



**Mycovia Pharmaceuticals Announces Positive New Clinical Findings Evaluating VIVJOA™ (oteseconazole) Capsules in Patients with Recurrent Vulvovaginal Candidiasis (RVVC)**

- *Extension study data suggest VIVJOA provides long-term reduction in the incidence of disease recurrence in RVVC patients*
- *85% of patients who took a 12-week course of VIVJOA completed 96 weeks without a recurrent VVC episode, with an average time of 92 weeks without recurrence*

Durham, N.C. – June 22, 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 shared topline results from evaluating VIVJOA™ (oteseconazole) capsules in patients suffering from recurrent vulvovaginal candidiasis (RVVC).

Also known as chronic yeast infection, RVVC is a distinct condition from vulvovaginal candidiasis (VVC) and is defined by the Centers for Disease Control and Prevention as three or more symptomatic episodes of yeast infection in 12 months. 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 VIOLET extension study followed the successful completion of Mycovia’s two global, pivotal Phase 3 VIOLET studies to assess the long-term protective profile of VIVJOA given its pharmacokinetic profile and extended half-life beyond the original 48-week study duration. U.S. participants in the VIOLET studies treated with a 12-week course of VIVJOA who did not experience a VVC episode during the 48-week study were offered the opportunity to participate in an extension study, during which they were monitored for an additional 48 weeks (96 weeks total).

Of the 71 patients enrolled in the observational extension study, 85% completed 96 weeks without a recurrent VVC episode. The average time without recurrence was 92 weeks. The authors concluded that VIVJOA may play an important role in providing long-term reduction in the incidence of disease recurrence for women with RVVC.

“These results are insightful because in this distinct patient population, we now have nearly two years of data evaluating VIVJOA in women with RVVC,” said Stephen Brand, Ph.D., Chief Development Officer at Mycovia Pharmaceuticals. “Prior to enrolling in the VIOLET study, these women had experienced a minimum of three acute yeast infection episodes in the previous year. The fact that the vast majority of these women did not experience a recurrence for nearly two years further demonstrates the sustained efficacy of VIVJOA.”

### **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 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](http://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](http://www.mycovia.com).

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