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

- *Oteseconazole Capsules were statistically superior to fluconazole, the current standard-of-care, in treating women with severe VVC*

- *Oteseconazole Capsules were found to be safe and more effective than fluconazole*

- *China commercial launch of Oteseconazole Capsules expected in late 2023*

Durham, N.C. – August 22, 2023 – Mycovia Pharmaceuticals, Inc. ("Mycovia"), an emerging biopharmaceutical company, today announced that Jiangsu Hengrui Pharmaceuticals Co., Ltd ("Hengrui") received approval in June from the National Medical Products Administration for Oteseconazole Capsules, an azole antifungal, indicated for the treatment of severe vulvovaginal candidiasis (VVC). Oteseconazole Capsules is contraindicated for females of reproductive potential, pregnant and lactating women, patients with known hypersensitivity to active ingredients, excipients and azoles.

The approval of Oteseconazole Capsules for the treatment of severe VVC in China is an important milestone under Mycovia's exclusive agreement with Hengrui to develop and commercialize oteseconazole in China, including Mainland China, Hong Kong, Macau and Taiwan, for the treatment or prevention of a range of fungal conditions.

The approval of Oteseconazole Capsules was based on a Phase 3 study with 322 patients at 27 sites. The primary study endpoint was the proportion of subjects with therapeutic cure (defined as the absence of symptoms and signs of VVC with negative fungal culture candidiasis) at Day 28.

In a randomized Phase 3 clinical study to evaluate the efficacy and safety of a two-day dosing regimen of SHR8008 (oteseconazole capsules) versus the current standard-of-care fluconazole in patients with severe VVC, therapeutic cure at Day 28 was significantly higher in the SHR8008 group than in the fluconazole group (66.88% vs 45.91%), $p = 0.0002$. Mycological cure at Day 28 was higher in the SHR8008 group than in the fluconazole group (82.50% vs 59.12%), $p < 0.0001$. Therapeutic cure and mycological cure at Day 14 were also statistically superior for subjects receiving SHR8008 compared to those receiving fluconazole. Reported adverse events were similar between treatment groups.

"We celebrate and congratulate our partner, Hengrui, on receiving its approval for Oteseconazole Capsules for the treatment of severe VVC," said Patrick Jordan, CEO of Mycovia and Managing Partner at NovaQuest Capital Management. "The disease burden in China is significant and the approval of Oteseconazole Capsules gives another treatment option for those women suffering with VVC."

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).

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 with financing needs that range from $30-100 million. For more information, please visit www.novaquest.com.

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