Mycovia Pharmaceuticals Announces Publication of Positive Phase 3 Data Evaluating VIVJOA™ (oteseconazole) Capsules in Patients with Recurrent Vulvovaginal Candidiasis (RVVC) in NEJM Evidence

- *Two global VIOLET Phase 3 studies met primary and key secondary endpoints, with authors concluding VIVJOA is highly efficacious in preventing recurrence of VVC through 48 weeks in participants with a history of RVVC*

- *VIVJOA is now the only U.S. Food and Drug Administration-approved option for postmenopausal and permanently infertile women with RVVC*

Durham, N.C. – July 26, 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 the publication of positive Phase 3 data evaluating VIVJOA™ (oteseconazole) capsules in patients with recurrent vulvovaginal candidiasis (RVVC) in the July edition of *NEJM Evidence*, available here. 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.

Titled "Efficacy and Safety of Oteseconazole in Recurrent Vulvovaginal Candidiasis," the article assessed Mycovia's two global, randomized, double-blind, placebo-controlled Phase 3 VIOLET studies, which comprised 656 women with RVVC who had experienced three or more symptomatic episodes of vulvovaginal candidiasis (VVC) within the previous 12 months. Of the 652 subjects whose presenting infections were cleared with fluconazole, 435 were randomly assigned to receive 150 mg of oral VIVJOA daily for seven days followed by once weekly for 11 weeks, and 217 were randomly assigned to matching placebo for 12 weeks. Baseline demographics were similar in both trials.

Both VIOLET studies met their primary and key secondary endpoints. At the end of the 48-week maintenance period, 93.3% and 96.1% of women with RVVC who received VIVJOA did not have a recurrence, compared to 57.2% and 60.6% of patients who received placebo (P<0.001).

Among the 22 women treated with VIVJOA who experienced an RVVC episode during the 48-week maintenance period, the average time it took to first recurrence of a VVC episode was 45.7 and 47.2 weeks, compared to 27.8 and 33.1 weeks for the 84 women treated with placebo who had a recurrence (P<0.001). In the intent-to-treat populations, the groups treated with VIVJOA had a significantly lower averaged percentage of occurrence of one or more positive *Candida* cultures through week 48 compared with the placebo groups (29.4% vs. 84.2% in VIOLET Trial 1, P<0.001; and 27.6% vs. 84.0% in VIOLET Trial 2, P<0.001).

Types and frequencies of treatment-emergent adverse events (TEAEs) were similar between subjects receiving VIVJOA or placebo, with no drug-related serious TEAEs or adverse effects on liver function, QT interval or pregnancy outcomes. Please see Important Safety Information below.

The authors concluded that VIVJOA "was highly efficacious in preventing recurrence of VVC through week 48 in participants with a history of RVVC, with potent activity against fluconazole-resistant *C. albicans* and *C. glabrata* species and mostly mild TEAEs."

"Publication of the VIOLET data in *NEJM Evidence* is significant, as VIVJOA has demonstrated notable effectiveness as a treatment option for postmenopausal and permanently infertile women living with chronic yeast infection," said Dr. Jack Sobel, co-lead author of the article and distinguished professor of Internal Medicine, Division of Infectious Diseases, and dean emeritus at Wayne State University. "We seek to further assess and amplify the results of treating appropriate RVVC patients with VIVJOA, which remains the only FDA-approved medication for this condition."

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) 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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