FDA Grants QIDP Designation to VT-1598 for Treatment of Valley Fever

Molecule Adds to Broad Portfolio of Best-In-Class Drug Candidates Discovered by Viamet

September 15, 2016, Research Triangle Park, North Carolina – Viamet Pharmaceuticals, Inc. today announced that the U.S. Food and Drug Administration (FDA) has granted Qualified Infectious Disease Product (QIDP) designation to VT-1598, a novel candidate for the oral treatment of coccidioidomycosis, or Valley Fever. Valley Fever is an invasive fungal infection found primarily in the southwest United States that affects an estimated 150,000 people annually.

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-1598, including the potential for priority review by the FDA, eligibility for Fast Track status, and a five-year extension of marketing exclusivity under the Hatch-Waxman Act. Previously, the FDA granted orphan drug designation to VT-1598 for the treatment of Valley Fever.

"The FDA's decision to grant QIDP designation to VT-1598 underscores the significant need for new, effective and safe therapies to treat Valley Fever. The fungus that causes Valley Fever lives in the soil and simply breathing the spores of this pathogen can lead to serious infections of the lung, brain and other internal organs. Anyone living in, or traveling to, the southwest United States is at risk of contracting this serious infection for which current treatment options are very limited," stated Robert Schotzinger, M.D., Ph.D., and CEO of Viamet.

VT-1598 is the third best-in-class product candidate in development by Viamet. The first product, VT-1161, is nearing completion of Phase 2b testing for the oral treatment of onychomycosis, a highly prevalent fungal infection of the nail, and recurrent vulvovaginal candidiasis, or recurrent yeast infection, a common and difficult to treat condition in women. The second product, VT-1129, is in Phase 1 testing for the oral treatment of cryptococcal meningitis, a life-threatening fungal infection of the brain.

About VT-1598
VT-1598 is an orally available inhibitor of fungal CYP51 that has demonstrated high potency against a broad range of fungal pathogens, including common molds and yeasts. VT-1598 is also potent against a fungal class referred to as endemic fungi, which includes *Coccidioides*, *Histoplasma* and *Blastomyces* species. Viamet is developing VT-1598 for the treatment of Valley Fever, a systemic fungal infection in the southwestern United States characterized by significant unmet need. In preclinical models of Valley Fever, VT-1598 was highly effective in treating disease localized to the central nervous system, a common site of dissemination in humans.

About Valley Fever
Valley Fever is heavily concentrated in the Southwestern United States, where the spores of the fungal pathogen *Coccidioides* live in the soil. Many of the estimated 150,000 cases of Valley Fever that occur annually are either self-limited or resolve with current therapies. However, approximately 5% to 10% of patients will develop a debilitating and sometimes fatal form of the disease at times associated with chronic lung infection and dissemination to other parts of the body. Patients with chronic forms of the illness experience symptoms that resemble those of the flu, and can range from mild to severe, including fever, cough, chest pain, chills, night sweats, headache, fatigue, joint aches and rash.

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 safety and efficacy 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, 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.