



Mycovia Pharmaceuticals Debuts with Initiation of Phase 3 Clinical Trials for Treatment of Recurrent Vulvovaginal Candidiasis

Durham, NC – September 6, 2018 – [Mycovia Pharmaceuticals](#), making its official debut as a company developing therapies in women’s health and dermatology, today announced the initiation of two Phase 3 clinical trials called VIOLET to evaluate the safety and efficacy of its lead candidate, VT-1161, in patients with recurrent vulvovaginal candidiasis (RVVC).

Mycovia was created following the [acquisition of Viamet Pharmaceuticals](#) by NovaQuest Capital Management to develop VT-1161 for the treatment of fungal infections including RVVC and onychomycosis, a common infection of the nail. RVVC is generally defined as three or more yeast infections per year and affects approximately 5-8 percent of women. While the physical symptoms of RVVC, which include itching, irritation, soreness and damage to the skin, are distressing, the emotional and psychological consequences can also have a significant impact on quality of life.

“Women’s health is an underserved therapeutic area with significant unmet need. There are currently no approved treatment options for RVVC in the U.S. today, despite the negative effects that the condition has on millions of women,” said Patrick Jordan, Chief Executive Officer of Mycovia and a Partner at NovaQuest Capital Management. “We founded Mycovia to continue studying the candidate as a potential treatment option while also exploring its effectiveness in additional fungal infections such as onychomycosis. We are encouraged by the progress made in the past few months that allowed us to enter into Phase 3 trials shortly after the company’s creation and look forward to continued studies in both RVVC and onychomycosis.”

“VT-1161 is highly potent against a broad spectrum of *Candida* species, the primary fungal pathogen responsible for RVVC, and in recently-completed Phase 2 studies clinically demonstrated a durable response against re-infection,” said Stephen Brand, Ph.D., Senior Vice President of Clinical Development at Mycovia. “VT-1161 has the potential to be a best-in-class treatment option for patients suffering from RVVC and to be the first FDA-approved treatment for this common disease.”

Following meetings with the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) and Japan’s Pharmaceuticals and Medical Devices Agency (PMDA), Mycovia has alignment with the regulatory agencies on the key aspects of the VIOLET trials. Two global multi-center, randomized, double-blind, placebo-controlled trials will be conducted in North America, Europe and Japan with approximately 60 global sites and 300 randomized patients per study. The company expects to complete studies of the RVVC program in the second half of 2020 in anticipation of regulatory submissions in the United States, European Union and Japan.

“The current treatment approach for patients with RVVC is typically treatment of the acute infection each time one occurs. In some cases, this is followed by long term suppressive therapy with oral fluconazole, a drug with a limited antifungal spectrum and which has been associated with drug-drug-interactions and potential pregnancy effects,” said Jack D. Sobel, M.D., Dean, Wayne State University School of Medicine and one of the clinical investigators in the VIOLET studies. “VT-1161 demonstrated a

high degree of efficacy and safety during the Phase 2 REVIVE study. The low re-infection rates observed in the VT-1161 treated patients were very impressive compared to other therapies previously studied in RVVC. I'm excited to continue to play a role in the development of this potentially important new therapy.”

More information on the VIOLET Phase 3 trials can be found at clinicaltrials.gov under the identifier numbers NCT03561701 and NCT03562156.

About VT-1161

VT-1161 is an orally available inhibitor of fungal CYP51 being developed by Mycovia for the treatment of recurrent vulvovaginal candidiasis (RVVC) and onychomycosis. VT-1161 is designed to have greater selectivity, fewer side effects and improved potency.

About Mycovia Pharmaceuticals

At Mycovia, we are passionate about developing targeted therapies in women’s health and dermatology. The company was formed in 2018 following the acquisition of Viamet Pharmaceuticals by NovaQuest Capital Management. For more information, please visit www.mycovia.com.

About NovaQuest

NovaQuest Capital Management is a leading investor in life sciences and healthcare through its BioPharma and Private Equity strategies. NovaQuest was formed in 2000 with the vision of building an investment platform to provide strategic capital to life sciences and healthcare companies. Today, NovaQuest Capital Management manages over \$1.8 billion through its BioPharma and Private Equity strategies. The investment team consists of highly seasoned operational and investment professionals with significant investment experience and deep life science and healthcare expertise. Furthermore, NovaQuest benefits from an extensive network of industry experts and relationships that assist in identifying, analyzing and growing NovaQuest portfolio companies and investments. For more information, please visit www.novaquest.com.

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