EMBARGOED UNTIL 8:00 AM ET April 28, 2022

FDA Approves Mycovia Pharmaceuticals' VIVJOA™ (oteseconazole), the First and Only FDA-Approved Medication for Recurrent Vulvovaginal Candidiasis (Chronic Yeast Infection)

- *Approval of VIVJOA™ marks a significant therapeutic advancement for reducing the incidence of RVVC, a condition with substantial unmet need, in permanently infertile and postmenopausal women*

- *VIVJOA™ is the first FDA approval in Mycovia's pipeline of novel treatments for fungal infections*

- *U.S. commercial launch of VIVJOA™ expected in Q2*

Durham, N.C. – April 28, 2022 – The U.S. Food and Drug Administration (FDA) approved 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. VIVJOA is the first and only FDA-approved medication for this condition and provides sustained efficacy demonstrated by significant long-term reduction of RVVC recurrence through 50 weeks versus comparators. VIVJOA is the first FDA-approved product for Mycovia Pharmaceuticals, Inc. (Mycovia), an emerging biopharmaceutical company dedicated to recognizing and empowering those living with unmet medical needs by developing novel therapies.

RVVC, also known as chronic yeast infection, is defined by the Centers for Disease Control and Prevention (CDC) as three or more symptomatic acute episodes of yeast infection in 12 months. RVVC is a distinct condition from vulvovaginal candidiasis (VVC), and until now, there have been no FDA-approved medications specifically indicated for it. Nearly 75% of all adult women will have at least one yeast infection in their lifetime, with approximately half experiencing a recurrence. Of those women, up to 9% develop RVVC.

"After nearly two decades of living with chronic yeast infection and feeling like there was no hope from the itchiness, irritation and constant dread of when the next yeast infection would return, I was overjoyed to even be a part of this clinical trial," said Leslie Ivey, RVVC patient and clinical trial participant. "It is gratifying to see RVVC finally get the attention it deserves."

Symptoms of RVVC 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.

VIVJOA's FDA approval is based upon the positive results from three Phase 3 trials of oteseconazole – two global, pivotal VIOLET studies and one U.S.-focused ultraVIOLET study, including 875 patients at 232

sites across 11 countries. In the two global VIOLET studies, 93.3% and 96.1% of women with RVVC who received VIVJOA did not have a recurrence for the 48-week maintenance period compared to 57.2% and 60.6% of patients who received placebo ($p < 0.001$). In the ultraVIOLET study, 89.7% of women with RVVC who received VIVJOA cleared their initial yeast infection and did not have a recurrence for the 50-week maintenance period compared to 57.1% of those who received fluconazole followed by placebo ($p < 0.001$). The most common side effects reported in Phase 3 clinical studies were headache (7.4%) and nausea (3.6%). VIVJOA is contraindicated in those with a hypersensitivity to oteseconazole, and based on data from rat studies, also in females who are of reproductive potential, pregnant, or lactating. Please see additional Important Safety Information below.

Patrick Jordan, CEO of Mycovia Pharmaceuticals and Partner at NovaQuest Capital Management, stated, "We celebrate this important milestone for Mycovia, as VIVJOA is the first antifungal in our pipeline to obtain FDA approval and achieves our goal to fulfill a previously unmet medical need among women suffering from RVVC. We are honored to lead this advancement in women's health."

"We believe the market need for VIVJOA is strong, and we are eager to execute our commercial plans," Jordan continued. "As we enter a new chapter of our history as a commercial biopharmaceutical company, we will continue driving our mission forward to develop novel therapies for overlooked conditions."

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 granted oteseconazole Qualified Infectious Disease Product and Fast Track designations.

"A medicine with VIVJOA's sustained efficacy combined with the clinical safety profile has been long needed, as until now, physicians and their patients have had no FDA-approved medications for RVVC," stated Stephen Brand, Ph.D., Chief Development Officer of Mycovia. "We are excited to be the first to offer a medication designed specifically for RVVC, a challenging and chronic condition that is expected to increase in prevalence over the next decade."

Mycovia is planning its commercial launch of VIVJOA™ in the second quarter of 2022.

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) 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, pivotal 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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