

## **Viamet Reports Positive Interim Results of Phase 2 Interdigital Tinea Pedis Study of VT-1161**

### ***Company reports positive interim safety and efficacy data from study in patients with moderate-to-severe interdigital tinea pedis***

March 12, 2014, Research Triangle Park, North Carolina – [Viamet Pharmaceuticals Inc.](#) today reported positive interim results from an ongoing Phase 2 study of VT-1161, the Company’s novel oral antifungal compound, in patients with moderate-to-severe interdigital tinea pedis (ITP), also known as athlete’s foot. This study is intended as a precursor to a Phase 2b study in patients with onychomycosis, a very common fungal infection of the nail. VT-1161 is an inhibitor of the fungal enzyme CYP51, the target of the current triazole antifungals, but is from a novel chemical class that was rationally designed by Viamet with the goal of providing a superior efficacy profile and avoiding many of the side effects that characterize these current triazole antifungal agents.

The ITP study will enroll approximately 48 patients in three VT-1161 oral dose groups versus placebo. In the initial portion of the study, patients were enrolled in the low-dose VT-1161 group, the mid-dose VT-1161 group and the placebo group. Both clinical and mycologic endpoints were evaluated at the test-of-cure visit on Day 42. Effective clinical cure was based upon an improvement in six clinical signs and symptoms, each of which was graded on a scale from 0 (absent) to 3 (severe). Mycologic cure was defined as a negative fungal culture. Effective therapeutic cure was defined as both effective clinical cure and mycologic cure.

The results of the interim analysis support the robust activity of VT-1161. In the intent-to-treat population (all randomized patients who received at least one dose of study drug), effective therapeutic cure was achieved in approximately 42% of patients in both the low- and mid-dose VT-1161 arms, whereas no patient in the placebo arm achieved effective therapeutic cure. Although the study was not powered to demonstrate statistical significance, a p-value of  $p < 0.05$  was obtained in both dose groups versus placebo. VT-1161 was also found to be well tolerated with no serious adverse events reported, and no patient discontinuing VT-1161 due to an adverse event. Based upon the favorable safety and tolerability profile, patients were enrolled into an additional high-dose cohort. Interim results from this final patient cohort are expected in late Q2 2014.

“We are very pleased with the interim results of this study, which along with the recently reported interim results of our Phase 2 study in patients with acute vulvovaginal candidiasis (AVVC), demonstrate clear evidence of antifungal activity. We look forward to examining a higher dose of VT-1161 in this study over the next several months,” noted Robert Schotzinger, MD, PhD, CEO of Viamet. “We believe that positive results from the current ITP study provide a strong rationale to conduct a larger Phase 2b study in patients with onychomycosis since the two diseases are caused by the same fungal pathogens. Current oral therapies for onychomycosis, which affects approximately 35 million individuals in the US, are suboptimal from a safety and tolerability perspective. In addition, current topical therapies provide only very low efficacy rates. Because of its unique properties, such as high penetration into the nail after oral administration, we believe that VT-1161 represents a promising agent for patients with this condition. In addition, we continue to study VT-1161 in patients with AVVC as a precursor to a larger Phase 2b study in patients with recurrent vulvovaginal candidiasis.”

#### **About Onychomycosis**

Onychomycosis is a fungal infection of the nail, most often caused by dermatophytes. Approximately 35 million individuals in the US are affected by this condition. In addition to being a significant cosmetic issue, onychomycosis can cause discomfort and pain, and in some individuals can make ambulation difficult. In diabetic patients, onychomycosis can also serve as the setting for bacterial infection, which can lead to serious

complications. Terbinafine and itraconazole are the only two oral agents currently approved for the treatment of onychomycosis in the US.

#### **About VT-1161**

VT-1161 is an oral, small molecule inhibitor of the fungal metalloenzyme, CYP51. VT-1161 is in Phase 2 clinical development for the treatment of a range of human fungal infections. Viamet utilized its proprietary Metallophile™ technology platform to design VT-1161 to be highly selective for the fungal CYP51 enzyme, while sparing human CYP enzymes in order to reduce the significant toxicities observed with currently marketed CYP51 inhibitors. VT-1161 has shown robust activity in multiple preclinical models of superficial, mucosal, and invasive fungal infections. Oral VT-1161 demonstrated excellent safety, pharmacokinetics and penetration into human skin and nail in Phase 1 studies. Phase 2a studies of oral VT-1161 are currently ongoing in patients with interdigital tinea pedis and in patients with acute vulvovaginal candidiasis. Subject to the successful completion of these studies, the Company expects to initiate Phase 2b trials of oral VT-1161 in patients with onychomycosis and recurrent vulvovaginal candidiasis.

#### **About the Viamet Group of Companies ([www.viamet.com](http://www.viamet.com))**

Viamet discovers and develops best-in-class inhibitors of metalloenzymes using its proprietary platform, the Metallophile™ Technology. The Metallophile™ Technology evolved from the Company's world-class expertise in bioinorganic chemistry and its extensive insights into metalloenzyme structure and function. The Metallophile™ Technology has enabled Viamet to rapidly build a portfolio of proprietary clinical-stage compounds and drug candidates that addresses significant unmet medical needs and represents significant commercial potential.

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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 and VT-1161, including that clinical trials 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-1, Inc., VPS-2, Inc. and VPS-3, Inc. The Viamet group of companies is based in the Research Triangle Park region of North Carolina, USA.