

## **Viamet Announces Initiation of REVIVE Phase 2b Study of VT-1161 in Recurrent Vulvovaginal Candidiasis**

***Company also announces very favorable prevention of recurrence data from Phase 2a study in acute vulvovaginal candidiasis***

February 12, 2015, Research Triangle Park, North Carolina - Viamet Pharmaceuticals today announced the initiation of the REVIVE (REcurrent Vulvovaginal Candidiasis Inhibition; an Oral VT-1161 Tablet Evaluation) Phase 2b clinical trial of VT-1161 for the treatment of recurrent vulvovaginal candidiasis (RVVC), a particularly refractory clinical condition. 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 favorable safety profile in a Phase 2a proof-of-concept study in the treatment of acute vulvovaginal candidiasis.

REVIVE, which is a randomized, double-blind, placebo-controlled study, will enroll approximately 200 patients with a documented history of RVVC at approximately 25 clinical sites throughout the U.S. The study will evaluate two dose levels of VT-1161 administered once-weekly for either 11 or 23 weeks following an initial one-week loading-dose period. The primary endpoint for the study will be the prevention of acute episodes of vulvovaginal candidiasis through 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.

An estimated 5-8% of women of child-bearing age suffer from recurring episodes of acute vulvovaginal candidiasis, a syndrome termed RVVC. There are currently no approved agents in the United States to prevent these recurring and difficult to treat infections. Current therapies, while effective for uncomplicated episodes of acute vulvovaginal candidiasis, are typically not effective in preventing recurrent infections. There is a significant unmet medical need for a safe and effective oral therapy to treat RVVC.

As previously reported, in a Phase 2a proof-of-concept study in acute vulvovaginal candidiasis, VT-1161 was safe and well tolerated through the test-of-cure visit on Day 28. Importantly, VT-1161 was also highly effective in resolving the associated signs and symptoms of the acute infection, as well as in achieving mycologic cure as determined by fungal culture and fungal KOH staining. In addition to the analysis on Day 28, patients were followed for an additional five months to assess for potential recurrence of infection. As has been previously observed in other clinical trials, approximately half of the patients in the Phase 2a trial who received oral fluconazole, the standard of care, experienced an additional episode of vulvovaginal candidiasis requiring re-treatment during the five months following the Day 28 assessment. In marked contrast, no patient in any VT-1161 dosing arm experienced a recurrence of the infection requiring retreatment during the five months following the Day 28 assessment.

Robert Schotzinger, MD, PhD, CEO of Viamet commented, “We are pleased to initiate the REVIVE clinical trial and to report the positive six-month follow-up data from our Phase 2a study. The lack of recurrent infections in the Phase 2a study significantly increases our confidence that the REVIVE study in RVVC will be successful. We look forward to advancing VT-1161 in this indication, for which there are currently no approved drugs in the US and for which the unmet medical need is significant.”

### **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 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](http://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.