



Mycovia Pharmaceuticals Announces Completion of Partner Jiangsu Hengrui Pharmaceuticals' Phase 3 Clinical Study Evaluating Oteseconazole for Treatment of Acute Vulvovaginal Candidiasis (VVC) in China

- Enrollment is also underway for Phase 3 clinical study evaluating oteseconazole for the treatment of recurrent vulvovaginal candidiasis (RVVC) in China -

Durham, N.C. – November 3, 2021 – [Mycovia Pharmaceuticals, Inc. \("Mycovia"\)](#) today announced that Jiangsu Hengrui Pharmaceuticals Co., Ltd ("Hengrui") has completed its Phase 3 clinical study of oteseconazole (SHR8008) compared to fluconazole in subjects with acute vulvovaginal candidiasis (VVC). The clinical study named SHR8008-302 is an important advancement 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 including recurrent vulvovaginal candidiasis (RVVC), onychomycosis and invasive fungal infections.

Hengrui initiated the randomized, double-blind, double-dummy, parallel group, fluconazole-controlled, multicenter Phase 3 study in April 2021 with the primary objective to evaluate the efficacy of oteseconazole versus fluconazole in women with acute VVC. The study took place at 27 sites with 320 subjects. The last subject completed her final visit on Sept. 30, 2021, and data will support an NDA in China for oteseconazole.

Additionally, enrollment is underway for Hengrui's randomized, double-blind, double-dummy, parallel group, fluconazole-controlled, multicenter Phase 3 clinical study named SHR8008-301. The two primary objectives are to evaluate the efficacy of oteseconazole in preventing VVC episodes over 50 weeks, and to compare the efficacy of oteseconazole versus fluconazole in the treatment of VVC episodes in women with RVVC. The first subject was enrolled in September 2021, and enrollment is expected to complete in Q3 2022.

RVVC, also known as chronic yeast infection, is a distinct condition from VVC and defined as three or more symptomatic acute episodes of yeast infection per year. RVVC affects nearly 138 million women worldwide and 29 million women in China.

"We are pleased by the progress of the oteseconazole program and will continue working closely with Mycovia to bring this impressive molecule to tens of millions of women who suffer from vulvovaginal candidiasis," said Lianshan Zhang, Senior Vice President & President of Global R&D of Hengrui. "Based on the collective data from global oteseconazole studies to date, we believe it could serve a significant unmet medical need across this country."

"We congratulate Hengrui in achieving these important study milestones to evaluate oteseconazole's potential as a valuable treatment for acute yeast infections and chronic yeast infection," said Patrick Jordan, CEO of Mycovia and Partner at NovaQuest Capital Management. "The disease burden in China is

significant, with a need for other treatment options. We're thankful to advance our partnership together to fulfill the unmet needs of millions of women."

More information about the Hengrui Phase 3 studies can be found at <https://clinicaltrials.gov/> under the NCT number NCT04956419 for the SHR8008-302 study and NCT05074602 for the SHR8008-301 study.

In the United States, the U.S. Food and Drug Administration (FDA) recently accepted for review Mycovia's New Drug Application (NDA) for oteseconazole for the treatment of RVVC and under the Prescription Drug User Fee Act (PDUFA), set a target action date of January 27, 2022. Oteseconazole was previously granted Qualified Infectious Disease Product (QIDP) and Fast-Track designations by the FDA. With this timeline and pending full review and FDA approval, Mycovia is preparing for a U.S. launch of oteseconazole in early 2022.

About Mycovia Pharmaceuticals

Mycovia Pharmaceuticals is a late-stage emerging biopharmaceutical company dedicated to recognizing and empowering those living with unmet medical needs by developing novel therapies. Our lead product candidate, oteseconazole (VT-1161), is a novel, oral therapy for RVVC that is designed with the goal of having greater selectivity, fewer side effects and improved efficacy. While not yet approved by the FDA, oteseconazole received FDA Qualified Infectious Disease Product and Fast-Track designations to support its potential to be the first FDA-approved treatment for RVVC. In 2019, Mycovia licensed oteseconazole to Hengrui to develop and commercialize oteseconazole in China, including mainland China, Hong Kong, Macau and Taiwan, and Gedeon Richter Plc., a Hungary-based pharmaceutical company, to commercialize and manufacture oteseconazole in Europe, Russia, the Commonwealth of Independent States, Latin America and Australia. 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. established in 1970, is a leading biopharmaceutical company based in China with annual net sales of over \$4.2 billion USD in 2020. Hengrui is devoted to empowering healthier lives through research, with capabilities across oncology, immunology, anesthesiology, cardiovascular diseases, metabolic diseases, and pain management. Hengrui has more than 240 clinical trials ongoing worldwide.

About Oteseconazole

Oteseconazole (VT-1161) is a novel, investigational oral therapy for the treatment of recurrent vulvovaginal candidiasis (RVVC). Oteseconazole is designed with the goal of having greater selectivity, fewer side effects and improved efficacy as compared with currently available antifungal agents. Oteseconazole received FDA Qualified Infectious Disease Product and Fast-Track designations and, if approved, could be the first FDA-approved treatment for RVVC. Oteseconazole Phase 3 clinical trials were conducted in 11 countries. For more information, please visit <https://www.clinicaltrials.gov>.

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 as three or more symptomatic acute episodes of yeast infection per year. 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 NovaQuest Capital Management

Founded by a team of accomplished industry professionals who began working together in 2000, NovaQuest Capital Management is a premier biopharma and life sciences investment firm. NovaQuest pioneered a PRODUCT FINANCE™ investment 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. Currently managing more than \$2.2 billion in capital, NovaQuest is actively investing from the \$1.2 billion Pharma Opportunities Fund V, evaluating global opportunities with financing needs that range from \$30-100 million. For more information, please visit www.novaquest.com.

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