Mycovia Pharmaceuticals Announces Positive Topline Results from its Third Phase 3 Clinical Trial (ultraVIOLET) of Oteseconazole for the Treatment of Recurrent Vulvovaginal Candidiasis

- ultraVIOLET Evaluated the Efficacy and Safety of Oteseconazole over 50 weeks -

- Efficacy of Oteseconazole Compared to Fluconazole in Treating Acute VVC Infection in Women with RVVC -

- NDA Submission Planned in First Half of 2021 -

Durham, N.C. – January 6, 2021 – 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 positive topline results from its Phase 3 clinical trial for oteseconazole (ultraVIOLET), its drug candidate for treating patients with recurrent vulvovaginal candidiasis (RVVC). RVVC, commonly known as chronic yeast infection, is a debilitating infectious condition defined as three or more episodes per year. Oteseconazole is designed to be highly selective for its pathogenic target, with fewer side effects and improved efficacy over current treatment options, including the current standard of care for vulvovaginal candidiasis (VVC), fluconazole.

The objective of the ultraVIOLET study was to assess the effectiveness of oteseconazole over 50 weeks in the prevention of recurring acute VVC episodes in women with a history of RVVC. The study also compared the efficacy of oteseconazole and fluconazole in the treatment of acute VVC episodes. A total of 220 patients were randomized at 51 clinical sites in the U.S.

The ultraVIOLET study met all primary and secondary endpoints:

- Primary endpoint (culture-verified recurrence from randomization through Week 50)
    - Oteseconazole recurrence rate of 5.1%, fluconazole to placebo recurrence rate of 42.2% (p-value < 0.001)
- Oteseconazole non-inferior to fluconazole in the resolution of signs and symptoms at Day 14
- Culture-verified recurrence from Day 14 through Week 50:
    - Oteseconazole recurrence rate of 3.8%, fluconazole to placebo recurrence rate of 41.1% (p-value < 0.001)
- Oteseconazole prevented a recurring episode in 95% of women for approximately one year
- Oteseconazole was generally safe and well tolerated; treatment-emergent adverse events were similar across treatment groups

"Today we celebrate this critical milestone in our Phase 3 clinical program for oteseconazole," said Patrick Jordan, Chief Executive Officer of Mycovia. "With positive data in hand from ultraVIOLET and our two pivotal Phase 3 VIOLET studies, we look forward to submitting a new drug application (NDA) for oteseconazole to the FDA in the first half of 2021. We express deep thanks to the hundreds of women

who participated in all our Phase 3 trials and to every clinical investigator who supported this achievement."

"Fluconazole is approved to treat acute VVC infections and women typically respond well to short-term treatment. Weekly off-label treatment with fluconazole can reduce recurrent episodes, but long-term cure is rarely obtained, and safety liabilities exist," said Stephen Brand, Ph.D., Chief Development Officer at Mycovia. "The results from ultraVIOLET demonstrate oteseconazole's effectiveness in treating acute episodes and reinforce its efficacy and safety profile in treating RVVC. With this data in hand, we are excited to take next steps in filing for FDA approval and bringing this treatment to women living with RVVC."

The ultraVIOLET data replicates findings from Mycovia's recently completed two Phase 3 pivotal studies. The global studies included more than 650 women from 11 countries. Subjects participating in the VIOLET studies in the U.S., who remained infection-free at their Week 48 visit, were offered the opportunity to participate in an extension study to be monitored for an additional 48 weeks, to further define the long-term protective profile of oteseconazole. Eighty-five subjects are currently enrolled in the extension study.

"These results build and extend on the impressive results from the VIOLET studies, and if approved, oteseconazole will provide a long overdue treatment option for the millions of women suffering from RVVC," said Dr. Jack Sobel, distinguished professor of Internal Medicine, Division of Infectious Diseases, and dean emeritus at Wayne State University.

Oteseconazole has received FDA Qualified Infectious Disease Product and Fast-Track designations. Mycovia plans to submit its NDA for oteseconazole in the first half of 2021 with an expected U.S. launch in 2021.

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.

About Oteseconazole
Oteseconazole (VT-1161) is a novel, investigational oral therapy in late-stage clinical development for the treatment of recurrent vulvovaginal candidiasis (RVVC). Oteseconazole is designed with the goal of having greater selectivity, fewer side effects and improved efficacy as compared with currently available antifungal agents. Oteseconazole received FDA Qualified Infectious Disease Product and Fast-Track

designations and, if approved, could be the first FDA-approved treatment for RVVC. Oteseconazole Phase 3 clinical trials were conducted in 11 countries. Mycovia anticipates filing its NDA submission in the first half of 2021 with an expected U.S. launch in 2021. For more information, please visit https://www.mycovia.com/pipeline.

About Recurrent Vulvovaginal Candidiasis

RVVC is a debilitating, chronic infectious condition that affects 138 million women worldwide each year. RVVC is defined as three or more episodes in one year. 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.

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