

Mindset Pharma Receives Approval For Phase II Clinical Trial Evaluating MSP-1014 For The Treatment Of Major Depressive Disorder

Toronto, June 22, 2023 (GLOBE NEWSWIRE) – [Mindset Pharma Inc. \(CSE: MSET\) \(FSE: 9DF\) \(OTCQB: MSSTF\)](#) (“Mindset” or the “Company”), a drug discovery company developing novel, optimized, next-generation psychedelic and non-psychedelic medications to treat neuropsychiatric and neurological disorders with unmet medical needs, today announces that it has received approval from the U.K. Medicines and Healthcare products Regulatory Authority (the “MHRA”) and the Research Ethics Committee to initiate a Phase II study of MSP-1014, its novel psilocin prodrug, evaluating its safety and efficacy in treating patients suffering from major depressive disorder (MDD).

About the MSP-1014 Phase II Trial

The Phase II study will be conducted in two parts. In Part 1, Mindset will assess the safety and tolerability of up to three escalating doses of MSP-1014. In conjunction with MSP-1014, study participants will receive Acceptance and Commitment Therapy (ACT).

In Part 2, a randomized and placebo-controlled study, Mindset will assess the safety and efficacy of a single dose of MSP-1014, selected from Part 1. An equal number of patients will receive MSP-1014 or placebo (non-active) control and all will receive 6 sessions of ACT.

About MSP-1014

MSP-1014 is a novel and patent-protected prodrug of psilocin, the active metabolite of psilocybin. MSP-1014 is anticipated to exert similar efficacy to psilocybin in improving symptoms of depression. Preclinical studies comparing MSP-1014 to psilocybin suggest that the tolerability of MSP-1014 may be superior to psilocybin.

Joseph Araujo, Chief Scientific Officer of Mindset, remarked:

“This is an exciting milestone as we prepare to enter our first-in-human clinical trial with our novel psilocin prodrug, MSP-1014. Based on pre-clinical data, we believe that MSP-1014 has the potential to be a better tolerated psychedelic therapeutic compared to psilocybin. This approval for a Phase II study should provide us with a strong efficacy signal and expedite our pathway to approval for MSP-1014 as a new effective and more tolerable treatment for patients suffering from MDD.”

James Lanthier, Chief Executive Officer added:

“Our team has worked diligently and tirelessly to achieve this major regulatory milestone. With today’s announcement, MSP-1014 now has a clear path to become one of the most clinically advanced psilocin-based novel chemical entity (NCE). As

psilocybin continues to make strides in its ongoing clinical development, the opportunity for novel optimized drug candidates is expanding significantly.

Moreover, this announcement demonstrates that Mindset is delivering on its commitment to making the leap to becoming a clinical stage biotech company focused on novel and patentable psychedelic-inspired therapeutics.”

MSP-1014, which sits outside of Mindset’s collaboration with the McQuade Center for Strategic Research and Development, is derived from Mindset’s “Family 1” of novel drugs, which enjoys robust composition of matter intellectual property protection in multiple jurisdictions. The Phase II clinical trial may commence as early as Q4 2023.

About Mindset Pharma Inc.

Mindset Pharma Inc. is a drug discovery and development company focused on creating optimized and patentable best-in-class innovative next-generation psychedelic medicines to treat neurological and psychiatric disorders with unmet needs. Mindset was established in order to develop next-generation pharmaceutical assets that leverage the breakthrough therapeutic potential of psychedelic drugs. Mindset is developing several novel families of next-generation psychedelic compounds, as well as an innovative process to chemically synthesize psilocybins in addition to its own proprietary compounds. The company has a co-development agreement with the McQuade Center for Strategic Research and Development, a member of the Otsuka Pharmaceuticals family of companies, covering multiple drug development programs.

For further information on Mindset, please visit our website at www.mindsetpharma.com.

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and other factors that could cause actual events or results to differ materially from those projected in the forward-looking information. Additional information regarding risks and uncertainties relating to the Company's business are contained under the heading "Risk Factors" in the Company's annual information form for the financial year ended June 30, 2020 dated March 5, 2021. The forward-looking information included in this news release is made as of the date of this news release and the Company does not undertake an obligation to publicly update such forward-looking information to reflect new information, subsequent events or otherwise, except as required by applicable law.

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