Mycovia Pharmaceuticals, Inc. Announces Last Patient Completes Final Visit in their Phase 3 "ultraVIOLET Study" for Oteseconazole (VT-1161) for the Treatment of Recurrent Vulvovaginal Candidiasis (RVVC)

- ultraVIOLET Trial Evaluating Efficacy of Oteseconazole (VT-1161) Compared to Fluconazole

- Top-line Data Remains on Track for Late 2020

Durham, N.C. – December 2, 2020 – Mycovia Pharmaceuticals, Inc. ("Mycovia"), an emerging biopharmaceutical company dedicated to recognizing and empowering those living with unmet medical needs by developing novel therapies, today announced the last patient has completed her final visit in Mycovia's last Phase 3 clinical trial of oteseconazole (VT-1161) in patients with recurrent vulvovaginal candidiasis (RVVC).

- 220 patients were randomized at 51 sites in the U.S.
- Top-line data remains on track for late 2020.
- Oteseconazole received FDA Qualified Infectious Disease Product Status and Fast-Track designation with NDA submission planned for 1H 2021.

The objective of the "ultraVIOLET Study" was to assess the effectiveness of oteseconazole through 50 weeks in the prevention of recurring acute VVC episodes in women with a history of RVVC, and also to compare the efficacy of oteseconazole and fluconazole (current standard of care) in the treatment of the acute VVC episode in this patient population.

Vulvovaginal candidiasis (VVC) is a common disorder, with nearly 75 percent of all adult women having had at least one "yeast infection" in their lifetime. The majority of these infections can be effectively managed with approved therapies. However, approximately half of these women experience a recurrence, with 6 to 9 percent developing recurrent VVC, defined as three or more episodes in one year. These women remain poorly served by the current standard-of-care treatment options. 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 migraine.

Mycovia's CEO, Patrick Jordan, shared his gratitude for the completion of the final pivotal clinical study: "We are delighted to complete our third Phase 3 trial to address an area of significant unmet medical need. RVVC affects 138 million women annually around the globe, and completing ultraVIOLET brings us a step closer to a treatment. We sincerely thank the study participants and healthcare professionals who were key to reaching this important milestone with us."

Stephen Brand, PhD, Chief Development Officer, stated, "This study was designed to complement and extend our recently completed global pivotal Phase 3 studies. While fluconazole has been used to treat acute VVC episodes in patients with recurrent disease, safety concerns remain and its activity against some non-*albicans* species that are more common in patients with complicated VVC is limited.

Oteseconazole has previously been shown to be as effective as fluconazole in treating the acute VVC patient population and has also demonstrated excellent activity against typically resistant pathogens. This study will provide additional insight into safety and overall clinical utility of oteseconazole."

About ultraVIOLET Clinical Trials
This study evaluated the effectiveness and safety of oteseconazole for the treatment of acute VVC episodes in patients with RVVC and consisted of 2 parts. The first part of the study was a 2-week period for the treatment of the patient's current VVC episode when the patient took either fluconazole or oteseconazole (according to a random assignment). The second part consisted of 11 weeks, when the patient took either oteseconazole or a placebo (according to the random assignment from the first part of the study), and then a 37-week follow-up period.

About Mycovia Pharmaceuticals
Mycovia Pharmaceuticals is a late stage emerging biopharmaceutical company dedicated to recognizing and empowering those living with unmet medical needs by developing novel therapies. Our lead product candidate, oteseconazole (VT-1161), is a novel, oral therapy for RVVC that is designed with the goal of having greater selectivity, fewer side effects and improved efficacy. While not yet approved by the FDA, oteseconazole received FDA Qualified Infectious Disease Product and Fast-Track designations to support its potential to be the first FDA-approved treatment for RVVC. Oteseconazole is currently in Phase 3 clinical trials designed to establish its safety and efficacy in RVVC patients. In 2019, Mycovia licensed oteseconazole to Jiangsu Hengrui Medicine Co., to develop and commercialize oteseconazole in China, including mainland China, Hong Kong, Macau and Taiwan, and Gedeon Richter Plc., a Hungary-based pharmaceutical company, to commercialize and manufacture oteseconazole in Europe, Russia, the Commonwealth of Independent States, Latin America and Australia. Mycovia also recognizes a tremendous potential for its oral fungal inhibitors and a growing need to treat a range of multi-drug resistant fungal pathogens. For more information, please visit www.mycovia.com.

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