



Mycovia Pharmaceuticals Initiates Additional Phase 3 Clinical Study Evaluating VT-1161 for the Treatment of Vulvovaginal Candidiasis

Durham, N.C. – February 27, 2019 – [Mycovia Pharmaceuticals](#), a company developing therapies in women’s health and dermatology, today announced the initiation of an additional Phase 3 clinical study called ultraVIOLET to evaluate the safety and efficacy of lead candidate, VT-1161, and its ability to treat acute infections in women with recurrent vulvovaginal candidiasis (RVVC) compared to fluconazole, the current standard of care.

“With recruitment underway in eleven countries for our two VIOLET Phase 3 studies evaluating VT-1161 in RVVC, we are delighted to begin enrolling patients in our third Phase 3 ultraVIOLET study,” said Stephen Brand, Ph.D., Senior Vice President of Clinical Development at Mycovia. “The ultraVIOLET study is designed to further evaluate the clinical utility of VT-1161 in treating acute episodes of vulvovaginal candidiasis when compared to the current standard of care, fluconazole. Previous clinical studies demonstrated that VT-1161 was superior to fluconazole in treating vulvovaginal candidiasis, and we are excited to evaluate VT-1161 compared to fluconazole in a larger population.”

“While millions of women experience recurrent yeast infections each year, there are currently no FDA-approved treatment options for RVVC in the U.S.,” said Patrick Jordan, Chief Executive Officer of Mycovia and a Partner at NovaQuest Capital Management. “We are pleased to have initiated three Phase 3 studies evaluating VT-1161 for the treatment of RVVC, a disease for which there are limited treatment options. Based on the results of previous clinical studies, we believe that VT-1161 has the potential to be a best-in-class treatment option for patients living with RVVC and to be the first FDA-approved treatment for this disease.”

Mycovia has reached agreement on pivotal study designs with the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) and Japan’s Pharmaceuticals and Medical Devices Agency (PMDA). The additional randomized, double-blind ultraVIOLET Phase 3 trial will be conducted in the United States with approximately 45 sites and 180 randomized patients. The company expects to complete all three Phase 3 trials of the RVVC program in the second half of 2020 in anticipation of regulatory submissions.

More information on Mycovia’s Phase 3 trials can be found at [clinicaltrials.gov](#) under the identifier numbers NCT03840616 for the ultraVIOLET trial and NCT03561701 and NCT03562156 for the VIOLET trials.

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 Recurrent Vulvovaginal Candidiasis (RVVC)

Recurrent vulvovaginal candidiasis (RVVC) is a debilitating, chronic infectious condition that affects millions of women. Primary symptoms include vaginal itching, burning, irritation and inflammation. Some women may experience abnormal vaginal discharge and painful sexual intercourse or urination, causing variable but often severe discomfort and pain. RVVC impacts quality of life, to a degree comparable to asthma and worse than diseases such as headache and migraine, yet despite the high prevalence, there are currently no agents in the United States approved to treat the condition.

About Mycovia Pharmaceuticals

Mycovia is 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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