Mycovia Pharmaceuticals, Inc. Announces Partner Jiangsu Hengrui Pharmaceuticals Co., Ltd.'s Recognition for the Inclusion of VIVJOA® (Oteseconazole) Capsules in the Chinese National Reimbursement Drug List

-75% of all women will develop vulvovaginal candidiasis (VVC) at least once in their lifetime
-VIVJOA is now included in the National Reimbursement Drug List for treating severe VVC in China

Durham, N.C. – April 2, 2025 – Mycovia Pharmaceuticals, Inc. ("Mycovia"), an emerging biopharmaceutical company, today announced that Jiangsu Hengrui Pharmaceuticals Co., Ltd ("Hengrui Pharma") held a recent conference in Shanghai, China to recognize the listing of VIVJOA® (oteseconazole) in the recent National Reimbursement Drug List (NRDL) by China's National Healthcare Security Administration, expanding patient accessibility to VIVJOA for the treatment of severe vulvovaginal candidiasis (VVC) in post-menopausal women and women not of reproductive potential. The 2024 NRDL listing process emphasized support for first-in-class therapies and innovative drugs. VIVJOA was among a small group of drugs selected.

"Hengrui Pharma is committed to national health and has been deeply cultivating and expanding its presence in the field of gynecological infections including the introduction of VIVJOA," said Mr. Hongbin Dai, President of Hengrui Pharma. "Inclusion of VIVJOA in the NRDL highlights the clinical significance of this innovative drug and will allow more people to benefit from this treatment. Hengrui Pharma is continuing to actively explore research in the treatment of multiple women's diseases, bringing more hope to patients."

The conference was attended by over 200 experts in gynecological infections and healthcare providers from across China, with presentations by Dr. Jack Sobel, distinguished professor of Internal Medicine, Division of Infectious Diseases, and dean emeritus at Wayne State University, recognized as a global key opinion leader on vulvovaginal candidiasis, and Dr. Stephen Brand, Chief Development Officer of Mycovia.

"In a Phase 3 clinical study, VIVJOA demonstrated statistically significant and clinically meaningful superiority to fluconazole at Day 14 and 28, the current standard-of-care, in treating severe VVC. The new listing for VIVJOA will provide improved access to many more women suffering with VVC in China, including those with fluconazole-resistant infections," said Stephen Brand. "Also, we are excited that Hengrui Pharma plans to evaluate the potential clinical utility for oteseconazole in multiple indications including and beyond women's health."

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.

In April 2022, the U.S. Food and Drug Administration (FDA) approved VIVJOA (oteseconazole) capsules as the first prescription medication for recurrent vulvovaginal candidiasis (RVVC, or chronic yeast

infection). VIVJOA is currently available in the US at over 200 Walgreens Specialty Pharmacies located throughout the U.S. In June 2023, VIVJOA received approval in China from the National Medical Products Administration and is indicated for the treatment of severe VVC.

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.
Jiangsu Hengrui Pharmaceuticals Co., Ltd. (Hengrui Pharma) is an innovative, global pharmaceutical company dedicated to the research, development and commercialization of high-quality medicines to address unmet clinical needs. With a global R&D team that includes 14 R&D centers and more than 5,500 professionals, Hengrui Pharma's therapeutic areas of focus include oncology, metabolic and cardiovascular diseases, immunological and respiratory diseases, and neuroscience. To date, Hengrui Pharma has commercialized 19 new molecular entity drugs and 4 other innovative drugs in China. Founded in 1970 with the core principle of putting patients first, Hengrui Pharma remains committed to advancing human health by striving to conquer diseases, improve health, and extend lives through the power of science and technology.

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