Mycovia Pharmaceuticals Announces Peer-Reviewed Publication of Positive Study Results of Oteseconazole for the Treatment of Acute Vulvovaginal Candidiasis

– Publication further supports advancement of Mycovia's oteseconazole clinical program –

Durham, N.C. – August 26, 2020 – Mycovia Pharmaceuticals, Inc. ("Mycovia") today announced the publication of results from a Phase 2 clinical study of its oral antifungal product candidate oteseconazole (VT-1161) for the treatment of acute vulvovaginal candidiasis (VVC). The results demonstrated that oteseconazole was safe and well tolerated in women with moderate to severe acute VVC, and more women experienced therapeutic cure in the treatment arms containing oteseconazole versus those treated with fluconazole, the current standard of care for the disease that affects 75 percent of women in their lifetime.[i] The study, "A Randomized Phase 2 Study of VT-1161 for the Treatment of Acute Vulvovaginal Candidiasis," was peer-reviewed and published in *Clinical Infectious Diseases*, a journal of the Infectious Diseases Society of America.

"The publication of these study results reinforces oteseconazole's potential as a much-needed treatment option for the millions of women who experience the painful and anxiety-ridden effects of yeast infections, whether acute or recurrent," said Stephen Brand, PhD, Chief Development Officer at Mycovia. "Taken together with our ongoing Phase 3 clinical trial programs, with topline results due later this year, we are eager to provide women and their health care providers with a potential novel therapy for a disease that has lacked meaningful innovation for three decades."

Brand continued, "For years, fluconazole has been the go-to therapy to treat VVC. Oteseconazole was designed to selectively inhibit fungal CYP51, an enzyme essential for fungal growth, thus avoiding off-target toxicities, drug-drug interactions and pregnancy concerns often associated with the azole drug class. In this study and others, oteseconazole has shown to be safe, and more potent than fluconazole against the Candida species that cause VVC."

The Phase 2 study evaluated the efficacy and safety of oteseconazole versus fluconazole in women who experienced a moderate-to-severe acute episode of VVC (n=55). Key findings highlighted in the publication include:

- 79.3% of women in the combined oteseconazole groups achieved therapeutic cure compared with 62.5% of those in the fluconazole group
- At three and six months, no women in the oteseconazole groups had evidence of mycological recurrence compared with 28.5% and 46.1% of women in the fluconazole group, respectively
- No serious adverse events or treatment-emergent adverse events leading to discontinuation were reported

Mycovia has three ongoing Phase 3 trials evaluating the clinical effectiveness of oteseconazole in women with RVVC over 48 Weeks – two global trials (VIOLET) and one U.S. trial (ultraVIOLET). The trials,

which are being conducted in 11 countries, completed enrollment in December 2019 with more than 870 patients. Subjects remaining free of infection at Week 48 may participate in an extension study and be followed for a further 48 weeks. Topline data from the VIOLET and ultraVIOLET trials are expected later this year, with an anticipated U.S. launch of oteseconazole in 2021.

The publication can be accessed on the *Clinical Infectious Diseases* website: https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa1204/5895051.

About Mycovia Pharmaceuticals

Mycovia Pharmaceuticals has a passion for developing breakthrough therapies in areas of unmet medical need, with an initial focus in women's health. 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 and an anticipated U.S. launch in 2021. For more information, please visit https://www.mycovia.com/pipeline.

Contacts

Mycovia Pharmaceuticals, Inc.
Tiffany Ahlers, 919-467-8539
tahlers@mycovia.com

Media

FleishmanHillard
Anuj Baveja, 919-334-3782
anuj.baveja@fleishman.com

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[i] Centers for Disease Control and Prevention. Vulvovaginal Candidiasis. Accessed 08.12.20.