Mycovia Pharmaceuticals Announces Presentation of Topline Results from Two Studies Evaluating VIVJOA™ (oteseconazole) Capsules in Patients with Recurrent Vulvovaginal Candidiasis (RVVC) at the 2022 IDSOG Annual Meeting

- *Presentations to include topline findings from VIOLET Phase 3 extension study and first analysis of VIVJOA in RVVC patients with diabetes*

Durham, N.C. – August 2, 2022 – Mycovia Pharmaceuticals, Inc. ("Mycovia"), an emerging biopharmaceutical company dedicated to recognizing and empowering those living with unmet medical needs by developing novel therapies, has announced that it will present topline results from two studies evaluating VIVJOA™ (oteseconazole) capsules in patients with recurrent vulvovaginal candidiasis (RVVC) at the 2022 Infectious Diseases Society for Obstetrics and Gynecology (IDSOG) Annual Meeting. VIVJOA is the first and only FDA-approved medication for RVVC indicated to reduce the incidence of RVVC in females with a history of RVVC who are NOT of reproductive potential.

The 2022 IDSOG Annual Meeting will gather healthcare professionals from Aug. 4-6, 2022, at the Reserve Hotel in Boston, Massachusetts, to discuss research and innovation in the epidemiology, pathophysiology, prevention, management and impact of infectious diseases in women.

"We are proud to return to the IDSOG Annual Meeting this year and discuss these two insightful studies of VIVJOA," said Stephen Brand, Chief Development Officer at Mycovia Pharmaceuticals. "With VIVJOA now available in the U.S., we are grateful for this platform to share the growing body of data evaluating VIVJOA in women with chronic yeast infection."

VIOLET Phase 3 Extension Study

Mycovia will present results from the VIOLET Phase 3 extension study, which followed the successful completion of Mycovia's two global, randomized, double-blind Phase 3 RVVC studies to assess the long-term protective profile of VIVJOA beyond the original 48-week study evaluation. U.S. participants in the VIOLET studies treated with a 12-week course of VIVJOA who did not experience a vulvovaginal candidiasis (VVC) episode during the 48-week study were offered the opportunity to participate in an extension study, during which they were monitored for an additional 48 weeks (96 weeks total).

Of the 71 VIVJOA-treated participants in the observational extension study, 85% completed 96 weeks without a recurrent VVC episode, where they had experienced at least three episodes in the year prior to study entry. Recurrence was significantly lower in the VIVJOA group from week 48 through week 96, as well as from randomization through week 96 ($P<0.001$). The authors concluded that VIVJOA may play an important role in providing long-term reduction in the incidence of disease recurrence for women with RVVC.

This study will be presented by Dr. Jack Sobel, distinguished professor of Internal Medicine, Division of Infectious Diseases, and dean emeritus at Wayne State University, during Poster Session 2 on Friday, Aug. 5, from 10:30 to 11:30 a.m. ET.

Post-hoc Analysis in RVVC Patients with Diabetes

In a second presentation, Mycovia will report on a post-hoc analysis that evaluated the efficacy of VIVJOA in RVVC patients with diabetes. Diabetics are more susceptible to yeast overgrowth due to weakened immune systems and immune alterations. Oteseconazole selectively inhibits fungal CYP51 and is highly active against *Candida albicans*, including fluconazole-resistant *C. albicans* and other *Candida* species that cause VVC.

A total of 10 women with diabetes received VIVJOA during the two global Phase 3 VIOLET clinical trials (Type 1 (n=2), Type 2 (n=3), gestational (n=2), unspecified type (n=2) and borderline (n=1) diabetes). Ninety percent of them remained free of recurrence during the 48-week study period and did not report any treatment-related adverse events.

This study will be presented by Dr. Paul Nyirjesy, professor of Obstetrics and Gynecology at Thomas Jefferson University and co-director of the Jefferson Vulvovaginal Health Center, during Poster Session 1 on Thursday, Aug. 4, from 10:05 to 11:05 a.m. ET.

“The data from these studies are critical to further advance our understanding of VIVJOA’s utility for RVVC, in particular in a subset of women who are at higher risk,” said Dr. Thorsten Degenhardt, Chief Operating Officer at Mycovia. “We hope our presentations will help healthcare professionals in conversations with their RVVC patients who are appropriate for our medication.”

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 by the Centers for Disease Control and Prevention as three or more symptomatic acute episodes of yeast infection in 12 months. 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 VIVJOA™

VIVJOA™ (oteseconazole) is an azole antifungal indicated to reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are NOT of reproductive potential. VIVJOA is the first and only FDA-approved medication that provides sustained efficacy demonstrated by significant long-term reduction of RVVC recurrence through 50 weeks versus comparators. Oteseconazole is designed to inhibit fungal CYP51, which is required for fungal cell wall integrity, and this selective interaction is also toxic to fungi, resulting in the inhibition of fungal growth. Due to its chemical structure, oteseconazole has a lower affinity for human CYP enzymes as compared to fungal CYP enzymes. The FDA approved VIVJOA based upon the positive results from three Phase 3 clinical trials of oteseconazole – two global VIOLET studies and one U.S.-focused ultraVIOLET study, including 875 patients at 232 sites across 11 countries.

Please click here for full Prescribing Information.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
VIVJOA is contraindicated in females of reproductive potential. Females who are NOT of reproductive potential are defined as: persons who are biological females who are postmenopausal or have another reason for permanent infertility (e.g., tubal ligation, hysterectomy, salpingo-oophorectomy).

VIVJOA is contraindicated in pregnant and lactating women.

VIVJOA is contraindicated in patients with known hypersensitivity to oteseconazole.

WARNINGS AND PRECAUTIONS
Based on animal studies, VIVJOA may cause fetal harm. The drug exposure window of approximately 690 days (based on 5 times the half-life of oteseconazole) precludes adequate mitigation of the embryo-fetal toxicity risks. Advise patients that VIVJOA is contraindicated in females of reproductive potential, and in pregnant and lactating women because of potential risks to a fetus or breastfed infant.

ADVERSE REACTIONS
The most frequently reported adverse reactions among VIVJOA-treated patients in clinical studies included headache (7.4%) and nausea (3.6%).

DRUG INTERACTIONS
VIVJOA is a Breast Cancer Resistance Protein (BCRP) inhibitor. Concomitant use of VIVJOA with BCRP substrates (e.g., rosuvastatin) may increase the exposure of BCRP substrates, which may increase the risk of adverse reactions associated with these drugs.

Please see full Prescribing Information and Patient Information.

To report SUSPECTED ADVERSE REACTIONS, contact Mycovia Pharmaceuticals, Inc. at 1-855-299-0637 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

About Mycovia Pharmaceuticals
Mycovia Pharmaceuticals is an emerging biopharmaceutical company dedicated to recognizing and empowering those living with unmet medical needs by developing novel therapies. VIVJOA™ (oteseconazole), the first FDA-approved product for Mycovia, is an azole antifungal indicated to reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are NOT of reproductive potential. Oteseconazole received FDA Qualified Infectious Disease Product and Fast-Track designations to become the first FDA-approved therapy for RVVC. In 2019, Mycovia licensed oteseconazole to Jiangsu Hengrui Pharmaceuticals Co., Ltd., 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 NovaQuest Capital Management
NovaQuest Capital Management, located in North Carolina's Research Triangle, is a life science investment firm with a specialization in biopharmaceuticals. Founded in 2010, and with more than $2.5 billion raised across four funds, NovaQuest provides tailored capital solutions that fund innovation in biopharmaceutical development and invests in compelling healthcare companies with products and technologies aimed at helping humans and animals live healthier, longer, more productive lives. Learn more at www.novaquest.com.

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