



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

-Interim Results Demonstrate Strong Clinical Benefit and Favorable Safety Profile-

-Final Data Expected in Fourth Quarter of 2016-

RESEARCH TRIANGLE PARK, N.C., March 9, 2016, – [Viamet Pharmaceuticals, Inc.](#) today reported positive results from a planned interim analysis of REVIVE (Recurrent Vulvovaginal Candidiasis Inhibition: an Oral VT-1161 Tablet Evaluation), its ongoing 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.

"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 quality of life," commented Robert Schotzinger, M.D., Ph.D., CEO of Viamet. "Despite the number of women affected by this disease, we are not aware of any approved therapies for RVVC in the U.S. VT-1161 has demonstrated a high degree of potency against *Candida* species, the causative fungal pathogens responsible for RVVC, a robust oral pharmacokinetic profile, and a favorable safety profile in previous studies. These attributes, coupled with the positive interim results from our REVIVE trial, suggest that VT-1161 has the potential to be a highly effective treatment option for patients with RVVC."

REVIVE is a randomized, double-blind, placebo-controlled, 48-week clinical trial of VT-1161 in patients with RVVC. The trial is evaluating two dose levels of VT-1161 administered once weekly for either 11 or 23 weeks, following an initial one-week daily loading dose period in each. At baseline, the mean number of AVVC episodes per patient in the prior 12 months ranged from 4.5 to 6.0 across the study arms. The trial enrolled 215 patients at 32 sites throughout the U.S. 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 were free of active infection after treatment with fluconazole, an antifungal agent approved in the U.S. for the treatment of AVVC. The primary efficacy endpoint is the proportion of subjects with one or more culture-verified AVVC episodes through 48 weeks.

A planned interim analysis was conducted when approximately 100 patients had completed the first 24 weeks of the trial. Across the four VT-1161 treatment arms, only 3% of the patients suffered a recurrence of AVVC through week 24 as compared to 48% of patients in the placebo arm. Notably, in the two high-dose VT-1161 arms there was not a single patient who suffered a recurrence through week 24. In addition, safety data from the interim analysis population demonstrated that VT-1161 was well tolerated with a favorable safety profile. In particular, there was no evidence of an adverse effect of VT-1161 on liver function.

"Given the positive interim efficacy and safety data from our REVIVE trial and the previously reported interim efficacy and safety data from our RENOVATE onychomycosis trial, we believe that VT-1161 has the potential to be a first-in-class therapy to prevent recurrent infections in patients with RVVC and a best-in-class therapy to treat onychomycosis, a common infection of the nail," stated Dr. Schotzinger. "We look forward to announcing top-line final results for both trials in the fourth quarter of 2016."

About VT-1161

VT-1161 is a potent and selective, orally-administered inhibitor of fungal CYP51 currently in Phase 2b clinical trials for the treatment of onychomycosis and recurrent vulvovaginal candidiasis (RVVC). 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 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

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.

About Onychomycosis

Onychomycosis, a fungal infection that primarily involves the nail bed and surrounding tissues, is an extremely common infection, affecting approximately 32 million individuals in the United States. The infection is characterized by deformation, discoloration, thickening and splitting of the nail, as well as separation of the nail plate from the nail bed. Damage to the nail can also result in pain when walking, limiting ambulation. The unsightly appearance of the infected nail and the perception that there is an active and contagious infection is a significant concern for many patients. Onychomycosis can also be a significant medical issue for diabetics or other patients with compromised immune systems or poor circulation of the lower extremities. In these patients, the infected nail can serve as an entry point for bacterial infection, which can in turn lead to serious complications such as tissue necrosis and amputation.

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:

Blair McCarthy Atkinson
MacDougal Biomedical Communications
Direct: +1 812 454 6257
Main: +1 781 235 3060
batkinson@macbiocom.com

Investor Contact:

John Woolford
Westwicke Partners
Direct: +1 443 213 0506
john.woolford@westwicke.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. and VPS-3, Inc. The Viamet group of companies are based in the Research Triangle Park region of North Carolina, USA.

###