Viamet Receives Fast Track Designation from the FDA for VT-1129 for the Treatment of Cryptococcal Meningitis

RESEARCH TRIANGLE PARK, N.C., June 1, 2016, – Viamet Pharmaceuticals, Inc, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for VT-1129 for the treatment of cryptococcal meningitis, a life-threatening fungal infection of the membranes covering the brain and spinal cord. VT-1129, an orally available inhibitor of fungal CYP51, has also received orphan drug designation for the treatment of cryptococcal meningitis and has been designated a Qualified Infectious Disease Product (QIDP) by the FDA.

Cryptococcal meningitis is a life-threatening fungal infection that occurs most often in immunocompromised patients such as HIV patients, transplant recipients and oncology patients. An estimated 3,400 hospitalizations related to cryptococcal meningitis occur annually in the United States. The disease is widespread in the developing world due to the high incidence of HIV infection and AIDS, with approximately one million cases occurring each year, resulting in 625,000 deaths.

VT-1129 is a highly selective inhibitor of fungal CYP51 that has shown significant potency against Cryptococcus species, the causative fungal species of cryptococcal meningitis. In preclinical models, VT-1129 has demonstrated robust activity against Cryptococcus species as well as the ability to achieve high concentrations within the central nervous system, the primary site of infection. Viamet is currently conducting a Phase 1 clinical trial of VT-1129 in healthy volunteers in the United States.

“We are pleased that the FDA has granted Fast Track designation status to VT-1129 for the treatment of cryptococcal meningitis, as this provides the opportunity to deliver this potential life-saving treatment to patients in a more rapid timeframe,” commented Robert Schotzinger, M.D., Ph.D., CEO of Viamet. “In preclinical models of cryptococcal meningitis, VT-1129 demonstrated the ability to fully eradicate the fungal pathogen from the brain, an astonishing result that leads us to believe that VT-1129 has the potential to be an important new weapon to treat this terrible disease.”

About Fast Track Designation
Fast track is a designation by the U.S. Food and Drug Administration (FDA) to facilitate the development, and expedite the review of experimental therapies to treat serious conditions and fill an unmet medical need. The purpose of the Fast Track program is to get important new drugs to patients earlier.

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.

Media Contact:
Blair McCarthy Atkinson
MacDougal Biomedical Communications
Direct: +1 812 454 6257
Main: +1 781 235 3060
batkinson@macbiocom.com
Investor Contact:
John Woolford
Westwicke Partners
Direct: +1 443 213 0506
john.woolford@westwicke.com

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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