Mycovia Pharmaceuticals, Inc. Announces Publication of 2-Year VIVJOA® Efficacy Results from an Extension of the VIOLET Phase 3 Studies in Women with Recurrent Vulvovaginal Candidiasis (RVVC) in the *Journal of Women's Health*

VIVJOA provided nearly 2 years of sustained efficacy against RVVC in a long-term extension of Phase 3 studies

Durham, NC — November 18, 2025 — Mycovia Pharmaceuticals, Inc. ("Mycovia") has announced the publication of long-term efficacy results from an extension study of the VIOLET Phase 3 clinical program which evaluated VIVJOA (oteseconazole) capsules in women with RVVC in the *Journal of Women's Health*. VIVJOA is the first and only available FDA-approved therapy for RVVC, or chronic yeast infections, in post-menopausal women or women who are not of reproductive potential.

The VIOLET studies were two Phase 3 multi-center, multi-national, double-blind, randomized, placebo-controlled clinical trials. These studies evaluated the efficacy and safety of VIVJOA in women with RVVC and provided pivotal data supporting US approval of VIVJOA for RVVC in 2022. Results demonstrated that VIVJOA was statistically superior ($P<0.001$) to placebo in reducing culture-verified VVC infections through 48 weeks; up to 96% of women receiving VIVJOA remained infection free versus 61% receiving placebo. Treatment-emergent adverse events were similar between VIVJOA and placebo groups. The most frequently reported adverse events among patients treated with VIVJOA across all Phase 3 RVVC clinical trials included headache (7.4%) and nausea (3.6%).

The long-term observational extension study followed women who did not experience an RVVC episode during the initial 48-week study period. Eighty-seven eligible US women from the VIOLET studies were enrolled and monitored for recurrent VVC infections for an additional 48 weeks, totaling 96 weeks. The study concluded 98% of women who were originally randomized to receive VIVJOA for 12 weeks remained infection free versus 82% who received placebo, demonstrating a continued long-term protective effect of VIVJOA against infection recurrence for women with RVVC for nearly 2 years.

"These results add to the body of evidence suggesting VIVJOA can provide improved clinical outcomes and a shorter dosing regimen compared to the standard of care, fluconazole, in managing RVVC," commented Dr. Samuel Lederman, lead author, Medical Director for Altus Research, practicing Ob/Gyn at Women's Care in West Palm Beach and Lake Worth, FL, and a participating principal investigator in the VIOLET and long-term extension study.

"These findings continue to demonstrate the long-term efficacy of VIVJOA in treating this chronic, often ignored, debilitating condition for many women," said Dr. Stephen Brand, Chief Development Officer of Mycovia. "On average, women in our Phase 3 clinical studies experienced 4 acute episodes in the 12-month period prior to enrolling into the study, with some experiencing up to 20 episodes. The fact that VIVJOA is able to provide an ongoing protective effect for nearly two years is a powerful result. We look forward to continuing efforts to support advances in RVVC."

For more information about the VIOLET studies, please visit https://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 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. RVVC has significant impact on the mental, emotional and physical health of women who are experiencing frequent VVC episodes as well as an economic burden.

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 available 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 US-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, Inc.

Mycovia Pharmaceuticals, Inc. is a 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, 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.

Mycovia also recognizes 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 https://mycovia.com.

Contacts

Mycovia Pharmaceuticals, Inc.

mediarelations@mycovia.com