



## **Viamet Reports Positive Results from Interim Analysis of RENOVATE Phase 2b Trial of VT-1161 in Onychomycosis**

***-Interim Results Demonstrate Strong Clinical Improvement and Favorable Safety Profile-***

***-Final Data Expected in Fourth Quarter of 2016-***

RESEARCH TRIANGLE PARK, N.C., March 2, 2016, – [Viamet Pharmaceuticals, Inc.](#) today reported positive results from a planned interim analysis of RENOVATE (REstoring Nail; an Oral VT-1161 Tablet Evaluation), its ongoing Phase 2b clinical trial of VT-1161 in onychomycosis of the large toenail. VT-1161, the company's lead product candidate, is a highly potent and selective, orally available inhibitor of fungal CYP51.

"Current therapies for onychomycosis are suboptimal with respect to efficacy, safety and dosing convenience," 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. We believe that these attributes, coupled with the positive interim results from our RENOVATE trial, suggest that VT-1161 has the potential to be a highly differentiated and effective new treatment option for patients with onychomycosis, a condition affecting approximately 32 million people in the United States."

RENOVATE is 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 is evaluating two dose levels of VT-1161 administered once weekly for either 10 or 22 weeks following an initial two-week loading dose period. The trial has enrolled approximately 260 patients with 25-75% involvement of the large toenail at baseline at 32 sites throughout the United States. During the trial, patients will be followed for 60 weeks. The primary efficacy endpoint is complete cure of the target toenail at week 48, a composite endpoint that requires both complete clinical cure and negative mycology.

The planned interim analysis was conducted when approximately 100 patients had completed the first 24 weeks of the trial. At baseline, mean involvement of the large toenail was 46% and the average number of toenails affected was 4.7 across the trial arms. In the intent-to-treat analysis, up to 59% of patients treated with VT-1161 had a negative dermatophyte culture by week 24. There was a 48% average reduction in the percentage of nail involvement at week 24 across the VT-1161 arms, as compared to a 6% reduction in the placebo arm. The median reduction in percentage nail involvement in the VT-1161 arms was as high as 67% at week 24. In addition, the percentage of patients with  $\leq 10\%$  (clear or almost clear) nail involvement at week 24 was as high as 35% across the VT-1161 arms compared to 0% in the placebo arm.

The plasma concentrations of VT-1161 achieved across the treatment arms were greater than those observed for other oral agents studied for the treatment of onychomycosis. Consistent with the high levels observed in the plasma, high levels of VT-1161 were also measurable in the nail.

Safety data from the interim analysis population through the week 24 visit demonstrated that VT-1161 was well-tolerated with a favorable safety profile. In particular, there was no evidence of an adverse effect on liver function.

### **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 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](http://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. and VPS-3, Inc. The Viamet group of companies are based in the Research Triangle Park region of North Carolina, USA.*

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