



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

RESEARCH TRIANGLE PARK, N.C., July 13, 2017, – [Viamet Pharmaceuticals, Inc.](#) today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to VT-1598, a novel oral agent for the treatment of coccidioidomycosis, also known as Valley Fever. Valley Fever is an invasive fungal infection that is highly concentrated in the San Joaquin Valley in California (where *Coccidioides immitis* is the predominant pathogen). It is also present in central and southern Arizona, western Texas, southern New Mexico, and parts of Mexico and Central and South America (where *Coccidioides posadasii* is the predominant pathogen). Infection occurs by inhalation of the microscopic fungal spores from the air in the affected regions. Current therapies for Valley Fever are limited by significant safety concerns, drug interactions and poor efficacy.

Fast Track designation is designed to facilitate the development and expedite the review of new drug candidates to treat serious conditions and fill an unmet medical need. Previously, the FDA granted orphan drug designation and Qualified Infectious Disease Product (QIDP) designation to VT-1598 for the treatment of Valley Fever.

“The FDA’s decision to award Fast Track designation to VT-1598 highlights the high unmet needs in the treatment of Valley Fever, and provides a process for Viamet to work closely with the FDA to bring this treatment to patients in an expedited manner,” said Robert Schotzinger, M.D., Ph.D., President and CEO of Viamet. “Each year, approximately 5-10% of the patients that contract Valley Fever develop chronic pulmonary or disseminated disease, which can be deadly. Preclinical studies have shown that VT-1598 has the potential to be a highly potent and highly selective antifungal agent with broad spectrum activity, and we look forward to continuing the advancement of this promising candidate.”

VT-1598 is one of several product candidates with best-in-class potential in development by Viamet. VT-1161, Viamet’s lead product candidate, recently completed two Phase 2b clinical trials, [RENOVATE](#) and [REVIVE](#), which investigated 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.

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 molds, yeasts and multi-drug resistant fungal pathogens such as *Candida auris*. VT-1598 is also potent against a fungal class referred to as endemic fungi, which includes *Coccidioides*, *Histoplasma* and *Blastomyces* species. VT-1598 blocks the production of ergosterol, an essential component of the fungal cell membrane. Viamet is developing VT-1598 for the treatment of serious and life-threatening invasive fungal infections. Given the preclinical profile of VT-1598, Viamet 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), Fast Track and orphan drug designation to VT-1598 for the treatment of coccidioidomycosis, or Valley fever.

About Valley Fever (Coccidioidomycosis)

Coccidioidomycosis, also called Valley Fever, is an infection caused by the fungal pathogen *Coccidioides*. Valley Fever is heavily concentrated in the Southwestern United States, as well as parts of Mexico, Central and South America, where the spores of *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 efficacy and safety profiles compared to currently marketed drugs.

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., 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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