



Cybin Granted IRB Approval for Phase II Clinical Trials of its Sublingual Psilocybin Formulation for the Treatment of Major Depressive Disorder

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TORONTO, CANADA – May 18, 2021 – [Cybin Inc. \(NEO:CYBN\)](#) (OTCQB:CLXPF), a biotechnology company focused on progressing psychedelic therapeutics, today announced that the Institutional Review Board (“IRB”) at the University of the West Indies Hospital, in Jamaica has granted approval to commence the study of its sublingual psilocybin formulation (“CYB001”) in a Phase II clinical trial for patients suffering with Major Depressive Disorder (“MDD”). Commencement of the clinical trial is subject to final confirmation of study material specifications by Jamaica’s Ministry of Health.

MDD is a disease that affected over 7.1% of the U.S. adult population in 2017 according to the National Institute of Mental Health. Globally, nearly 300 million people suffer from depression according to the World Health Organization.

Psilocybin has been granted Breakthrough Therapy Designation by the U.S. Food and Drug Administration to multiple entities in the USA, and this specific trial will become the first of its kind comparing a 25mg psilocybin capsule with Cybin’s proprietary sublingual film formulation.

The clinical trial will consist of a Phase IIa study of 40 patients to identify the bio-equivalent dose of Cybin’s proprietary sublingual psilocybin formulation versus a 25mg oral capsule. Sublingual delivery is designed to enable rapid absorption of molecules into the bloodstream via the mouth, rather than utilizing the gastrointestinal tract. The goal of the trial is to demonstrate the potential benefits of Cybin’s sublingual delivery method which seeks to deliver faster onset of action, shorter treatment duration, and a lower effective dose.

“IRB approval for our study protocols is an important step forward to begin testing our proprietary psilocybin formulation delivered via absorption under the tongue in patients with Major Depressive Disorder. We are planning several additional studies to expand our clinical understanding of this potentially ground-breaking therapeutic. Cybin continues to expand on its 4 active drug programs targeting depression, addiction and other psychiatric conditions alongside its growing portfolio of 50+ proprietary psychedelic molecules. This latest IRB approval moves Cybin closer to unlocking the potential of more scalable therapeutics,” stated Doug Drysdale, Chief Executive Officer.

Upon successful completion of the Phase IIa study, Cybin plans to study the safety and efficacy of its CYB001 psilocybin drug candidate in a randomized, placebo-controlled Phase IIb study, in 120 patients with MDD. The primary endpoint of this study is expected to be a reduction in the Montgomery-Asberg Depression Rating Scale (“MADRS”) of depression symptoms at 30 days.

The clinical trial will adhere to ICH-GCP (“The International Conference on Harmonization-Good Clinical Practice”) guidelines, with the aim to utilize clinical data across the world in jurisdictions such as the United States, Canada and Europe.

About Cybin

Cybin is a leading biotechnology company focused on progressing psychedelic therapeutics for mental illness and addiction by utilizing proprietary drug discovery platforms, innovative drug delivery systems, novel formulation approaches and treatment regimens for psychiatric disorders.

Cautionary Notes and Forward-Looking Statements

Certain statements in this news release related to the Company are forward-looking statements and are prospective in nature. Forward-looking statements are not based on historical facts, but rather on current expectations and projections about future events and are therefore subject to risks and uncertainties which could cause actual results to differ materially from the future results expressed or implied by the forward-looking statements. These statements generally can be identified by the use of forward-looking words such as “may”, “should”, “could”, “intend”, “estimate”, “plan”, “anticipate”, “expect”, “believe” or “continue”, or the negative thereof or similar variations. Forward-looking statements in this news release may include statements regarding enhanced liquidity, the value of additional capital markets exposure, access to institutional and retail investors, the Company’s new strategic brand messaging campaign, and psychedelic drug development programs to potentially treat mental health disorders. There are numerous risks and uncertainties that could cause actual results and Cybin’s plans and objectives to differ materially from those expressed in the forward-looking information. Actual results and future events could differ materially from those anticipated in such information. These and all subsequent written and oral forward-looking information are based on estimates and opinions of management on the dates they are made and are expressly qualified in their entirety by this notice. Except as required by law, the Company does not intend to update these forward-looking statements.

Cybin makes no medical, treatment or health benefit claims about Cybin's proposed products. The U.S. Food and Drug Administration, Health Canada or other similar regulatory authorities have not evaluated claims regarding psilocybin, psychedelic tryptamine, tryptamine derivatives or other psychedelic compounds or nutraceutical products. The efficacy of such products has not been confirmed by approved research. There is no assurance that the use of psilocybin, psychedelic tryptamine, tryptamine derivatives or other psychedelic compounds or nutraceuticals can diagnose, treat, cure or prevent any disease or condition. Vigorous scientific research and clinical trials are needed. Cybin has not conducted clinical trials for the use of its proposed products. Any references to quality, consistency, efficacy and safety of potential products do not imply that Cybin verified such in clinical trials or that Cybin will complete such trials. If Cybin cannot obtain the approvals or research necessary to commercialize its business, it may have a material adverse effect on Cybin's performance and operations.

The NEO Exchange has neither approved nor disapproved the contents of this news release and is not responsible for the adequacy and accuracy of the contents herein.

Investor Contacts:

Tim Regan/Scott Eckstein

KCSA Strategic Communications

Cybin@kcsa.com

Lisa M. Wilson

In-Site Communications, Inc.

lwilson@insitecony.com

Media Contacts:

John Kanakis

Cybin Inc.

John@cybin.com