



Viamet Presents Positive Results from Phase 2b Trial of VT-1161 in Onychomycosis at the American Academy of Dermatology Annual Meeting

Results demonstrate robust efficacy and favorable safety profile for VT-1161

RESEARCH TRIANGLE PARK, N.C., March 06, 2017 - [Viamet Pharmaceuticals, Inc.](#), announced today the presentation of results from RENOVAE (**R**estoring **N**ail: An **O**ral **VT-1161** **T**ablet **E**valuation), its Phase 2b clinical trial of VT-1161 in onychomycosis of the toenail at the 75th American Academy of Dermatology (AAD) Annual Meeting. The positive efficacy and safety outcomes of the study were presented as part of a late-breaking research forum. VT-1161 is a highly potent and selective orally available inhibitor of fungal CYP51.

In the Phase 2b study, VT-1161-treated patients met the primary endpoint of complete cure of the target toenail at 48 weeks at a rate that was highly statistically significant compared with patients in the placebo group. Complete cure, which requires both a normal appearing nail and negative mycology testing, is the endpoint historically required by the U.S. Food and Drug Administration (FDA) for approval. 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 VT-1161 arms achieving statistical significance vs. placebo. Complete cure rates for evaluable patients through week 48, calculated using an analysis similar to that used for the FDA approval of terbinafine, the current standard-of-care for onychomycosis, were as high as 51% in the VT-1161 groups. 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. There was also no evidence of an adverse effect of VT-1161 on liver function.

“The robust efficacy and safety results from the RENOVAE study demonstrate the promise of VT-1161 as a best-in-class therapy for onychomycosis,” said Amir Tavakkol, Ph.D., Chief Development Officer of Viamet, and conference presenter. “These data are among the strongest to be reported for onychomycosis, particularly when viewed in comparison to terbinafine, which was approved based on a 31% intent-to-treat and 38% evaluable complete cure rate, and given the significant safety concerns which limit its use. The continued improvement of complete cure rate observed through week 60 of the study in the VT-1161 arms speaks to the durability of response and the potential for lower relapse rates. We look forward to advancing VT-1161 into Phase 3 testing.”

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 target 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 35 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.

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