Viamet Announces RENOVATE Phase 2b Onychomycosis Results to be Presented at the American Academy of Dermatology 2017 Annual Meeting

RESEARCH TRIANGLE PARK, N.C., March 1, 2017 – Viamet Pharmaceuticals, Inc. today announced that the results from RENOVATE (RESToring Nail; an Oral VT-1161 Tablet Evaluation), its Phase 2b clinical trial of VT-1161 in approximately 260 patients with onychomycosis of the toenail, will be presented in a late-breaking research forum at the American Academy of Dermatology 2017 Annual Meeting, to be held March 3-7, 2017, in Orlando, Florida. VT-1161, the company’s lead product candidate, is a highly potent and selective, orally-administered inhibitor of fungal CYP51.

Amir Tavakkol, Ph.D., Viamet’s Chief Development Officer, will give a presentation titled “Efficacy and Safety Outcomes from a Randomized, Double-Blind, Placebo-Controlled Phase 2b Study of Four Oral VT-1161 Regimens in the Treatment of Patients with Moderate-Severe Distal-Lateral Subungual Onychomycosis (DLSO),” summarizing key efficacy and safety data from the study. The presentation will take place during the Late-Breaking Research: Clinical Trials session at the conference, scheduled for Saturday, March 4 from 9:00 AM - 11:00 AM (EST).

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 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, 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. 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. 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.

About the RENOVATE Study

RENOVATE was a randomized, double-blind, placebo-controlled, clinical trial of VT-1161 in patients with distal-lateral subungual onychomycosis (DLSO) of the large toenail. The trial evaluated two dose levels of VT-1161 (300 mg and 600 mg) administered once weekly for either 10 or 22 weeks following an initial two week, once-daily loading dose period. The trial enrolled 259 patients with 25-75% DLSO involvement of the large toenail at baseline at 32 sites throughout the United States. At baseline, mean DLSO involvement of the large toenail was 46% and the average number of toenails affected was 4.6 across the trial arms. The primary efficacy endpoint was complete cure of the large toenail at week 48, a composite endpoint that requires both complete clinical cure and negative mycology. Patients were also evaluated for complete cure at week 60.

About Onychomycosis

Onychomycosis, a fungal infection that primarily involves the nail, 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.

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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., 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.