A Brighter Future for Mental Health

CNSX: MBIO

MINDBIO ANNOUNCES CLINICAL TRIAL MILESTONE IN PHASE 2B MICRODOSING TRIALS TARGETING EXISTENTIAL DISTRESS, DEPRESSION & ANXIETY IN ADVANCED STAGE CANCER

One of two Phase 2B trials currently dosing and underway:

- Phase 2B trialing MB22001 in patients with Major Depressive Disorder, and;
- Phase 2B trialing MB22001 in patients with Advanced Stage Cancer

Vancouver, British Columbia – October 24, 2024 – **MindBio Therapeutics Corp. (CSE: MBIO); (Frankfurt: WF6),** (the "**Company**" or "**MindBio"),** a leading biopharmaceutical company in psychiatric medicine development, targeting depressive disorders with psychedelic microdosing treatments is delighted to report on progress of its trial of MB22001 in advanced stage cancer patients.

In this Phase 2B clinical trial in advanced stage cancer patients experiencing symptoms of anxiety and or depression, *N*=40, will be randomised under double-blind conditions to receive 7 sessions of Meaning Centred Psychotherapy alongside 13 doses of either MB22001 (4ug-12ug) or inactive placebo. The Company has started dosing the 20th participant and reached the half-way milestone in this important work.

The commercial objective is to target global special access schemes assuming Phase 2B completion produces positive results. For example, Health Canada's special access or (SAP) program and Australia's Special Access Scheme (SAS) and Authorised Prescriber (AP) schemes which allow certain registered health practitioners to access unapproved therapeutic goods for patients under their care.

Special access schemes for late-stage cancer patients are highly relevant to MindBio's work and it is known that pharmacotherapeutic interventions are commonly used to treat anxiety and depression in cancer care; however, they have notable limitations with several meta-analyses of placebo-controlled trials of antidepressants failing to demonstrate a clear effect of treatment in cancer patients. [1-3]

Meaning-Centred Psychotherapy (MCP) was developed in response to the despair, hopelessness, loss of meaning and desire for hastened death that commonly occurs in people

with advanced cancer[4] and there is compelling evidence for the use of MCP to improve meaning and quality of life in this population.[5]

The Company's thesis is that MB22001 will be an effective pharmacological treatment alongside MCP and will improve symptoms of anxiety and depression, compared to when MCP is administered on its own.

The Company's thesis is now backed by 4 years of data collection and analysis in prior clinical trial works. In addition to improvements in mood, a 60% reduction in depressive symptoms, improved sleep and enhanced feelings of creativity and energy, there have been improvements in a range of **secondary outcome measures** in depressed patients following an 8-week treatment course with MB22001. This includes a 52% reduction in anxiety (HAM-A), and self-reported reductions in stress (35%), anxiety (59%) and depression (40%) using the DASS questionnaire. Participant's psychological quality of life was improved by 37% as measured by the WHOQOL.

Safety analysis has shown a favorable adverse event profile with a low frequency of adverse events. No clinically significant abnormalities were seen in follow up blood tests, electrocardiograms or echocardiograms. Tolerability of treatment is important when dosing vulnerable patients in their last stages of life in cancer care.

These results give management a high level of confidence that MB22001 could be useful in treating cancer patients suffering from end of life distress and the Company is looking forward to sharing top line data in 2025.

Justin Hanka, Chief Executive Officer of MindBio said, "We are delighted with the progress of our cancer trials as we continue to dose patients in multiple Phase 2B programs".

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

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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.

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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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