MindBio Therapeutics Ethics Approval for Landmark World First Phase 2 Clinical Trial of Take-Home LSD-Microdosing for Major Depressive Disorder

- ***Ethics approval received for take-home LSD-Microdosing clinical trial in depressed patients***
- ***Clinical trial has been approved by the Clinical Trials Registry***
- ***One of two approved take home Phase 2 LSD-Microdosing Clinical Trials running in 2023***

VANCOUVER, BC / ACCESSWIRE / May 23, 2023 / MindBio Therapeutics Corp. (CSE:MBIO)(Frankfurt:WF6), (the "**Company**" or "**MindBio**") is pleased to announce that ethics approval has been received for a world's first Phase 2a take home LSD-Microdosing clinical trial in patients with Major Depressive Disorder. The trial has also been approved by the Clinical Trials Registry.

Depressive disorders are a leading cause of "years lived with disability" globally and there is a clear need for the development of new, alternative antidepressant therapies. In this open-label trial in 20 patients with major depressive disorder (MDD) the tolerability and feasibility of an 8 week regimen of LSD-Microdosing will be tested. The results will inform a continuation trial, a much larger Phase 2b randomized triple-dummy active placebo controlled trial in patients with Major Depressive Disorder.

Major depressive disorder (MDD) is the leading cause of global disability, with over 260 million people affected. In Aotearoa/New Zealand, the jurisdiction of this study, approximately 6% of persons experience a depressive episode each year. In the US, the Centers for Disease Control and Prevention (CDC) predicts that about 16 million adults in the US will experience depression each year. Despite this prevalence, current medical therapies are limited by slow onset, variable tolerability, with partial or total lack of efficacy in approximately one third of patients[1]. Surveys have shown that while people who take antidepressants feel they are helpful for mood, many report problems with drug withdrawal (74%), sexual dysfunction (72%), weight gain (65%), and emotional numbing (65%), all of which negatively impact quality of life[2].

With the compounding effects of high depressive disorder prevalence and low efficacy of antidepressant therapies there is a clear need for the development of new, alternative therapies with better efficacy and tolerability. New effective treatments would provide great benefit by reducing the health and economic burden of depression for patients, their families and the community at large.

In 2022, MindBio's Phase 1 take-home LSD-Microdosing clinical trial in 80 healthy participants yielded positive topline results. The randomized, double blind and placebo controlled clinical trial found on dose days, participants in the LSD-Microdosing group experienced increases in:

1. Happiness
2. Social connectivity

3. Creativity
4. Wellness
5. Energy

Chief Executive Officer of MindBio Therapeutics, Justin Hanka said "We are pleased to be advancing our microdosing treatments to Phase 2 clinical trials. Psychedelic microdosing proposes to be a globally scalable solution to treating mental health conditions and we are excited by the data we are seeing and the potential future commercialization opportunities for these medicines."

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References:

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2. Cartwright, C., Gibson, K., Read, J., Cowan, O., & Dehar, T. (2016). Long-term antidepressant use: patient perspectives of benefits and adverse effects. *Patient Prefer Adherence*, *10*, 1401-1407. https://doi.org/10.2147/ppa.S110632

About MindBio Therapeutics

MindBio is a biotech/biopharma company focused on creating novel and emerging treatments for mental health conditions and is conducting world first take-home LSD-Microdosing human clinical trials. MindBio is a leader in microdosing of psychedelic medicines and is advancing its drug and technology protocols through clinical trials. MindBio has developed a multi-disciplinary platform for developing treatments and is involved in psychedelic medicine development and digital therapeutics, has completed Phase 1 clinical trials microdosing Lysergic Acid Diethylamide (LSD) in 80 patients, has a Phase 2 clinical trial in development microdosing LSD in patients with Major Depressive Disorder and a Phase 2 clinical trial in development microdosing LSD in late stage cancer patients experiencing existential distress. MindBio invests in research that forms the basis for developing novel and clinically proven treatments including digital technologies and interventions to treat debilitating health conditions such as depression, anxiety and other related mental health conditions.

Cautionary Note Concerning Forward-Looking Statements:

The press release contains "forward-looking statements" within the meaning of applicable securities laws. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "budget," "believe," "project," "estimate," "expect," "scheduled," "forecast," "strategy," "future," "likely," "may," "to be," "could," "would," "should," "will" and similar references to future periods or the negative or comparable terminology, as well as terms usually used in the future and conditional. Forward-looking statements are based on assumptions as of the date they are provided. However, there can be no assurance that such assumptions will reflect the actual outcome of such items or factors.

Additionally, there are known and unknown risk factors that could cause the Company's actual results and financial conditions to differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important risk factors that could cause actual results and financial conditions to differ materially from those indicated in the forward-looking statements, include among others: general economic, market and business conditions in Canada and Australia; market volatility; unforeseen delays in timelines for any of the transactions or events described in this press release. All forward-looking information is qualified in its entirety by this cautionary statement.

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