Bright Minds Biosciences Provides Clinical Program Updates and Outlines Anticipated Milestones for 2023

-- First-in-human Phase 1 trial for lead program, BMB-101, a highly selective 5-HT_{2C} agonist, is underway in Australia --

-- Company has transitioned from a discovery to a development organization –

-- Company to attend BIO-Europe Spring Conference in Basel, Switzerland, March 20-22, 2023 --

VANCOUVER, British Columbia, Feb. 27, 2023 -- Bright Minds Biosciences Inc. (CSE:DRUG) (NASDAQ:DRUG) ("**Bright Minds**" or the "**Company**"), a biotechnology company focused on developing novel drugs for the targeted treatment of neuropsychiatric disorders, epilepsy, and pain, today provided an update on its clinical programs, anticipated upcoming milestones and strategic priorities for advancing its development pipeline of innovative treatments to heal the central nervous system (CNS) and brain through the regulation of serotonin.

"This is an exciting time for Bright Minds, as the company successfully transitions from a discovery to a development organization. We are pleased with the progress of our Phase 1 first-in-human trial of BMB-101 and believe there are large potential market opportunities for the treatment of refractory epilepsies, beyond Dravet syndrome and a host of other indications, such as psychosis and addiction disorders. Through an extensive medicinal chemistry and rational drug design program, Bright Minds has successfully developed 5-HT_{2C}, 5-HT_{2A} and 5-$HT_{2A/2C}$ agonists devoid of 5-HT_{2B} agonism. We are progressing our next-generation psychedelics program and have nominated two clinical candidates. BMB-202, a fast, C_{max} driven 5-HT_{2A} agonist for the treatment of depression, is expected to enter a first-in-human trial late this year. The team has put in place a top-tier development organization with clinical, regulatory, manufacturing, and controls functions for future product pipeline investigational new drug submissions in the United States. In addition, last May, we established a scientific advisory board consisting of preeminent physicians and scientists across mental health disciplines whose expertise will serve to aide in the development of our clinical programs," said Ian McDonald, CEO and Co-founder of Bright Minds Biosciences.

Program Updates and 2023 Milestones

BMB-101:
A highly selective and potent 5-HT_{2C} agonist has entered first-in-human Phase I clinical evaluation. The trial is being conducted in Adelaide, Australia, by CMAX Clinical Research, a clinical trial center specializing in a range of early-phase trials and first-in-human studies.

Three-part study to evaluate the safety, tolerability, pharmacokinetic (PK), and food effect in healthy volunteers is underway.

- Part 1 - single ascending dose - completed
  - 4 cohorts (6 drug and 2 placebo) - single dose (oral solution)
  - Reached the planned top dose, which approached preclinical exposure limits
  - Well tolerated with predictable PK
  - Most common adverse event was oral paresthesias from liquid formulation
- Part 2 - food effect – completed
  - 12 subjects - crossover with and without breakfast
  - Well tolerated with and without food
  - Effect of food on BMB-101 levels was relatively small, and therefore BMB-101 can be administered without the need for fasting.
- Part 3 - multiple ascending dose – cohort 1 complete
  - 4 cohorts (6 drug and 2 placebo) – twice a day dosing for 7 days after meals
  - Study (with results) completes in 2Q 2023

Good Manufacturing Practices (GMP) production completed for BMB-101 drug substance and drug product.

BMB-202:

- A highly selective 5-HT_{2A} agonist, lead candidate within psychedelic program
- Expected to enter first-in-human trial in late 2023
- Dose range finding study completed
- Ready for Good Laboratory Practice (GLP) toxicology program

Strengthened Leadership Team to Guide Development Organization

- Appointed Mark A. Smith M.D., Ph.D., as Chief Medical Officer. Dr. Smith is an experienced executive in CNS drug development and has directed more than 50 clinical trials across all stages of development. Dr. Smith brings an extensive background in psychiatry that will guide the clinical implementation of the Company's next generation 5-HT_{2A} agonists.
- Appointed Jan Torleif Pedersen, MSc PhD., as Chief Scientific Officer. Dr. Pedersen brings 25+ years of expertise in neuroscience research management and has a proven track record in major pharma drug discovery and development.
- Appointed David Weiner, MD, to its board of directors as a non-executive director. Dr. Weiner brings extensive experience in the discovery and clinical development of novel therapeutics for neurological, psychiatric and rare diseases.

Other Recent Developments

- Following the appointment of Dr. Weiner to the board of directors and audit committee, the Company has regained compliance with NASDAQ's independent director and audit committee requirement.
- The Company will attend the BIO-Europe Spring Conference to be held in Basel, Switzerland, March 20-22, 2023, and virtually, March 28-30, 2023.

About BMB-101

BMB-101, a 5-HT_{2C} selective and biased agonist, has demonstrated compelling activity in a host of *in vitro* and *in vivo* non-clinical tests. Compared to Lorcaserin, BMB-101 exhibits strong Gq signaling coupled with minimal beta-arrestin recruitment. Mechanistically, Serotonin (5-Hydroxytryptamine, 5-HT) is a monoamine neurotransmitter widely expressed in the central nervous system, and drugs modulating 5-HT have made a major impact in mental health disorders. Central 5-HT systems have long been associated with the control of ingestive behaviors and the modulation of the behavioral effects of psychostimulants, opioids, alcohol and nicotine. Results of clinical trials and animal studies indicate that 5-HT_{2C} receptor agonists may have therapeutic potential in the treatment of addiction by decreasing the intake of opioids as well as impulsive behavior that can escalate compulsive drug use.

5-HT_{2C} receptors are considered to be involved in epileptiform activity and its activation is thought to have anticonvulsant properties. In well-established and predictive animal models, BMB-101 demonstrated a significant reduction in both the number and intensity of epileptic seizures and is a promising candidate for the treatment of Dravet Syndrome and other forms of epilepsies. BMB-101 is currently being evaluated in a Phase I trial (NCT 05397041) designed to assess the compound's safety, tolerability, pharmacokinetics, and food effect in healthy volunteers.

About BMB-202

BMB-202 is a highly selective 5-HT_{2A} agonist with proprietary intellectual property. BMB-202 exhibits a more than 30-fold selectivity over 5-HT_{2C} and more than 500-fold selectivity over 5-HT_{2B}. BMB-202 has shown two-fold superior potency compared to psilocin in vitro. BMB-202 is a fast acting, short duration, C_{max} driven compound. We call these fast-on-fast-off compounds with anticipated patient discharge around two hours. BMB-202 exhibits excellent drug-like properties and brain penetrance and has demonstrated antidepressant drug profile *in vivo*. BMB-202 is the first clinical candidate from an extensive portfolio of selective 5-HT_{2A} and 5-$HT_{2A/2C}$ agonists inspired from natural compound scaffolds.

About Dravet Syndrome

Dravet syndrome is an epilepsy syndrome that begins in infancy or early childhood and can include a spectrum of symptoms ranging from mild to severe. Children with Dravet syndrome exhibit focal (confined to one area) or generalized (throughout the brain) convulsive seizures that start before 15 months of age (often before age one). These initial seizures are often prolonged and involve half of the body, with subsequent seizures that may switch to the other side of the body. These initial seizures are frequently associated with fever. Other seizure types emerge after 12 months of age and can be quite varied. Status epilepticus – a state of continuous seizure requiring emergency medical care – may occur frequently in these children, particularly in the first five years of life. Dravet syndrome affects an estimated 1:15,700 individuals in the U.S., or 0.0064% of the population[1]. Approximately 80-90% of those, or 1:20,900 individuals, have both an SCN1A mutation and a clinical diagnosis of DS. This represents an estimated 0.17% of all epilepsies. As an area of high, unmet medical need, there currently exist only three FDA-approved medications for the treatment of DS: (1) Fintepla® (fenfluramine), which has a black-box label; (2) Diacomit® (stiripentol) and (3) Epidolex® (cannabidiol).

About Bright Minds

Bright Minds is focused on developing novel transformative treatments for neuropsychiatric disorders, epilepsy, and pain. Bright Minds has a portfolio of next-generation serotonin agonists designed to target neurocircuit abnormalities that are responsible for difficult to treat disorders such as resistant epilepsy, treatment resistant depression, PTSD, and pain. The Company leverages its world-class scientific and drug development expertise to bring forward the next generation of safe and efficacious drugs. Bright Minds' drugs have been designed to potentially retain the powerful therapeutic aspects of psychedelic and other serotonergic compounds, while minimizing the side effects, thereby creating superior drugs to first-generation compounds, such as psilocybin.

Investor Contacts:
Lisa Wilson
E: lwilson@insitecony.com

T: 917-543-9932

Ian McDonald
CEO and Director
E: ian@brightmindsbio.com
T: 917-543-9932

This news release includes certain statements that may be deemed "forward-looking statements." All statements in this new release, other than statements of historical facts, that address events or developments that the Company expects to occur, are forward-looking statements. Forward-looking statements are statements that are not historical facts and are generally, but not always, identified by the words "expects," "plans," "anticipates," "believes," "intends," "estimates," "projects," "potential," and similar expressions, or that events or conditions "will," "would," "may," "could," or "should" occur. Forward-looking information in this news release includes statements related to BMB-101's potential use for treatments of refractory epilepsy, psychosis, addiction, and other indications, BMB's entry into human trials on the schedule contemplated or at all and the result of such trials, including the ability of BMB-202 to be utilized for treatment of depression or at all, and the Company's attendance at the BIO-Europe Spring Conference. Although the Company believes the expectations expressed in such forward -looking statements are based on reasonable assumptions, such statements are not guarantees of future performance and actual results may differ materially from those in the forward-looking statements. Factors that could cause the actual results to differ materially from those in forward-looking statements include market prices, continued availability of capital and financing, results of clinical trials with respect to each of BMB-101 and BMB-202, regulatory conditions with respect to in-human drug trials, and general economic, market or business conditions. Investors are cautioned that any such statements are not guarantees of future performance and actual results or developments may differ materially from those projected in the forward-looking statements. Forward-looking statements are based on the beliefs, estimates and opinions of the Company's management on the date the statements are made. Except as required by applicable securities laws, the Company undertakes no obligation to update these forward-looking statements in the event that management's beliefs, estimates or opinions, or other factors, should change.

Neither the Canadian Securities Exchange nor its Regulation Services Provider accepts responsibility for the adequacy or accuracy of this release.

---

[1] Wu, Yvonne W., et al. "Incidence of Dravet syndrome in a US population." Pediatrics 136.5 (2015): e1310-e1315.