



Viamet Presents Phase 2b Results Demonstrating Unprecedented Efficacy of Oral VT-1161 in the Treatment of Recurrent Vulvovaginal Candidiasis

- Late-breaker poster at ASM Microbe 2017 represents the first scientific presentation of the Company's REVIVE Study data -

RESEARCH TRIANGLE PARK, N.C., June 4, 2017, – [Viamet Pharmaceuticals, Inc.](#), today announced the presentation of multiple studies supporting VT-1161, the Company's lead product candidate for the treatment of fungal infections, at the American Society for Microbiology's ASM Microbe 2017 in New Orleans, Louisiana. VT-1161 is a highly potent and selective, orally available inhibitor of fungal CYP51 that has demonstrated broad-spectrum activity against yeast, dermatophyte, endemic and multi-drug resistant fungal pathogens. The Phase 2b REVIVE study, presented during the late-breaker poster session, demonstrated unprecedented efficacy in women diagnosed with recurrent vulvovaginal candidiasis (RVVC). All VT-1161 treatment arms in the per protocol and intent-to-treat analyses achieved statistical significance versus placebo for the study primary endpoint. VT-1161 was well tolerated with a favorable safety profile.

Poster AAID LB21 titled, "Oral VT-1161 is Highly Effective and Safe in Patients with Recurrent Vulvovaginal Candidiasis - Results of REVIVE, a Multicenter Phase 2b Study," is the first scientific presentation describing the robust clinical efficacy and safety of VT-1161 in patients with RVVC. In addition to Viamet contributors, collaborators on the poster included investigators from Drexel University College of Medicine, Philadelphia, Pennsylvania and Wayne State University, Detroit, Michigan. In the per protocol analysis, which included patients evaluable through 48 weeks, the recurrence rate of vulvovaginal candidiasis in the placebo arm was 66%. In contrast, the proportion of subjects with one or more vulvovaginal candidiasis episodes was 0% to 11% in the four VT-1161 arms of the study, with all arms achieving statistical significance vs. placebo ($p < 0.0001$). 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). Throughout the course of 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 an adverse effect on liver function, which has been an issue for other oral treatment approaches for RVVC.

"While the physical symptoms of RVVC are distressing, it is often the emotional and psychological consequences of the recurrent infections that have a significant impact on the patient. VT-1161 has demonstrated a high degree of potency against *Candida* species, the causative fungal pathogens responsible for RVVC, and potentially a higher barrier to drug resistance, underscoring the potential to be a first-in-class treatment option for patients suffering from RVVC," commented Robert Schotzinger, M.D., Ph.D., CEO of Viamet. "These results suggest that VT-1161 may be a promising agent to treat RVVC, a condition associated with a very high burden of disease and for which there are no approved therapies in the U.S."

Additional VT-1161 presentations during the conference featured results from a Phase 1 study, which demonstrated that VT-1161 was safe and well-tolerated in both Japanese and Western subjects, and an *in vitro* study in which VT-1161 displayed a low potential for the emergence of drug resistance in multiple *Candida* species.

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)

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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