



Viamet Reports Positive Results from RENOVATE Phase 2b Trial of Oral VT-1161 in Onychomycosis

-Results Demonstrate Robust Efficacy and Very Favorable Safety Profile-

RESEARCH TRIANGLE PARK, N.C., January 6, 2017, – [Viamet Pharmaceuticals, Inc.](#) today reported positive results from RENOVATE (REstoring Nail; an Oral VT-1161 Tablet Evaluation), its Phase 2b clinical trial of VT-1161 in onychomycosis of the large toenail. Onychomycosis is a chronic fungal infection involving the nail, nail bed, and surrounding tissues. 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 complete cure rates at 48 weeks. In the intent-to-treat analysis, complete cure rates were 0% in the placebo arm compared to a range of 32% to 42% in the four VT-1161 arms of the study with all arms achieving statistical significance vs. placebo. In the per protocol analysis, which includes patients evaluable through week 48, the cure rates were as high as 55% in the VT-1161 groups. There was an 87% median reduction in the percentage of nail involvement at week 48 across the VT-1161 arms, as compared to a 9% reduction in the placebo arm with all arms achieving statistical significance vs. placebo. Complete cure rates continued to improve through week 60, with all active arms having a complete cure rate of greater than 40% in the intent-to-treat analysis. Throughout the study, VT-1161 was very well tolerated with a favorable safety profile. The incidence of adverse events was similar across the VT-1161 arms relative to placebo. No patient in any VT-1161 arm discontinued the study due to a laboratory abnormality and less than 1% of patients across the VT-1161 arms discontinued the study due to an adverse event. There was also no evidence of an adverse effect of VT-1161 on liver function.

The U.S. Summary Basis of Approval for terbinafine, the current standard-of-care for onychomycosis, contains an intent-to-treat cure rate of approximately 31% at 48 weeks, but safety concerns limit its use. Topical therapies, while safer, suffer from low cure rates, which range from 6 to 18% on an intent-to-treat basis, and require daily application to each affected toe nail for approximately one year, which leads to poor patient compliance.

“Current therapies for onychomycosis are suboptimal with respect to efficacy, safety, dosing convenience and duration of response,” commented Robert Schotzinger, M.D., Ph.D., CEO of Viamet. “VT-1161 has demonstrated a high degree of *in vitro* potency against the most common fungal pathogens that cause onychomycosis, a favorable oral pharmacokinetic profile, and a favorable safety profile in previous studies. The increasing complete cure rates at 60 weeks are encouraging signs that VT-1161 may provide patients with a longer duration of response and therefore lower relapse rates. We believe that these attributes, coupled with the positive efficacy and safety results from our RENOVATE trial, suggest that VT-1161 has the potential to be a best-in-class and effective new treatment option for patients with onychomycosis. We look forward to presenting the full study results at a future scientific conference.”

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 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 target 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 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 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 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, 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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