



FDA Grants QIDP Designation to VT-1129 for Treatment of Cryptococcal Meningitis

Initiation of Phase 1 Program Expected in 4Q 2015

Company to Highlight Potential of VT-1129 at ICAAC/ICC 2015

September 16, 2015, 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-1129, the company's novel candidate for the treatment of cryptococcal meningitis. Created under the Generating Antibiotics Incentives Now (GAIN) Act of 2012, QIDP designation provides Viamet with significant incentives for the development of VT-1129, 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.

"The FDA's decision to grant QIDP designation to VT-1129 supports our belief that VT-1129 has the potential to provide a marked impact in the treatment of cryptococcal meningitis, which is associated with significant mortality and morbidity globally. QIDP designation may expedite development of this promising therapy, accelerating the potential availability to patients afflicted with this life-threatening fungal infection of the brain," commented Robert Schotzinger, M.D., Ph.D., and CEO of Viamet. "Based on our successful progress to date, we expect to initiate the Phase 1 clinical program for VT-1129 in the fourth quarter of 2015."

The company also announced that VT-1129 will be highlighted in two presentations at the 2015 American Society for Microbiology (ASM) Interscience Conference of Antimicrobial Agents and Chemotherapy (ICAAC) and International Society of Chemotherapy (ISC) International Congress of Chemotherapy and Infection (ICC). The conference will take place September 17-21, 2015 in San Diego, CA.

The presentations will illustrate that VT-1129 is a potent inhibitor of the CYP51 enzyme in *Cryptococcus neoformans*, the fungal organism responsible for cryptococcal meningitis. CYP51, a metalloenzyme essential for fungal proliferation and survival, is the target of several marketed antifungal therapies. In preclinical studies, VT-1129 exhibited robust activity against clinical *Cryptococcus* isolates, including isolates highly resistant to fluconazole, a widely prescribed antifungal agent. At ICAAC/ICC 2015, preclinical data will be presented demonstrating that VT-1129 is highly selective for fungal CYP51 versus closely related human metalloenzymes, including CYP3A4, CYP2C9, CYP2C19, CYP17 and CYP19. Inhibition of human metalloenzymes is a common reason for toxicity with many marketed antifungal therapies.

About VT-1129

VT-1129 is a potent and highly selective inhibitor of fungal CYP51. VT-1129 blocks the production of ergosterol, an essential component of the fungal cell membrane, which is critical to fungal proliferation and survival. In preclinical models, oral VT-1129 has demonstrated very high potency against *Cryptococcus* species, achieves high concentrations within the central nervous system, and markedly improves survival in cryptococcal meningitis models. VT-1129 has been granted orphan drug and QIDP designation by the U.S. Food & Drug Administration (FDA).

About Cryptococcal Meningitis

Cryptococcal meningitis is a life-threatening fungal infection of the brain and the spinal cord. This infection occurs most often in immunocompromised patients, including those with HIV infection, transplant recipients and oncology patients. It is estimated that there are 3,400 hospitalizations associated with cryptococcal meningitis annually in the United States. Worldwide, approximately 1 million new cases of cryptococcal meningitis occur each year, resulting in 625,000 deaths.

About Metalloenzymes

Enzymes are complex proteins that help to accelerate biochemical reactions in the body. Metalloenzymes are unique in that they contain a metal atom, commonly iron or zinc, at the center of the enzyme active site. Since many metalloenzymes have been clearly associated with disease, the metal in the enzyme is commonly a target for pharmaceutical intervention. It is estimated that approximately 10% of marketed drugs act by blocking metalloenzyme activity. Inhibitors of metalloenzymes are found across numerous therapeutic indications and many of the inhibitors have achieved blockbuster commercial status. The development of new metalloenzyme inhibitors remains a core focus of the pharmaceutical industry today and the primary focus for Viamet.

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.