Mycovia Pharmaceuticals Announces Presentations of its Supportive Phase 3 Clinical Study (ultraVIOLET) Evaluating the Safety and Efficacy of Oteseconazole (VT-1161) for the Treatment of Recurrent Vulvovaginal Candidiasis (RVVC) and Susceptibility Testing Against Clinical Isolates at IDWeek 2021 Virtual Conference

Durham, N.C. – September 29, 2021 – 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 data evaluating oteseconazole for treatment of recurrent vulvovaginal candidiasis (RVVC) will be presented at the IDWeek 2021 Virtual Conference, taking place from Sept. 29 to Oct. 3. IDWeek is the joint annual meeting of the Infectious Diseases Society of America, Society for Healthcare Epidemiology of America, the HIV Medical Association, the Pediatric Infectious Diseases Society and the Society of Infectious Diseases Pharmacists.

Dr. Mark G. Martens, FACOG, Vice President, Academic Affairs/Chief Academic Officer, Tower Health, will present findings on "A Phase 3, Randomized, Double-Blind Study to Evaluate the Efficacy and Safety of Oteseconazole (VT-1161) Oral Capsules versus Fluconazole and Placebo in the Treatment of Acute Vulvovaginal Candidiasis Episodes in Subjects with Recurrent Vulvovaginal Candidiasis (ultraVIOLET)."

Dr. Mahmoud Ghannoum, Professor and Director of the Center for Medical Mycology, Case Western Reserve University and University Hospitals Cleveland Medical Center, will present an e-poster titled "Susceptibility Testing of Oteseconazole (VT-1161) Against Clinical Isolates from Phase 3 Clinical Studies in Subjects with Recurrent Vulvovaginal Candidiasis."

Recordings of both presentations will be available to view on the IDWeek website until Sunday, Oct. 3.

RVVC, also known as chronic yeast infection, is a distinct condition from vulvovaginal candidiasis (VVC) and defined as three or more symptomatic acute episodes of yeast infection per year. Oteseconazole is designed to be highly selective for its pathogenic target, with fewer side effects and improved efficacy over current treatment options, including the current standard of care for RVVC, fluconazole.

"We are pleased to be part of IDWeek this year and grateful to share our latest data and findings, highlighting oteseconazole's therapeutic potential for RVVC," stated Patrick Jordan, CEO of Mycovia Pharmaceuticals and Partner at NovaQuest Capital Management. "The data presented at IDWeek continues to build on the growing body of research as we work to provide an accessible option to the nearly 138 million women worldwide and 6 million women in the U.S. alone who suffer from this condition. With no FDA-approved therapy for RVVC, the unmet need is particularly noteworthy."

Key takeaways from the studies included:

Efficacy and Safety of Oteseconazole from Phase 3 ultraVIOLET study

- 219 subjects with a history of RVVC (defined as three or more acute episodes of yeast infection within prior 12 months) were enrolled at 51 United States sites.

- The study successfully met both its primary and key secondary endpoints.
- Oteseconazole was found to be superior to fluconazole/placebo in the proportion of subjects with one or more culture-verified acute VVC episode through Week 50 in the intent-to-treat ($P<0.001$).
- Oteseconazole demonstrated non-inferiority to fluconazole in treating the presenting acute episode of acute VVC at Day 14 Test of Cure evaluation visit.
- Oteseconazole was shown to be safe and effective in treatment of acute VVC, treatment of RVVC and prevention of recurrence of acute VVC episodes in RVVC subjects.

Susceptibility Testing of Oteseconazole Against Clinical Isolates from Phase 3 Clinical Studies in Subjects with RVVC

- Vaginal cultures obtained at screening and all subsequent study visits throughout the duration of the studies (approximately 50 weeks) were submitted to a central mycology laboratory for fungal species identification and storage. Susceptibility testing was conducted in accordance with the CLSI Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeast M27-Ed4.
- *Candida albicans* was identified as the primary causative pathogen in 87% of women with RVVC presenting with an acute infection, followed by *C. glabrata* (8%). A total of 1,910 isolates were collected.
- Oteseconazole demonstrated very low MIC values against most *Candida* strains, including fluconazole-resistant isolates, aligning with clinical study outcomes. Oteseconazole MICs against *C. glabrata* strains were approximately 6-fold lower than fluconazole.

The U.S. Food and Drug Administration (FDA) recently accepted for review Mycovia's New Drug Application (NDA) for oteseconazole and set a target action date of January 27, 2022, under the Prescription Drug User Fee Act (PDUFA). Oteseconazole was previously granted Qualified Infectious Disease Product (QIDP) and Fast-Track designations by the FDA. With this timeline and pending full review and FDA approval, Mycovia is preparing for a U.S. launch of oteseconazole in early 2022.

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. 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 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. For more information, please visit https://www.clinicaltrials.gov.

About Recurrent Vulvovaginal Candidiasis

RVVC is a debilitating, chronic infectious condition that affects 138 million women worldwide each year. RVVC, also known as chronic yeast infection, is a distinct condition from vulvovaginal candidiasis (VVC) and defined as three or more symptomatic acute episodes of yeast infection per year. 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.

About NovaQuest Capital Management

Founded by a team of accomplished industry professionals who began working together in 2000, NovaQuest Capital Management is a premier biopharma and life sciences investment firm. NovaQuest pioneered a PRODUCT FINANCE™ investment solution for the industry, providing at-risk, nondilutive funding that enables partner companies to advance pivotal clinical trials, launch new brands, license products, and acquire accretive products or companies. NovaQuest has invested in scores of biopharmaceutical assets across therapeutic areas with a clinical success rate significantly higher than the industry average. Currently managing more than $2.2 billion in capital, NovaQuest is actively investing from the $1.2 billion Pharma Opportunities Fund V, evaluating global opportunities with financing needs that range from $30-100 million. For more information, please visit www.novaquest.com.

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