Mycovia Pharmaceuticals Announces Positive Topline Results from Phase 3 VIOLET Studies of Oteseconazole in Patients with Recurrent Vulvovaginal Candidiasis

– Oteseconazole met studies' primary efficacy endpoint in treatment of RVVC through Week 48 –

– NDA submission planned for first half of 2021 –

Durham, N.C. – December 9, 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 positive topline results from its two pivotal Phase 3 VIOLET clinical trials for oteseconazole, its drug candidate for treating patients with recurrent vulvovaginal candidiasis (RVVC). RVVC, commonly known as chronic yeast infection, is a debilitating infectious condition that affects nearly 138 million women worldwide each year. RVVC is defined as three or more episodes in one year.

"We are delighted that the results from the Phase 3 VIOLET studies reinforce the findings from Phase 2 clinical trials, bringing us another step closer to launching the potential first FDA-approved therapy indicated for the treatment of RVVC," said Patrick Jordan, Chief Executive Officer of Mycovia. "RVVC impacts millions of women, yet the treatment landscape for this global population has been relatively unchanged for decades. Mycovia is at the vanguard for these women as we bring forward an innovative therapy in oteseconazole to address this significant unmet need."

Topline data shows that Mycovia's pivotal Phase 3 VIOLET studies successfully met their primary endpoint (p-value <0.001), defined as the proportion of subjects with one or more culture-verified acute vulvovaginal candidiasis (VVC) episodes during the maintenance phase (post-randomization through Week 48) in the intent-to-treat population. Additionally, all key secondary endpoints met statistical significance (p-value <0.001) through Week 48. Oteseconazole also protected greater than 90% of participants from having a recurrence during the maintenance phase.

Oteseconazole was generally safe and well tolerated. Treatment-emergent adverse events (TEAEs) were similar across treatment and placebo groups. Related TEAEs were also balanced and included: headache <1%, nausea <1%, and diarrhea <1%. No drug-related severe adverse events (SAEs) were reported.

"The results from the VIOLET studies build on the robust data generated from previous clinical studies that have demonstrated oteseconazole's groundbreaking potential as a therapeutic option for RVVC," said Stephen Brand, Ph.D., Chief Development Officer at Mycovia. "Our results show that oteseconazole was able to prevent a recurring infection over the course of these 48-week studies in 96% and 93% of women. In addition, these studies provided further support for the excellent safety profile, clearly differentiating oteseconazole from other antifungal agents. We are grateful for the more than 650 women who participated in these studies and all the clinical trial investigators, as we believe their experience will usher in a new paradigm for treating this debilitating chronic disease."

The VIOLET 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 three episodes of acute VVC in the past 12 months.

“These results are very encouraging for the millions of women who are seeking relief from chronic yeast infections,” said Dr. Jack Sobel, distinguished professor of Internal Medicine, Division of Infectious Diseases, and dean emeritus at Wayne State University, “Given there are currently no FDA-approved options indicated to treat RVVC, I hear firsthand from many of my patients about not only the distressing physical symptoms, but also the emotional and psychological impact of this disease on their lives. I’m hopeful that, if approved, oteseconazole will be an important option for many women who are in need of a new therapy.”

Oteseconazole is designed to be highly selective, with fewer side effects and improved efficacy over current treatment options, including the current standard of care for VVC, fluconazole. In addition to VIOLET, Mycovia is also currently evaluating the clinical effectiveness of oteseconazole in women with RVVC in a Phase 3 ultraVIOLET clinical trial, a U.S. study evaluating the safety and efficacy of oteseconazole in addition to its ability to treat acute episodes of VVC in women with RVVC compared to fluconazole. Mycovia expects to have topline results from ultraVIOLET in late 2020, and data from these three clinical studies will be submitted as part of its planned NDA submission in the first half of 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, with all topline data expected in 2H 2020. 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 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 migraine.

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