



**Mycovia Pharmaceuticals Completes Enrollment in its Third Phase 3 Clinical Trial for VT-1161 (ultraVIOLET) in Patients with Recurrent Vulvovaginal Candidiasis**

*ultraVIOLET trial evaluating efficacy of VT-1161 compared to fluconazole with topline data expected in 2H2020*

Durham, N.C. – December 18, 2019 – [Mycovia Pharmaceuticals, Inc.](#) (“Mycovia”) today announced it has completed enrollment for its ongoing Phase 3 ultraVIOLET clinical trial for VT-1161. Mycovia is developing VT-1161, an oral antifungal product candidate, for the treatment of Recurrent Vulvovaginal Candidiasis (RVVC), a debilitating, chronic infectious condition that affects nearly 138 million women worldwide each year and for which there is currently no approved treatment in the U.S.

“We are thrilled to announce the completion of enrollment for ultraVIOLET – one of our three ongoing Phase 3 clinical trials for VT-1161 – which comes on the heels of the accelerated completion of enrollment for our two global VIOLET clinical trials,” said Stephen Brand, PhD, Senior Vice President, Clinical Development at Mycovia. “This is a significant milestone for the VT-1161 clinical program, which has the potential to be the first FDA-approved therapy for RVVC. Each day, we are reminded of the significant unmet need, and we look forward to reporting topline data from these studies in the second half of 2020.”

Brand continued, “VT-1161 was rationally designed to overcome the limitations associated with fluconazole, the current standard of care for vaginal candidiasis. Previous studies have shown VT-1161 to be more potent than fluconazole against *Candida albicans*, the most common causative pathogen associated with RVVC. VT-1161 has also demonstrated strong activity against *Candida glabrata* and other non-*albicans* species, which are often resistant to fluconazole.”

Mycovia initiated the randomized, double-blind, placebo-controlled ultraVIOLET trial in February 2019 to evaluate the safety and efficacy of VT-1161, in addition to its ability to treat acute episodes of vulvovaginal candidiasis in women with RVVC compared to fluconazole. The ultraVIOLET trial is being conducted at 51 sites in the U.S. and has enrolled over 200 patients. In previous clinical studies, VT-1161 has been shown to have a favorable safety profile, with no discernable adverse effect on liver function, and has been generally well tolerated in more than 1,200 patients to date.

Mycovia continues to build its global commercial capabilities in addition to its anticipated launch of VT-1161 in the U.S. in 2021. Earlier this year, the company signed global exclusive licensing agreements to expand access to VT-1161 in other parts of the world. In October, Mycovia licensed VT-1161 to Gedeon Richter, a Hungary-based leader in women’s health that will

commercialize and manufacture the drug in Europe, Latin America, Australia, Russia and the Commonwealth of Independent States. In June, Mycovia licensed VT-1161 to Jiangsu Hengrui Medicine, the largest pharmaceutical company in China by market cap and one of the largest in the world, to develop and commercialize VT-1161 in China, including mainland China, Hong Kong, Macau and Taiwan.

More information about Mycovia's Phase 3 trials can be found at [clinicaltrials.gov](https://clinicaltrials.gov) under the identifier numbers NCT03840616 for the ultraVIOLET trial and NCT03561701 and NCT03562156 for the VIOLET trials.

### **About Mycovia Pharmaceuticals**

Mycovia Pharmaceuticals has a passion for developing breakthrough therapies in areas of unmet medical need, with an initial focus in women's health. Our lead product candidate, VT-1161, is a novel, oral therapy for RVVC that is designed to have greater selectivity, fewer side effects and improved efficacy than current treatment options. VT-1161 received FDA Qualified Infectious Disease Product and Fast-Track designations to support its potential as the first FDA-approved treatment for RVVC. In 2019, Mycovia licensed VT-1161 to Jiangsu Hengrui Medicine Co., to develop and commercialize VT-1161 in China, including mainland China, Hong Kong, Macau and Taiwan, and Gedeon Richter Plc., a Hungary-based pharmaceutical company, to commercialize and manufacture VT-1161 in Europe, Russia, the Commonwealth of Independent States, Latin America and Australia. Mycovia also recognizes that there is tremendous potential for its oral fungal inhibitors to treat a range of multi-drug resistant fungal pathogens. For more information, please visit [www.mycovia.com](http://www.mycovia.com).

### **About 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.

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