Mycovia Pharmaceuticals Announces U.S. FDA Acceptance and Priority Review of New Drug Application for Oteseconazole for the Treatment of Recurrent Vulvovaginal Candidiasis

- Six-month priority review granted for oteseconazole with PDUFA target action date set for January 27, 2022 -

- NDA supported by positive data from VIOLET and ultraVIOLET Phase 3 clinical trials evaluating oteseconazole in more than 870 women with RVVC in 11 countries -

- Mycovia preparing for the U.S. launch of oteseconazole in early 2022 pending full FDA approval -

Durham, N.C. – July 28, 2021 – Mycovia Pharmaceuticals, Inc. (Mycovia), an emerging biopharmaceutical company dedicated to recognizing and empowering those living with unmet medical needs by developing novel therapies, today announced the U.S. Food and Drug Administration (FDA) has accepted for review its New Drug Application (NDA) for oteseconazole, an oral antifungal product for the treatment of recurrent vulvovaginal candidiasis (RVVC). Also known as chronic yeast infection, RVVC is a distinct condition from vulvovaginal candidiasis (VVC) and defined as three or more symptomatic acute episodes of yeast infection per year. RVVC affects nearly 138 million women worldwide each year and 6 million women in the U.S. alone. There are currently no FDA-approved treatments.

The FDA previously granted oteseconazole Priority Review, which is a designation reserved for potential drugs that, if approved, would mark significant improvements in the safety or effectiveness in the treatment of serious conditions. Under the Prescription Drug User Fee Act (PDUFA), the FDA set a six-month period with a target action date of January 27, 2022.

Mycovia's NDA for oteseconazole is supported by positive results from three Phase 3 trials – two global VIOLET studies and one U.S.-focused ultraVIOLET study, including more than 870 patients at 232 sites across 11 countries. Both VIOLET studies met their primary and key secondary endpoints. Additionally, results from ultraVIOLET demonstrated oteseconazole's effectiveness in treating the initial episode of VVC and reinforced its efficacy and safety profile in treating RVVC as compared to fluconazole, the current standard of care for VVC. Combined Phase 3 data showed that oteseconazole protected more than 90% of participants from having a recurrence for nearly a year.

"RVVC is a different condition from yeast infections, simply known as VVC, so it requires a different treatment," said Patrick Jordan, CEO of Mycovia Pharmaceuticals and Partner at NovaQuest Capital Management, which formed Mycovia in 2018. "Research shows that fluconazole, the standard of care for VVC, is more than 90% effective in treating an initial episode of VVC[1], but in studies of patients with RVVC, greater than 50% of women experience a recurrence following maintenance therapy discontinuation[2]."

“We designed oteseconazole to address this need as a highly selective targeted oral therapy that demonstrates improved efficacy with fewer side effects than current treatment options, including fluconazole,” Jordan continued. “Supported by rigorous clinical trials evaluating the safety and efficacy of oteseconazole, we are eager for the FDA to review the application for our product, which has the potential to be the first FDA-approved therapy indicated for RVVC.”

Oteseconazole was granted Qualified Infectious Disease Product (QIDP) and Fast-Track designations by the FDA. With this timeline and pending full FDA review and 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 Jiangsu Hengrui Medicine Co., 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 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.mycovia.com/pipeline.

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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[1]Treatment of vaginal candidiasis with a single oral dose of fluconazole. Multicentre Study Group. Eur J Clin Microbiol Infect Dis. 1988 Jun;7(3):364-7. doi: 10.1007/BF01962338. PMID: 2842157.
[2]Sobel JD, Wiesenfeld HC, Martens M, Danna P, Hooton TM, Rompalo A, Sperling M, Livengood C 3rd, Horowitz B, Von Thron J, Edwards L, Panzer H, Chu TC. Maintenance fluconazole therapy for recurrent vulvovaginal candidiasis. N Engl J Med. 2004 Aug 26;351(9):876-83. doi: 10.1056/NEJMoa033114. PMID: 15329425.