Mycovia Pharmaceuticals Completes Successful Pre-NDA Meeting with FDA for Oteseconazole for the Treatment of Recurrent Vulvovaginal Candidiasis

– Mycovia on track to report topline results from Phase 3 VIOLET studies in fourth quarter 2020 –

Durham, N.C. – November 12, 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 successful completion of its pre-New Drug Application (NDA) meeting with the U.S. Food and Drug Administration (FDA) for its oral antifungal product candidate oteseconazole (VT-1161) for the treatment of recurrent vulvovaginal candidiasis (RVVC). The purpose of the meeting was to discuss and align on the clinical, non-clinical and chemistry, manufacturing and controls (CMC) requirements for Mycovia's planned NDA submission.

"We are pleased with our pre-NDA meeting discussions with the FDA and believe we are well positioned for a successful regulatory submission pending the results of our pivotal studies," said Thorsten Degenhardt, PhD, Chief Operating Officer at Mycovia. "Millions of women experience three or more episodes of vulvovaginal candidiasis each year and need new therapeutic options. Oteseconazole has the potential to bring meaningful relief, as there are currently no FDA-approved treatments for RVVC. Based on our previously granted Qualified Infectious Disease Product and Fast-Track designations, we are confident in our ability to work with the FDA to rapidly address this significant unmet need."

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 vulvovaginal candidiasis, fluconazole. In previous clinical studies, including a Phase 2b trial in women with RVVC, oteseconazole was shown to have a positive impact in preventing disease recurrence. Oteseconazole has demonstrated a favorable safety profile, no discernable adverse effect on liver function and has been generally well tolerated in more than 1,200 patients to date.

Mycovia currently has three ongoing Phase 3 trials evaluating the clinical effectiveness of oteseconazole in women with RVVC – two global trials (VIOLET) and one U.S. trial (ultraVIOLET). The VIOLET studies were also statistically powered to evaluate the impact of oteseconazole on quality of life. The trials, which are being conducted in 11 countries, completed enrollment in December 2019, enrolling more than 870 patients. Last month, Mycovia announced that the last patient had completed her final visit in the VIOLET studies, with topline data expected in the fourth quarter of 2020. The company anticipates filing its 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 is currently in Phase 3 clinical trials being conducted in 11 countries, with topline data expected later in 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.

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