MindBio Therapeutics Announces Landmark Women's Health CNS Drug Trials

ASSESSING THE EFECTS OF MICRODOSING MB22001 IN MENSTRUATING PERSONS WITH AND WITHOUT PREMENSTRUAL SYNDROME AND PREMENSTRUAL DYSPHORIC DISORDER

Multiple clinical trials in women's health approved for take-home use of MB22001

MB22001 aims to address huge unmet need in the ~25% of women experiencing PMS symptoms

MB22001 to be used acutely to address the mood sensitive phases of the menstrual cycle

World first clinical trials will assess both the pharmacokinetic and pharmacodynamic responses from a CNS drug across key stages of the menstrual cycle

Mood elevating and antidepressant effects of MB22001 have already been demonstrated in Phase 1 and Phase 2A clinical trials

VANCOUVER, BC / ACCESSWIRE / April 30, 2024 / MindBio Therapeutics Corp. (CSE:MBIO)(Frankfurt:WF6), (the "**Company**" or "**MindBio**"), a clinical stage biopharma company developing innovative psychiatric treatments using microdoses of psychedelic medicines to revolutionize mental health treatments, is delighted to announce the regulatory approval of a series of clinical trials in women's health using MB22001, a proprietary titratable form of Lysergic Acid Diethylamide (LSD) designed for self-administered take home use by patients. MindBio remains the only company in the world with regulatory approvals for the take-home use of this type of scheduled drug in clinical trials.

Background

Premenstrual syndrome (PMS) is estimated to affect ~25% of all persons who menstruate - equivalent to 956 million persons worldwide [1]. A particularly severe form of PMS is termed premenstrual dysphoric disorder (PMDD) which affects 3-8% of persons who menstruate. Collectively severe PMS and PMDD create a massive health burden with negative effects on well-being, employment, social functioning and relationships with partners and children [2]. Current treatments for these issues are selective serotonin reuptake inhibitors (SSRIs), given either continuously or daily during the luteal phase of the menstrual cycle. While SSRIs can be effective for some with PMDD approximately 40% of women with PMDD do not respond to SSRIs (or oral contraceptives) [4]. Common side effects of SSRIs when used for PMDD include nausea, decreased energy, somnolence, fatigue, decreased libido and sweating [5] and almost half of persons with PMDD discontinue SSRIs within the first six months of taking them [6].

Similarly, the other main treatment for PMS/PMDD oral contraceptives have limited efficacy and numerous side effects. New treatments for PMS/PMDD are desperately needed.

MB22001 is a proprietary titratable form of Lysergic Acid Diethylamide (LSD: A psychedelic medicine), designed for take-home self-administration by patients. The Company's thesis is that MB22001 can be used acutely during specific periods of the menstrual cycle, with targeted dosing to treat negative mood symptoms. This thesis is based on three main facts a) The acute dose day mood elevating effects of MB22001 have been demonstrated in MindBio's Phase 1 trials b) MindBio's Phase 2a open-label trial in depressed patients show long-term improvements in mood and c) reports in the grey literature of persons self-medicating for PMS/PMDD using LSD microdoses (e.g. [3]).

MindBio has two significant women's health trials approved:

An open-label trial to test menstrual cycle effects and tolerance to MB22001 microdosing in healthy people with a menstrual cycle (MDMENS). MDMENS is an open-label counter-balanced Phase 1 trial with sequential visits. The purpose of MDMENS is to a) test for menstrual cycle effects in response to 20 µg microdoses of MB22001 b) test for tolerance effects in response to 20 µg microdoses of MB22001 and to c) serve as a pilot and control group for the second approved trial known as the MDPMD trial.

The MDPMD trial is a randomised, triple-blind, placebo-controlled, parallel groups, trial of MB22001 microdosing in persons with Premenstrual Syndrome (PMS)/Premenstrual Dysphoric Disorder (PMDD). The primary hypothesis to be tested in the MDPMD trial is whether a regimen of luteal phase focussed microdoses can reduce symptomatology in persons with PMS/PMDD with superiority to placebo. MDPMD will be triple-blinded with participants, investigators and outcome assessors blinded to the intervention. All participants in MDPMD will have the option of entering a three-cycle open-label extension period to test for long-term durability and safety.

The research team for MindBio's women's health trials includes leading menstrual cycle researchers from three continents.

Broader Significance of MindBio's Women's Health Trials

To our knowledge MDMENS will be the first study to investigate the response to psychedelics across the menstrual cycle. Given the changes in serotonin receptor and transporter densities that occur across the menstrual cycle [4-6] this is a glaring knowledge gap that MindBio's studies will fill. The data collected from these series of trials will add significantly to MindBio's massive repository of data and should be of considerable interest to all companies/researchers interested in psychedelic medicine.

More broadly, although inclusion of females in biomedical and clinical research has been mandated for over 30 years by the National Institutes of Health (NIH) - a requirement echoed internationally across funding, ethical and publishing organisations, improving clinical research in females is not as simple as representing the female sex in a random sample. Across the

lifecycle of females there are major changes in hormones that are known to affect how drugs act in the body. This has largely been ignored by the pharmaceutical industry. Some work has been completed on how the menstrual cycle affects pharmacokinetics (PK - how the body processes drugs), but almost none on how the menstrual cycle affects pharmacodynamics (PD - how the body responds to drugs). It is perhaps not surprising then that females are disproportionately affected by adverse effects from commonly available medicines [1, 2]. There are next to no clinical trials that have investigated both PK and PD of a Central Nervous System (CNS) drug across the key points of the menstrual cycle making this work significant globally and of interest to all pharmaceutical companies interested in CNS drug trials.

MindBio's Completed Clinical Trials

In February 2024, MindBio completed its Phase 2a trial of MB22001 in patients with Major Depressive Disorder. In this open label trial, patients experienced a 60% drop in depressive symptoms and 53% of patients entering the trial with MDD, at week 8 were in remission from their depression with a mean 14.1 point drop in MADRS score (Montgomery-Asberg Depression Rating Scale). Prior trial results using MB22001 recorded statistically significant improvements in sleep quality and increases in subjective feelings of "Happiness", "Social Connectivity", "Energy", "Creativity" and "Wellness" with reduced "Anger" and "Irritability". MB22001 is a promising and potential market disruptive medicine for treating depressive illness.

Chief Executive Officer of MindBio Therapeutics, Justin Hanka said "Microdosing MB22001 is a disruptive treatment methodology, it represents a scalable, affordable and accessible solution using psychedelics to address the global escalation of depression. This is a potential market disruption to first line treatments for depression and conditions such as PMDD. We are the global leaders in psychedelic microdosing and we are strategically positioning MB22001 to replace anti-depressant use with lower side-effects."

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Follow CEO Justin Hanka on LinkedIn: https://www.linkedin.com/in/justinhanka/

For further information, please contact:

Justin Hanka, Chief Executive Officer
61 433140886
justin@mindbiotherapeutics.com

Media Inquiries

Kristina Spionjak
pr@hlthcommunications.com

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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. 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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