



Viamet Reports Positive Results from REVIVE Phase 2b Trial of Oral VT-1161 in Recurrent Vulvovaginal Candidiasis

-48 Week Results Demonstrate Strong Clinical Benefit and Very Favorable Safety Profile-

RESEARCH TRIANGLE PARK, N.C., January 6, 2017, – [Viamet Pharmaceuticals, Inc.](#) today reported positive efficacy and safety results from REVIVE (Recurrent Vulvovaginal Candidiasis Inhibition: an Oral VT-1161 Tablet Evaluation), a Phase 2b clinical trial of VT-1161 for the treatment of recurrent vulvovaginal candidiasis, or RVVC. RVVC is defined as three or more episodes of acute vulvovaginal candidiasis, or AVVC (commonly referred to as a vaginal yeast infection), in a 12-month period. VT-1161, the company's lead product candidate, is a highly potent and selective, orally available inhibitor of fungal CYP51.

The study met its primary endpoint of proportion of subjects with one or more culture-verified AVVC episodes through 48 weeks. In the per protocol analysis, which includes patients evaluable through 48 weeks, the recurrence rate in the placebo arm was 66%. In contrast, patients in all VT-1161 arms had markedly lower rates of AVVC recurrence. The proportion of subjects with one or more culture-verified AVVC episodes was 0% to 11% in the four VT-1161 arms of the study with all arms achieving statistical significance vs. placebo. Throughout the study, VT-1161 was very well tolerated with a favorable safety profile, and the incidence of adverse events was lower in all of the VT-1161 arms compared to placebo. In addition, no patient in any VT-1161 arm discontinued the study early due to an adverse event or laboratory abnormality. There was also no evidence of an adverse effect of VT-1161 on liver function.

"It is estimated that RVVC affects 5% to 8% of U.S. women during their child-bearing years and has a significant negative impact on their overall quality of life, affecting them emotionally, physically, and economically. Despite the number of women affected by this disease, there are currently no approved therapies for RVVC in the U.S.," commented Robert Schotzinger, M.D., Ph.D., CEO of Viamet. "VT-1161 has demonstrated a high degree of potency against *Candida* species, the causative fungal pathogens responsible for RVVC, demonstrating the potential to be a first-in-class treatment option for these patients. It has shown a robust oral pharmacokinetic profile and maintained a favorable safety profile in previous studies. These very positive results from our REVIVE trial suggest that VT-1161 has the potential to be a first-in-class, highly effective and safe treatment option for patients with RVVC. We look forward to presenting the full study results at a future scientific conference."

REVIVE 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 AVVC 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 an AVVC infection, and had completed treatment of the active infection with fluconazole, an antifungal agent approved in the U.S. for the treatment of AVVC. The primary efficacy endpoint was the proportion of subjects with one or more culture-verified AVVC episodes through 48 weeks.

About VT-1161

VT-1161 is a potent and selective, orally-administered inhibitor of fungal CYP51 which recently completed Phase 2b clinical trials for the treatment of recurrent vulvovaginal candidiasis (RVVC) and onychomycosis, or fungal nail infection. 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 *Candida* species and dermatophytes, including those species that cause RVVC and onychomycosis. Given



the clinical and pre-clinical profile of VT-1161, the Company 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.

About RVVC

Recurrent vulvovaginal candidiasis (RVVC) is defined as the occurrence of three or more episodes of acute vulvovaginal candidiasis (AVVC) 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 US 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.

Media Contact:

Stefanie Tuck
MacDougal Biomedical Communications
Main: +1 781 235 3060
stuck@macbiocom.com

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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