Mycovia Pharmaceuticals, Inc. Announces Last Patient Completes Final Visit in their Global Phase 3 "VIOLET Studies" for Oteseconazole (VT-1161) for the treatment of recurrent vulvovaginal candidiasis (RVVC)

-Top-line Data Remains on Track for Late 2020-

Durham, N.C. – October 21, 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 that the last patient has completed their final visit in Mycovia's Phase 3 pivotal clinical trials of oteseconazole (VT-1161) in patients with recurrent vulvovaginal candidiasis (RVVC).

- More than 650 patients were randomized at 125 sites across 11 countries.
- 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.

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 appreciation for the completion of the clinical component of the studies: "We are grateful for study participants, the dedicated healthcare professionals, study coordinators, and staff who contributed to this important effort that enables us to report top-line data later this year. That this global milestone could be achieved in the face of a pandemic is a testament to the inspiring commitment by patients and caregivers to advance a treatment for RVVC."

Stephen Brand, PhD, Chief Development Officer, stated, "We are eager to recapitulate the data previously generated in our Phase 2 RVVC study in these completed Phase 3 studies, and are delighted that the number of subjects completing these nearly year-long studies far exceeds the subject numbers required to demonstrate a statistically significant treatment effect in each

study. With drug resistance and safety concerns continuing to rise with currently available treatment options, oteseconazole has the potential to differentiate itself from the azole drugs considered standard of care, and be the first FDA approved drug to help women with RVVC who have been largely ignored for too long."

About VIOLET Clinical Trials

These studies evaluated the safety of oteseconazole and its ability to prevent recurring episodes of VVC over 48 weeks in subjects with an established disease history of at least 3 episodes of acute VVC in the past 12 months. The VIOLET studies were also statistically powered to evaluate the impact of oteseconazole on quality of life.

Subjects participating in the US, who remained infection-free at their Week 48 visit, were offered the opportunity to participate in an extension study and will be monitored for an additional 48 weeks to further define the long-term protection profile of oteseconazole.

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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