Mycovia Pharmaceuticals Initiates Extension Clinical Studies to Further Evaluate Long-Term Efficacy of Oteseconazole (VT-1161) in Patients with Recurrent Vulvovaginal Candidiasis

Observational studies open to U.S. patients enrolled in Phase 3 VIOLET clinical trials who remain free of disease after 48 weeks

Durham, N.C. – February 11, 2020 – Mycovia Pharmaceuticals, Inc. ("Mycovia") today announced it has initiated extension studies as part of its ongoing Phase 3 VIOLET clinical trials for oteseconazole (VT-1161). Mycovia is developing oteseconazole, an oral antifungal product candidate, for the treatment of Recurrent Vulvovaginal Candidiasis (RVVC), a debilitating, chronic infectious condition that affects nearly 138 million women worldwide each year and for which there is currently no approved treatment in the U.S.

"We are delighted by the progress we're making with our oteseconazole clinical program, including the VIOLET trials," said Stephen Brand, PhD, Senior Vice President, Clinical Development at Mycovia. "The addition of an extension component to these studies will enable us to further evaluate the long-term effectiveness of oteseconazole in preventing recurrent episodes of vulvovaginal candidiasis in women who remain disease-free at their last scheduled study visit at Week 48."

Brand continued, "The impact of RVVC on women is significant, as it reaches beyond the debilitating physical symptoms to emotional and psychological consequences, negatively affecting quality of life and resulting in an estimated annual economic burden of $14.4 billion due to lost productivity. We believe the data from the extension part of the trials will further validate oteseconazole's potential as an important therapeutic option for women who are living with this chronic disease.''

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 vaginal 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, together with a favorable safety profile, with 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 trials, which are being conducted in 11 countries, completed enrollment in December 2019, enrolling more than 870 patients. All U.S. sites participating in the VIOLET trials will have the option to participate in the extension studies, which will be open to patients who remain disease-

free at the conclusion of the initial 48-week period. The extension studies will last an additional 48 weeks. Topline data from the VIOLET trials are expected in the second half of 2020, with an anticipated U.S. launch of oteseconazole in 2021.

More information about Mycovia's Phase 3 trials can be found at clinicaltrials.gov under the identifier numbers NCT03561701 and NCT03562156 for the VIOLET trials and NCT03840616 for the ultraVIOLET trial.

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 to have greater selectivity, fewer side effects and improved efficacy over current treatment options. Oteseconazole received FDA Qualified Infectious Disease Product and Fast-Track designations to support its potential as the first FDA-approved treatment for RVVC. 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 that there is tremendous potential for its oral fungal inhibitors to treat a range of multi-drug resistant fungal pathogens. For more information, please visit www.mycovia.com.

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 headache and migraine.

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