



Mycovia Pharmaceuticals Announces Presentation of Oteseconazole (VT-1161) Phase 3 Data Demonstrating Safety and Efficacy for Treatment of Recurrent Vulvovaginal Candidiasis (RVVC) at the 2021 IDSOG Annual Meeting

Durham, N.C. – July 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 from its Phase 3, randomized, double-blind, placebo-controlled VIOLET studies to measure the efficacy and safety of oteseconazole (VT-1161) for the treatment of recurrent vulvovaginal candidiasis (RVVC) will be presented at the 2021 Virtual Annual Meeting of the Infectious Diseases Society for Obstetrics and Gynecology (IDSOG). Dr. Jack Sobel, Distinguished Professor of Internal Medicine, Division of Infectious Diseases, and Dean Emeritus at Wayne State University, will lead the oral presentation of the VIOLET data during IDSOG’s Scientific Session 1 on Thursday, July 29 at 10:45 a.m. EST.

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 VVC, fluconazole. Key takeaways from the VIOLET studies included:

- More than 650 patients with a history of RVVC (defined as three or more episodes of yeast infection during a 12-month period) were enrolled at 181 centers in 11 countries.
- The studies successfully met both their primary and key secondary endpoints.
- Oteseconazole protected more than 90% of participants from having a recurrence during the 48-week maintenance phase, compared to approximately 40% of those in the control group.
- 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.

Study investigators concluded that oteseconazole oral dosing was shown to be effective in the treatment of RVVC and prevention of recurrence of acute VVC episodes during the maintenance phase through Week 48.

“We are pleased to be part of this year’s IDSOG Annual Meeting and are grateful for the opportunity to share data from our VIOLET studies, as well as spotlight oteseconazole’s therapeutic potential for RVVC,” said Patrick Jordan, CEO of Mycovia Pharmaceuticals and Partner at NovaQuest Capital Management. “With no FDA-approved therapy for RVVC, the toll on women’s physical and mental health is significant. This meeting provides a chance to generate increased discussion with healthcare professionals about RVVC and the need for improved treatment options.”

RVVC affects nearly 138 million women worldwide each year and 6 million women in the U.S. alone. There are currently no FDA-approved treatments. If approved, oteseconazole will be the first FDA-approved therapy indicated for RVVC.

The U.S. Food and Drug Administration (FDA) recently accepted for review Mycovia's New Drug Application (NDA) for oteseconazole and under the Prescription Drug User Fee Act (PDUFA), set a target action date of January 27, 2022. 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.mycovia.com/pipeline>.

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.

Contacts

Mycovia Pharmaceuticals, Inc.
mediarelations@mycovia.com

Media

FleishmanHillard
Elizabeth Comtois, 919-334-3786
Elizabeth.comtois@fleishman.com