oral fluconazole, a drug with a limited antifungal spectrum and which has been associated with safety liabilities, drug-drug-interactions and potential pregnancy effects," said Dr. Sobel, Wayne State University School of Medicine, one of the clinical investigators in the REVIVE study. "VT-1161 demonstrated a high degree of efficacy and very impressive safety during the 48-week REVIVE study. The low re-infection rates observed in the VT-1161 treated patients were very impressive compared to other therapies previously studied in RVVC."

The presentation titled, "Results from a Phase 2, Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Study to Evaluate the Efficacy and Safety of VT-1161 Oral Tablets in the Treatment of Patients with Recurrent Vulvovaginal Candidiasis," was delivered by Dr. Sobel. In the intent-to-treat population, defined as all randomized subjects, the proportion of subjects with one or more vulvovaginal candidiasis episodes through 48 weeks ranged from 0-7% in the VT-1161 arms compared to 52% in the placebo arm ( $p < 0.0001$  for all active arms compared to placebo). In the per protocol analysis, which included patients evaluable through 48 weeks, the recurrence rate of one or more vulvovaginal candidiasis episodes in the placebo arm was 66% while the four VT-1161 arms ranged from 0-11% ( $p < 0.0001$  for all active arms compared to placebo). Throughout the study, VT-1161 was very well tolerated and there was a lower incidence of adverse events reported in all VT-1161 arms compared to placebo. VT-1161 also showed no evidence of adverse effects on laboratory parameters, which have been an issue for other oral treatment approaches for RVVC. In addition, VT-1161 displayed potent activity against a range of *Candida* species including *C. glabrata*, which is becoming more pronounced and which has shown resistance to other antifungal agents such as fluconazole.

### About the Phase 2b REVIVE study

REVIVE (**RE**current **V**ulvovaginal **C**andidiasis **I**nhibition: an Oral **VT**-1161 **T**ablet **E**valuation) was a randomized, double-blind, placebo-controlled, 48-week clinical trial of VT-1161 in patients with RVVC. The



trial evaluated two dose levels of VT-1161 (150 mg and 300 mg) administered once weekly for either 11 or 23 weeks, following an initial one-week daily loading dose period. The trial enrolled 215 patients at 32 sites throughout the U.S. At baseline, the mean number of vulvovaginal candidiasis episodes per patient in the prior 12 months ranged from 4.6 to 5.2 across the study arms. Patients were eligible to enroll in the trial if they had a documented history of RVVC, presented to the physician with a vulvovaginal candidiasis infection, and had completed treatment of the active infection with fluconazole, an antifungal agent approved in the U.S. for the treatment of vulvovaginal candidiasis. The primary efficacy endpoint was the proportion of subjects with one or more culture-verified vulvovaginal candidiasis episodes through 48 weeks.

#### **About VT-1161**

VT-1161 is a potent and selective, orally-administered inhibitor of fungal CYP51 which recently successfully completed Phase 2b clinical trials for the treatment of [onychomycosis](#), or fungal nail infection, and recurrent vulvovaginal candidiasis (RVVC), a common and difficult to treat infection in women. VT-1161 blocks the production of ergosterol, an essential component of the fungal cell membrane. In preclinical studies, VT-1161 has demonstrated broad-spectrum activity against both dermatophytes and *Candida* species, including those species that cause onychomycosis and RVVC. Given the clinical and preclinical profile of VT-1161, Viamet believes that it may avoid the side effects that limit the use of current oral antifungal therapies, such as liver toxicity and drug-drug interactions. The U.S. Food and Drug Administration (FDA) has granted Qualified Infectious Disease Product (QIDP) and Fast Track designations to [VT-1161 for the treatment of RVVC](#).

#### **About RVVC**

Recurrent vulvovaginal candidiasis (RVVC) is defined as the occurrence of three or more episodes of vulvovaginal candidiasis within a 12-month period. RVVC is estimated to occur in 5% to 8% of women in the United States during their child-bearing years. The infection involves the vaginal mucosa and surrounding tissues and can be a source of significant discomfort. RVVC is ranked by patients above migraine and similar to asthma and chronic obstructive pulmonary disease with regard to its negative impact on quality of life and also results in a significant loss of work time. There are currently no approved therapies in the U.S. for the treatment of RVVC.

#### **About Viamet ([www.viamet.com](http://www.viamet.com))**

Viamet discovers and develops breakthrough therapies based on our leadership in metalloenzyme chemistry and biology. Our clinical portfolio includes novel agents to treat both chronic and life threatening fungal infections. We also leverage our metalloenzyme expertise in other therapeutic areas including oncology and orphan diseases. Focusing on the needs of patients and clinicians, we design our drug candidates to achieve superior efficacy and safety profiles compared to currently marketed drugs.

*This press release includes forward-looking statements. Actual results may vary materially from these statements. There are many important risks affecting Viamet's business, including that clinical trials may not be commenced, or if commenced, may not be successful, regulatory approvals may not be obtained and approved products, if any, may not achieve commercial success. The Viamet group of companies includes Viamet Pharmaceuticals Holdings, LLC and its operating subsidiaries, Viamet Pharmaceuticals, Inc., VPS-2, Inc., VPS-3, Inc. and Viamet Pharmaceuticals (Bermuda), Ltd. The Viamet group of companies are based in the Research Triangle Park region of North Carolina, USA and Hamilton, Bermuda.*

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