Mycovia Pharmaceuticals Announces Presentation of Results from Three Safety Studies Evaluating VIVJOA® (oteseconazole) in Subjects with Renal or Hepatic Impairment, and the Impact on QT Prolongation at the 2024 IDSOG Annual Meeting

- Presentations expand VIVJOA safety profile and prescribing information in hepatic and renally impaired patients

Durham, N.C. – August 1, 2024 – Mycovia Pharmaceuticals, Inc. ("Mycovia"), an emerging biopharmaceutical company, has announced that it will present topline results from three Phase 1 studies evaluating VIVJOA® (oteseconazole) at the 2024 Infectious Diseases Society for Obstetrics and Gynecology (IDSOG) Annual Meeting, Portland, Oregon August 1-3. VIVJOA is the first FDA-approved medication for recurrent vulvovaginal candidiasis (RVVC), or chronic yeast infections, in post-menopausal women or women who are not of reproductive potential.

The 2024 IDSOG Annual Meeting will gather healthcare professionals to discuss research and innovation in the epidemiology, pathophysiology, prevention, management and impact of infectious diseases in women.

"We are proud to return to the IDSOG Annual Meeting this year to discuss these insightful studies of VIVJOA," said Dr. Stephen Brand, Chief Development Officer at Mycovia Pharmaceuticals. "With VIVJOA now available in the US, we are grateful for this platform to share the growing body of safety data evaluating VIVJOA in women with chronic yeast infection."

During Poster Session 1 on Thursday, August 1, from 3:30 to 4:30 pm PST, Dr. Brand will present: **Pharmacokinetic and Safety Results From Two Phase 1 Studies of VIVJOA in Women With Severe Renal Insufficiency Not Requiring Dialysis vs Normal Renal Function and Women With Moderate Hepatic Impairment vs Normal Hepatic Function**

During Oral Abstract Session 6 on Saturday August 3, from 11:00 am to 12:30 pm, Dr. Brand will present: **Single-Center, Randomized, Double-Blind, Placebo- and Active-Controlled, Parallel, Nested Crossover, Thorough QT Study of VIVJOA in Healthy Women**

Among drug-specific characteristics of antifungal agents, renal disposition and nephrotoxicity are important clinical considerations as many patients requiring antifungal therapy have compromised organ functions or are receiving other potentially nephrotoxic or hepatotoxic medications.

VIVJOA data presented will include safety and tolerability in women with mild to severe renal insufficiency as well as in women with mild and moderate hepatic impairment, pharmacokinetic parameters, and cardiac repolarization, further characterizing VIVJOA's use in women treated for RVVC.

These new findings are reflected in the recently revised prescribing information.

"The data from these studies are critical to further advance our understanding of VIVJOA's utility for RVVC, in particular in a subset of women who are at higher risk for kidney, liver or cardiac issues," said Dr. Thorsten Degenhardt, Chief Operating Officer. "We hope our presentations will help healthcare professionals in conversations with their RVVC patients who are appropriate for our medication."

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 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 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 embryofetal 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 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.

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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