Viamet Announces Initiation of RENOVATE Phase 2b Study of Oral VT-1161 in Onychomycosis

Company also announces favorable skin and nail penetration data from Phase 2a study in tinea pedis

March 10, 2015, Research Triangle Park, North Carolina - Viamet Pharmaceuticals today announced the initiation of the RENOVATE (REstoring Nail; an Oral VT-1161 Tablet Evaluation) Phase 2b clinical trial of VT-1161 for the treatment of toenail onychomycosis. VT-1161 is a novel, orally-available, highly potent and selective inhibitor of fungal CYP51, a well validated antifungal target. As previously reported by Viamet, VT-1161 demonstrated robust antifungal activity and a very favorable safety profile in a Phase 2a proof-of-concept study in the treatment of tinea pedis.

RENOVATE, which is a randomized, double-blind, placebo-controlled study, will enroll approximately 250 patients with toenail onychomycosis at approximately 25 clinical sites throughout the U.S. The study will evaluate two dose levels of VT-1161 administered once weekly for either 10 or 22 weeks following an initial two-week loading dose period. The primary endpoint for the study will be the percentage of patients achieving complete cure of the target nail at week 48 of the study, which extends either 24 or 36 weeks beyond the conclusion of dosing with VT-1161 depending on the dose group.

Onychomycosis, a chronic fungal infection of the nail and nail unit, affects approximately 32 million individuals in the U.S. The infection can cause deformation, discoloration, thickening and splitting of the nail, as well as separation of the nail from the nail bed. The condition can also result in pain and discomfort and cause difficulties in walking. In diabetic patients, onychomycosis can also serve as an entry point for secondary bacterial infections, which can lead to serious complications. If untreated, onychomycosis generally will not improve, and may worsen over time. Although oral and topical agents have been approved for the treatment of onychomycosis in the U.S., the use of oral agents is limited primarily by safety concerns such as liver toxicity, while the use of topical agents is limited by low efficacy rates.

As previously reported, in a Phase 2a proof-of-concept study in tinea pedis, VT-1161 was safe and well tolerated through the test-of-cure visit on day 42 utilizing a 14 day dosing regimen. Importantly, VT-1161 was also effective in resolving the associated signs and symptoms of tinea pedis, as well as in achieving mycologic cure as determined by fungal culture and fungal KOH staining. In addition to the analysis on day 42, patients were evaluated on day 84 to assess the levels of VT-1161 in the toenail and skin, both of which were found to be significantly higher than published results following 28 days of dosing with either terbinafine or itraconazole, the two approved oral therapies for onychomycosis in the U.S. Also of note, the concentration of VT-1161 in the nail was significantly higher on day 84 than upon the completion of dosing at day 14, indicating continued accumulation of VT-1161 in the nail beyond the dosing period.

Robert Schotzinger, MD, PhD, CEO of Viamet commented, "We are pleased to initiate the RENOVATE clinical trial and to report the positive nail and skin penetration data from our Phase 2a tinea pedis study. The high degree of penetration of VT-1161 into the skin and nail observed in the Phase 2a study significantly increases our confidence that the RENOVATE study in onychomycosis will be successful. We look forward to advancing VT-1161 in this indication, for which current oral agents are suboptimal with respect to safety and current topical agents are suboptimal with respect to efficacy."

About VT-1161

VT-1161 is a potent and selective, orally-available inhibitor of fungal CYP51. VT-1161 blocks the production of ergosterol, an essential component of the fungal cell membrane. In *in vitro* and *in vivo* studies, VT-1161 has demonstrated broad spectrum activity against both Candida species and dermatophytes, including those species that cause recurrent vulvovaginal candidiasis (RVVC) and onychomycosis. Because VT-1161 is highly selective for fungal CYP51, the Company believes that it may avoid the side effects that limit the use of commonly prescribed antifungal therapies, such as liver toxicity and drug-drug interactions.

About Viamet (www.viamet.com)

Viamet is a biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics based on a proprietary metalloenzyme medicinal chemistry platform, the Metallophile® Technology. The Company is using this platform to design drugs that are expected to have greater selectivity and safety as well as improved potency compared to currently available therapeutics. The Company's initial product candidates include a portfolio of highly potent and selective novel antifungal agents.

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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 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 is based in the Research Triangle Park region of North Carolina, USA.