Mycovia Pharmaceuticals Announces U.S. Availability of VIVJOA™ (oteseconazole) Capsules, the First and Only FDA-Approved Medication for Recurrent Vulvovaginal Candidiasis (Chronic Yeast Infection)

- *VIVJOA is a new option for postmenopausal and permanently infertile women with recurrent vulvovaginal candidiasis (RVVC)*

- *VIVJOA is now available in a network of partner pharmacies that includes mail order and local pickup options*

Durham, N.C. – July 18, 2022 – 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 U.S. availability of VIVJOA™ (oteseconazole) capsules, 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.

As the first and only medication approved by the U.S. Food and Drug Administration for RVVC, commonly known as chronic yeast infection, a 12-week course of VIVJOA provides sustained efficacy demonstrated by significant long-term reduction of RVVC recurrence for nearly a year (50 weeks) versus comparators.

"The Mycovia team has worked tirelessly to bring VIVJOA to commercial availability, and we feel immense reward in this achievement today because of the patients we may serve," said Patrick Jordan, CEO of Mycovia and Managing Partner at NovaQuest Capital Management. "We are ready to execute our launch strategy with clear objectives to reach appropriate RVVC patients and fulfill this previously unmet medical need among women suffering from chronic yeast infection."

Potential appropriate patients for VIVJOA are women with RVVC who are postmenopausal or are permanently infertile due to a surgical procedure or for other reasons/conditions.

"Through our efforts, we will help patients understand that chronic yeast infection is a distinct condition from acute yeast infection, and VIVJOA was designed and studied in clinical trials to reduce the incidence of recurrent vaginal yeast infection in females with a history of RVVC," added Tiffany Ahlers, Chief Commercial Officer of Mycovia. "To support effective two-way communication between patients and healthcare providers, we will encourage patients to ask their doctor if VIVJOA is right for them."

Mycovia's patient support program, My VIVJOA, powered by vitaCare, is a comprehensive program designed to help patients with insurance coverage support, seamlessly applied savings and ongoing education. VitaCare is a technology and services platform that helps patients navigate key access and adherence barriers for branded medications. VitaCare will help patients understand and verify insurance

coverage, identify available savings opportunities, assist providers in their communication with payors, and offer a seamless path for filling the VIVJOA prescription primarily through an appropriate mail order or local pharmacy partners.

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 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) capsules are 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) capsules, the first FDA-approved product for Mycovia, are 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.

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