Mycovia Pharmaceuticals Submits New Drug Application to the U.S. FDA for Oteseconazole for the Treatment of Recurrent Vulvovaginal Candidiasis

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

- Oteseconazole's Qualified Infectious Disease Product and Fast-Track designations allow for six-month priority review by FDA following its acceptance of the NDA -

Durham, N.C. – June 1, 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 it has submitted 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 debilitating infectious condition defined as three or more episodes per year. Although 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.

"We are thrilled to take this pivotal step in our journey to bring oteseconazole to millions of women suffering from RVVC," said Patrick Jordan, CEO of Mycovia Pharmaceuticals and Partner at NovaQuest Capital Management, which formed Mycovia in 2018. "If approved, oteseconazole will be the first FDA-approved therapy for the treatment of this disease. We are proud to be at the forefront of a growing movement in healthcare to focus on undertreated conditions like RVVC, which can negatively impact so many aspects of a woman's life physically, emotionally and financially."

Oteseconazole was designed to be highly selective for its pathogenic target, with fewer side effects and improved efficacy over current treatment options, including fluconazole, the current standard of care for vulvovaginal candidiasis (VVC). Oteseconazole's clinical development plan was comprised of three 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 acute episodes of VVC and reinforced its efficacy and safety profile in treating RVVC as compared to fluconazole. Combined Phase 3 data showed that oteseconazole protected more than 90% of participants from having a recurrence for nearly a year.

"RVVC is an area of tremendous unmet need for which there is currently no FDA-approved treatment. Research shows that fluconazole, the standard of care for VVC, is more than 90% effective in treating an acute episode of VVC[1], but in studies of patients with RVVC, greater than 50% of RVVC women experience a recurrence following maintenance therapy discontinuation[2]," said Thorsten Degenhardt, PhD, Chief Operating Officer of Mycovia. "We believe, if approved, oteseconazole will provide an important treatment option for healthcare professionals and their patients."

Given oteseconazole's Qualified Infectious Disease Product (QIDP) and Fast-Track designations, Mycovia anticipates a six-month review following the FDA's acceptance of the NDA. With this timeline and pending full 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 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 is defined as three or more episodes in one 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
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 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 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.