



Mycovia Pharmaceuticals, Inc. Announces First Participant Enrolled in an Investigator-Initiated Phase 2 Study for Cryptococcal Meningitis

- Cryptococcal meningitis is a serious fungal infection causing an estimated 112,000 deaths annually

-The PLATFORM-CM trial is evaluating oteseconazole and other investigational products against the standard of care for treating cryptococcal meningitis

Durham, NC — June 4, 2025 — [Mycovia Pharmaceuticals, Inc.](#) (“Mycovia”) has announced enrollment of the first participant in an investigator-initiated clinical trial evaluating oteseconazole and other investigational products for cryptococcal meningitis, an investigational use that has not been approved by FDA. The Phase 2 PLATFORM-CM study marks a significant research effort aimed at improving treatment options for cryptococcal meningitis.

Dr. David Boulware, Professor of Medicine, Infectious Disease and International Medicine at the University of Minnesota, School of Public Health, and Dr. David Meya, Associate Professor at the School of Medicine at the College of Health Sciences, Makerere University in Uganda, designed the study and will serve as Principal Investigators. PLATFORM-CM is an open-label randomized trial with single or potentially multiple interventional arms to compare the efficacy and safety of antifungal investigational therapies, including oteseconazole, to the standard of care WHO first-line therapy in treating cryptococcal meningitis. The clinical trial will be conducted at three sites in Uganda and will involve up to 200 participants who will be treated for 18 weeks with oteseconazole.

“We are excited to initiate this important study and enroll our first research participant,” said Dr. Boulware. “Our goal is to generate meaningful data that will show a reduction in death for patients that cannot use or who have developed resistance to current standard of care treatments.”

Globally, cryptococcal meningitis causes an estimated 152,000 cases and 112,000 deaths annually, and is one of the leading causes of death among people living with HIV in Africa. Several challenges exist with the current standard of care therapy including medication access and stability, supplier limitations, and substantial toxicity. Additional treatments are needed for cryptococcal meningitis, particularly those which have less toxicity, greater efficacy, a prolonged half-life, and minimal drug-drug interactions. The World Health Organization has identified *Cryptococcus* as a critical Fungal Priority Pathogen.

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. Preclinical studies have demonstrated that oteseconazole is potent against fluconazole-sensitive and -resistant strains of *Cryptococcus*.

“Mycovia is committed to making a meaningful impact in our global community and driving innovation for unmet or underserved medical needs through clinical research and collaboration,” commented Dr. Stephen Brand, Chief Development Officer of Mycovia. “This study will serve to further evaluate oteseconazole beyond its currently approved indication and expand upon the



encouraging preclinical data that suggests oteseconazole may have clinical utility in treating this serious fungal infection of the brain and central nervous system.”

For more information about the trial, please visit <https://clinicaltrials.gov>.

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 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 <https://mycovia.com>.

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