Mycovia Pharmaceuticals' Phase 3 ultraVIOLET Study Evaluating the Efficacy and Safety of VIVJOA™ (oteseconazole) in Women with Recurrent Vulvovaginal Candidiasis (RVVC) Published in the American Journal of Obstetrics and Gynecology

- *VIVJOA was statistically superior to placebo in preventing recurrence of infection in women with RVVC and noninferior to fluconazole in treating acute VVC in women with RVVC*

- *VIVJOA is the only U.S. FDA-approved medicine for postmenopausal and permanently infertile women with RVVC*

Durham, N.C. – August 25, 2022 – Mycovia Pharmaceuticals, Inc. ("Mycovia"), an emerging biopharmaceutical company, today announced the publication of its phase 3 ultraVIOLET study evaluating the efficacy and safety of VIVJOA™ (oteseconazole) capsules in the treatment of recurrent vulvovaginal candidiasis (RVVC) and its efficacy versus fluconazole in the treatment of acute vulvovaginal candidiasis (VVC) in the *American Journal of Obstetrics and Gynecology (AJOG)*. 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 peer-reviewed article highlighted Mycovia's randomized, double-blind, placebo-controlled phase 3 ultraVIOLET study, which was conducted to evaluate the efficacy and safety of VIVJOA in preventing recurrent episodes of VVC in women with RVVC and to compare VIVJOA to fluconazole in treating acute VVC episodes in women with RVVC.

The authors concluded that VIVJOA was statistically superior to placebo in preventing recurrence of VVC through 50 weeks in women with a history of RVVC. From post-randomization through week 50, 94.9% of patients treated with VIVJOA did not have a VVC episode, compared to 57.8% of patients treated with fluconazole in the induction phase followed by placebo in the maintenance phase ($P<0.001$).

In addition, VIVJOA was as efficacious as fluconazole in treating acute VVC episodes in women with RVVC. In the intent-to-treat population, 93.2% of patients treated with VIVJOA had a resolved VVC episode by Day 14, compared to 95.8% of patients treated with fluconazole. In the modified intent-to-treat population, which included participants with a positive potassium hydroxide test at screening, positive culture result at screening and negative culture result at Day 14, a higher proportion of patients treated with VIVJOA cleared their initial VVC episode by Day 14 compared to fluconazole (98.5% versus 94.1%, respectively).

The data from ultraVIOLET, together with Mycovia's two global phase 3 VIOLET studies, were key to supporting the company's new drug application and the FDA's April 2022 approval of VIVJOA.

"To-date, treatment needs for women with RVVC have not been met by available antifungal agents approved for uncomplicated yeast infections, including the most frequently prescribed agent,

fluconazole," said Dr. Mark G. Martens, study author, Professor of Obstetrics and Gynecology at Drexel University College of Medicine and Medical Director for Academics, and Program Director-OB-GYN at Mohawk Valley Health System.

"We are encouraged not only by the research findings evaluating VIVJOA versus fluconazole, but also by a renewed recognition of RVVC as a growing and troublesome condition for millions of women today," Dr. Martens continued. "The FDA approval of VIVJOA for postmenopausal and permanently infertile women highlights the fact that RVVC is a distinct condition from VVC, as it becomes the first FDA-approved agent for this specific disease. Finally, healthcare providers in the United States and their appropriate patients for this medication can address the significant health burden caused by this previously unmet need."

About ultraVIOLET

The ultraVIOLET study included 219 women with a history of RVVC who were enrolled at 38 U.S. sites. Eligible participants presenting with an active VVC infection (positive microscopic identification of *Candida Spp*. and a vulvovaginal signs and symptoms score of 3 or higher) entered an induction phase in which they were randomly assigned 2:1 to receive either VIVJOA (600 mg on Day 1, 450 mg on Day 2 and matching placebo capsules), or fluconazole (three 150 mg oral doses every 72 hours and matching placebo capsules). Following the two-week induction phase, the 185 participants with resolved acute VVC infection entered the maintenance phase and received 150 mg of VIVJOA or placebo weekly for 11 weeks. Participants were followed for an additional 37 weeks.

The rates in patients who had at least one treatment-emergent adverse event (TEAE) were similar in both groups (54% of participants in the VIVJOA group and 64% of participants in the fluconazole followed by placebo group). The most frequently reported individual TEAEs were urinary tract infection, bacterial vaginosis, headache, nausea, diarrhea, upper respiratory tract infection and pyrexia. Urinary tract infection, bacterial vaginosis, headache and diarrhea were reported less frequently in the VIVJOA group than in the fluconazole followed by placebo group.

"We are pleased to see the publication of our U.S.-based ultraVIOLET study in this prominent journal that reaches healthcare providers in women's health. This marks the latest in a growing body of peer-reviewed papers and presentations that further demonstrate VIVJOA's potential to reduce the incidence of recurrent yeast infection in women with a history of RVVC," said Stephen Brand, Chief Development Officer at Mycovia Pharmaceuticals.

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, 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.

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