Mycovia Pharmaceuticals, Inc. Announces Publication of Partner Jiangsu Hengrui Pharmaceuticals' Phase 3 Clinical Study Evaluating the Efficacy and Safety of VIVJOA® (Oteseconazole) Versus Fluconazole in Women with Vulvovaginal Candidiasis (VVC) in the Journal Antimicrobial Agents and Chemotherapy

- *VIVJOA demonstrated statistically significant and clinically meaningful superiority to fluconazole, the current standard-of-care, in treating women with severe VVC*

- *Treatment-emergent adverse events were similar between patients treated either with VIVJOA or fluconazole*

Durham, N.C. – January 31, 2024 – Mycovia Pharmaceuticals, Inc. ("Mycovia"), an emerging biopharmaceutical company, today announced that its partner Jiangsu Hengrui Pharmaceuticals Co., Ltd ("Hengrui") has published its phase 3 study evaluating the efficacy and safety of VIVJOA® (oteseconazole) capsules versus fluconazole in the treatment of severe vulvovaginal candidiasis (VVC) in Chinese women in the journal Antimicrobial Agents and Chemotherapy.

The peer-reviewed article describes the results of a multi-center, randomized, double-blinded, phase 3 study designed to evaluate efficacy and safety of VIVJOA as a two-day dosing regimen versus fluconazole in women with severe VVC.

The authors concluded that VIVJOA was statistically superior to fluconazole in treating severe VVC. At Day 28, 66.88% of patients treated with VIVJOA had therapeutic cure (absence of signs and symptoms of VVC and negative culture of *Candida* species), compared to 45.91% of patients treated with fluconazole ($p = 0.0002$). Mycological cure (negative culture of *Candida* species) and clinical cure (absence of signs and symptoms of VVC) at Day 28 was higher in the patients treated with VIVJOA compared to patients treated with fluconazole (82.50% vs. 59.12%, $p < 0.0001$ and 71.25% vs. 55.97%, $p = 0.0046$, respectively). At Day 14, therapeutic cure and mycological cure were superior for patients treated with VIVJOA compared to those treated with fluconazole (52.50% vs. 38.36%, $p = 0.0112$ and 81.88% vs. 66.67%, $p = 0.0019$, respectively.

The rates of patients who had at least one treatment-emergent adverse event (TEAE) were similar in both groups (51.3% of patients in the VIVJOA group and 42.9% of patients in the fluconazole group). Of the patients experiencing a TEAE, similar rates of treatment-related adverse events were reported (21.9% in the VIVJOA group and 19.9% in the fluconazole group). The most commonly reported TEAEs were urinary tract infection and bacterial vulvovaginitis.

“These clinical data describe the first head-to-head study of VIVJOA versus fluconazole, considered to be the standard-of-care for treating VVC for over 30 years. Following its recent approval in China, VIVJOA offers health care providers and their appropriate patients with a novel, safe and efficacious oral treatment option,” said Stephen Brand PhD, Chief Development Officer at Mycovia. “The results also expand on available clinical susceptibility data by demonstrating potent MIC activity of oteseconazole against wild-type and resistant *Candida albicans* isolates from this patient population, in addition to clinical isolates resistant to fluconazole, including *Candida glabrata.*”

Vulvovaginal candidiasis is an exceedingly common mucosal infection usually caused by *Candida albicans* but can occasionally be caused by other *Candida* species or yeasts. Typical symptoms include vulvovaginal itching, irritation, burning, soreness, fissuring, redness, vaginal discharge, and dyspareunia. Approximately 70% to 75% of women in all strata of the society will experience at least one episode during their lifetime.

Oteseconazole is designed to selectively inhibit fungal CYP51, which is required for fungal cell wall integrity, and this 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.

In April 2022, the U.S. Food and Drug Administration (FDA) approved VIVJOA (oteseconazole) Capsules, as the first medication for Recurrent Vulvovaginal Candidiasis (chronic yeast infection). In June 2023, VIVJOA received approval in China from the National Medical Products Administration and is indicated for the treatment of severe VVC.

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.

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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.

About Jiangsu Hengrui Pharmaceuticals Co., Ltd.

Hengrui Pharma is a leading global pharmaceutical company headquartered in China with a focus on research, development, manufacturing, and commercialization of innovative and high-quality healthcare products. Innovation is the core development strategy. Hengrui Pharma ranked 21st among the top 1,000 global pharmaceutical companies in 2021.[1] Hengrui Pharma has been on the Pharma Exec's annual listing of the top global pharmaceutical companies for the fourth consecutive year, rising from the 47th in 2019 to the 32nd in 2021.[2]

1. https://torreya.com/publications/pharma-1000-report-torreya-2021-11-08.pdf; page 49 and 56.

2. https://www.pharmexec.com/view/2022-pharm-exec-top-50-companies; page 24