Mycovia Pharmaceuticals, Inc. Announces Partner Jiangsu Hengrui Pharmaceuticals Co., Ltd's Commercial Launch of VIVJOA® (Oteseconazole) Capsules for the Treatment of Severe Vulvovaginal Candidiasis (VVC) in China

- *VVJOA is now a new option for treating severe VVC in China*

- *A 2-Day Oral Course of VIVJOA provides significantly better cure rates than fluconazole in severe VVC*

Durham, N.C. – February 7, 2024 – Mycovia Pharmaceuticals, Inc. ("Mycovia"), an emerging biopharmaceutical company, today announced that Jiangsu Hengrui Pharmaceuticals Co., Ltd ("Hengrui") has commercially launched VIVJOA® (oteseconazole) in China, making available an innovative oral azole antifungal indicated for the treatment of severe vulvovaginal candidiasis (VVC). VIVJOA is contraindicated for females of reproductive potential, pregnant and lactating women, and patients with known hypersensitivity to active ingredients, excipients, and azoles.

The availability of VIVJOA for the treatment of severe VVC in China is an important achievement of Mycovia's 5-year partnership with Hengrui. The 2-day oral regimen, recently approved by the National Medical Products Administration, was previously shown in a randomized phase 3 study to have superior efficacy to the current standard-of-care, fluconazole, in women presenting with severe VVC.

"We celebrate our partner, Hengrui, on bringing VIVJOA to the Chinese market, the second largest pharmaceutical market in the world" said Patrick Jordan, CEO of Mycovia and Managing Partner at NovaQuest Capital Management. "The disease burden in China is significant, and access to VIVJOA provides health care providers and women suffering with severe VVC a new treatment option."

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. 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 (RVVC, or chronic yeast infection). VIVJOA is currently available in the US at over 300 Walgreens Community Specialty Pharmacies.

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 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, 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

About NovaQuest Capital Management
Founded by a team of accomplished industry professionals in 2010, NovaQuest Capital Management is a premier biopharma and life sciences investment firm. NovaQuest pioneered a Product Finance solution for the industry, providing at-risk, nondilutive funding that enables partner companies to advance pivotal clinical trials, launch new brands, license products, and acquire accretive products or companies. NovaQuest has invested in scores of biopharmaceutical assets across therapeutic areas with a clinical success rate significantly higher than the industry average. NovaQuest is actively evaluating and investing into global opportunities. For more information, please visit www.novaquest.com.

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