Bright Minds Biosciences Announces Successful Completion of 28-Day Toxicology Studies and Advancement to First-in-Human Clinical Trial

VANCOUVER, British Columbia, March 14, 2022 -- Bright Minds Biosciences (“Bright Minds,” “BMB” or the “Company”) (Nasdaq: DRUG) (CSE: DRUG), a biotechnology company focused on developing novel drugs for the targeted treatment of neuropsychiatric disorders, epilepsy, and pain, today announced the successful completion of 28-day repeat-dose toxicity studies for its lead product, BMB-101. Importantly, there were no major toxicological findings after twice daily oral administration of BMB-101 throughout the study period. The studies were conducted by the Company’s contract research partner, ITR Laboratories Canada in Baie d’Urfé, Québec, Canada.

Dr. Revati Shreeniwas, Bright Minds’ Chief Medical Officer, stated, “Dravet Syndrome, a severe form of epilepsy characterized by frequent, prolonged seizures, is a terribly debilitating disease and, unfortunately, remains an area of high unmet medical need. We’re encouraged and hopeful that BMB-101 will provide a new and effective approach to its treatment. These data, generated in our 28-day toxicology studies, provide further support for advancing our clinical program,” concluded Dr. Shreeniwas.

Repeat-dose oral toxicity studies were conducted in mice and dogs. These Good Laboratory Practice (GLP) compliant studies found that BMB-101, at doses up to 40 and 30 mg/kg/day in mice and dogs, respectively, were well tolerated at all dose levels. These data provide new information on a lack of major toxic effects after 28 days, including a lack of any effect to target organs. A no-observed-adverse-effect level (NOAEL) was identified in both species, which will be used in selecting starting dose levels and for establishing safety criteria for human exposure.

“We are delighted to have completed this important milestone, which is pivotal for supporting our forthcoming first-in-human clinical trial, currently expected to begin in 2Q22,” said Ian McDonald, Bright Minds’ Chief Executive Officer. “We have now officially entered the clinical development stage for our lead product, BMB-101, which represents an exciting new chapter for the Company and, hopefully, therapeutic alternative for patients suffering from Dravet Syndrome.”

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 Locaserin, 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 behavior and the modulation of behavioral effects of psychostimulants, opioids, alcohol and nicotine. Over the past decade, the various 5-HT receptor subtypes have been cloned and characterized. Results of clinical trials and animal studies indicate that 5-HT_{2C} up 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.

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 initially show 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 provoked by exposure to increased temperatures or temperature changes, such as getting out of a bath. 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 (Wu 2015). 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.

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