FDA Grants QIDP and Fast Track Designations to VT-1161 for Treatment of Recurrent Vulvovaginal Candidiasis

October 12, 2016, Research Triangle Park, North Carolina – Viamet Pharmaceuticals, Inc. today announced that the U.S. Food and Drug Administration (FDA) has granted Qualified Infectious Disease Product (QIDP) and Fast Track designations to VT-1161, a novel oral agent for the treatment of recurrent vulvovaginal candidiasis (RVVC), or recurrent vaginal yeast infection, a common and difficult to treat condition in women. There are no approved therapies in the United States for RVVC.

"Recurrent vulvovaginal candidiasis affects an estimated 5 - 8% of women of child-bearing age in the United States," said Robert Schotzinger, M.D., Ph.D. and CEO of Viamet. "The large number of women afflicted by this condition, combined with the lack of approved therapies, highlight the immense need for a safe and effective treatment for RVVC. We are very pleased with the FDA's decision to grant QIDP and Fast Track designations to VT-1161, and look forward to the continued development of this novel therapy."

Created under the Generating Antibiotics Incentives Now (GAIN) Act of 2012, QIDP designation provides significant incentives for the development of innovative antimicrobial agents like VT-1161, including the potential for priority review by the FDA, and a five-year extension of marketing exclusivity under the Hatch-Waxman Act. Fast Track designation from the FDA supports the development and expedited review of new therapies with a goal to deliver important new drugs to patients earlier in order to fill unmet medical needs.

VT-1161, the company's lead product candidate, is nearing completion of Phase 2b testing for the oral treatment of RVVC and onychomycosis, a highly prevalent fungal infection of the nail. Viamet is also developing VT-1129, currently in Phase 1 testing for the treatment of cryptococcal meningitis, a life-threatening fungal infection of the brain, and VT-1598 for the treatment of coccidioidomycosis, or Valley Fever.

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 recurrent vulvovaginal candidiasis (RVVC) and onychomycosis. 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 and dermatophyte species, 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

RVVC is defined as the occurrence of three or more episodes of acute 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.

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 safety and efficacy profiles compared to currently marketed drugs.

Contact:
Blair McCarthy Atkinson
MacDougal Biomedical Communications Direct:
+1 812 454 6257
Main: +1 781 235 3060
batkinson@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 (NC), Inc., Viamet Pharmaceuticals (Bermuda), Ltd., VPS-2, Inc. and VPS-3, Inc. The Viamet group of companies is based in the Research Triangle Park region of North Carolina, USA.