



A Brighter Future for Mental Health

CSE: MBIO

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## **MINDBIO ANNOUNCES SUCCESSFUL OUTCOME OF MANDATORY INDEPENDENT SAFETY AUDIT IN PHASE 2B CLINICAL TRIALS**

**Vancouver, British Columbia – 28 January, 2025 – MindBio Therapeutics Corp. (CSE: MBIO); (Frankfurt: WF6),** (the “Company” or “MindBio”), is a clinical stage biopharmaceutical company in psychiatric medicine development using microdoses of psychedelic medicines to treat depressive disorders. The Company is delighted to report the outcome of a mandatory independent safety audit of its two currently dosing Phase 2B clinical trials.

MindBio is currently dosing in two landmark clinical trials:

1. Phase 2B trial in 90 patients with Major Depressive Disorder. This is a triple blind, double dummy, active placebo-controlled trial.
2. Phase 2B trial in 40 patients with Advanced Stage Cancer, suffering from end of life distress, anxiety and depression. This is a double blind, placebo-controlled trial of MB22001 as an adjunct to the use of Meaning Centred Psychotherapy, (the standard of mental health care in advance-stage cancer patients).

The Company is pleased to report the mandatory and independent safety review conducted recently at the midpoint of both trials, found no serious adverse events or serious side effects in participants and the trials have been approved for continuation. After a short break over the holiday period, patient recruitment and dosing has resumed this week with the Company on track to complete the trials in late 2025.

This is positive news for the Company and is confirmatory of MindBio’s early results in Phase 1 and Phase 2A trials which found its lead candidate MB22001 was well tolerated by patients and had a low side effect profile compared to anti-depressants.

MB22001, a form of lysergic acid diethylamide, is administered by patients at home in microdoses and it is the Company’s thesis that this non-hallucinogenic use of psychedelic medicines is the most scalable way to productise drugs in the category in direct competition to first line anti-depressant medications. To this end, the Company has developed a safety and monitoring protocol using proprietary technology to ensure medication adherence, report diversion to clinicians and collect biophysical information from patients 24 hours a day 7 days a week. The trials remain the only clinical trials in the world where patients can legally administer this type of psychedelic medicine by themselves without clinical supervision out in the community and the Company has demonstrated the safe administration of thousands of doses to date.

Justin Hanka, Chief Executive Officer of MindBio said, “We are very pleased with the outcome of this mandatory independent safety audit of our clinical trials. Whilst we won’t know the outcome of the trials until late 2025, this is a very good sign that side effects are not a problem with our lead candidate drug MB22001 and we can confidently continue our work”.

We invite you to join us in support of creating a brighter future for mental health.

Receive our latest updates here: <https://www.mindbiotherapeutics.com/get-updates>

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### **About MindBio Therapeutics**

MindBio is a leading biotech/biopharma company focused on creating novel and emerging treatments for mental health conditions and is conducting world first take-home Microdosing (MB22001) human clinical trials. MB22001 is MindBio’s lead candidate drug, a proprietary titratable form of Lysergic Acid Diethylamide (LSD) designed for take-home microdosing. 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 in 80 healthy participants and has completed a Phase 2a clinical trial in patients with Major Depressive Disorder, both trials with positive top line data reported. Currently underway are two Phase 2B trials, one in cancer patients experiencing existential distress and another in patients with Major Depressive Disorder. The Company is also approved for multiple Phase 1/Phase 2B trials in women’s health. 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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