Mycovia Pharmaceuticals Announces Early Completion of Enrollment for Global Phase 3 Clinical Trials for VT-1161 (VIOLET) for the Treatment of Recurrent Vulvovaginal Candidiasis

VIOLET trials being conducted at more than 160 sites in 11 countries with topline data expected in 2H2020

Durham, N.C. – November 12, 2019 – Mycovia Pharmaceuticals, Inc. ("Mycovia") today announced it has completed enrollment for both ongoing global Phase 3 VIOLET clinical trials for VT-1161 ahead of schedule, advancing timelines for the company's pivotal studies. VT-1161, an oral antifungal product candidate, is being developed 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 pleased to announce that we have reached our recruitment goal ahead of target for VT-1161, which has the potential to be the first FDA-approved therapy for RVVC," said Stephen Brand, PhD, Senior Vice President, Clinical Development at Mycovia. "Between our two VIOLET trials and our third ongoing Phase 3 clinical study for VT-1161, ultraVIOLET, we have already enrolled more than 800 patients. The accelerated completion of our enrollment is a clear sign that there is a significant unmet need among the millions of women living with RVVC."

Previous studies have shown VT-1161 to be more potent than fluconazole against Candida albicans, the most common causative pathogen associated with RVVC. Moreover, VT-1161 has also demonstrated potent activity against Candida glabrata and other non-albicans species, which are innately resistant to fluconazole. "We believe VT-1161 represents a potentially important treatment option for patients seeking relief from this condition," said Brand.

Mycovia initiated the two identical Phase 3 VIOLET clinical trials in September 2018 with a goal of randomizing 300 women in each study in countries with high prevalence of RVVC to ensure a diversified patient population and to support regulatory filing requirements in Europe and Japan. The VIOLET clinical trials are randomized, double-blind, placebo-controlled studies being conducted at 161 sites in 11 countries across North America, Europe and Japan to evaluate the safety and efficacy of VT-1161 in the treatment of patients with RVVC.

"To date, VT-1161 has been shown to have a favorable safety profile and has been generally well tolerated in more than 1,200 patients, without evidence of side effects often associated with currently available treatments," said Jack D. Sobel, M.D., Dean of the School of Medicine at Wayne State University and one of the clinical investigators in the VIOLET studies. "Additionally, data from Mycovia's Phase 2b study showed VT-1161 to be highly effective in

preventing acute VVC episodes over the 48-week study period. As the VIOLET clinical trials follow an identical protocol to the Phase 2b study, I look forward to the data readouts and am excited by the prospect of a new therapeutic option for RVVC."

Topline data will be available in the second half of 2020, and Mycovia continues to build its global commercial capabilities in anticipation of launching VT-1161 in the U.S. in 2021. The company recently signed global exclusive licensing agreements to expand access to VT-1161 in other parts of the world. In October 2019, 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 2019, Mycovia licensed VT-1161 to Jiangsu Hengrui Medicine, the largest pharmaceutical company in China 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 under the identifier numbers NCT03561701 and NCT03562156 for the VIOLET trials and NCT03840616 for the ultraVIOLET trial.

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. 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.

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.

Contacts
Mycovia Pharmaceuticals, Inc.
Tiffany Ahlers, 919-467-8539
tahlers@mycovia.com

Media
FleishmanHillard
Anuj Baveja, 919-334-3782
anuj.baveja@fleishman.com

###