



Viamet Receives Orphan Drug Designation from the FDA for VT-1598 for the Treatment of Coccidioidomycosis

RESEARCH TRIANGLE PARK, N.C., May 25, 2016, – [Viamet Pharmaceuticals, Inc.](#) today announced that the U.S. Food and Drug Administration (FDA) Office of Orphan Products Development has granted orphan drug designation to VT-1598 for the treatment of coccidioidomycosis, or Valley Fever. VT-1598 is a selective, orally available inhibitor of fungal CYP51 that has demonstrated high potency in preclinical studies against *Coccidioides* species, the fungal pathogens responsible for Valley Fever.

Valley Fever, a common lung infection in the southwestern U.S., affects approximately 150,000 people in the U.S. annually. Approximately 5% to 10% of Valley Fever sufferers develop a more severe form of the disease and some of these patients will develop a chronic pulmonary infection, which can be associated with dissemination of the fungal infection to other parts of the body. While current therapies are effective in some patients, they are often poorly tolerated and morbidity and mortality remain significant.

In preclinical studies, VT-1598 has demonstrated significantly greater potency against *Coccidioides* clinical isolates than fluconazole, an antifungal therapy commonly used as the primary treatment for Valley Fever. In preclinical models of Valley Fever, oral VT-1598 was highly effective in treating disease localized to the central nervous system, the most difficult to treat site of dissemination in humans.

“We are pleased that the FDA has granted orphan status to VT-1598 for the treatment of Valley Fever. We believe that the unique properties of VT-1598 provide the potential for a new treatment option for patients suffering from this disease,” commented Robert Schotzinger, M.D., Ph.D., CEO of Viamet. “Valley Fever is a disease with considerable unmet need and we look forward to progressing this very exciting product candidate.”

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 in preclinical studies. VT-1598 is particularly potent against a fungal class referred to as the endemic fungi, which includes *Coccidioides*, *Histoplasma* and *Blastomyces* species. Viamet is developing VT-1598 for the treatment of Valley Fever, a common lung infection in the southwestern United States characterized by high 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 U.S., where the spores of the fungal pathogen *Coccidioides* live in the soil. Most 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 more severe form of the disease and a certain percentage of these patients will develop a chronic pulmonary infection at times associated with 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 the Orphan Drug Act

The Orphan Drug Act (ODA) provides for granting special status to a drug or biological product to treat a rare disease or condition. This status is referred to as orphan designation (or sometimes “orphan status”). For a drug to qualify for orphan designation both the drug and the disease must meet certain criteria specified in the ODA and the FDA’s implementing regulations at 21 CFR Part 316. Orphan designation



qualifies the sponsor of the drug for various development incentives of the ODA, including tax credits for qualified clinical testing.

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, 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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