Bright Minds Biosciences Initiates Dosing in Phase I Clinical Trial of BMB-101 for Dravet Syndrome

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VANCOUVER, British Columbia, Aug. 31, 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 that it has dosed the first patient in a Phase I trial (NCT 05397041) for its lead product, BMB-101, for the treatment of Dravet Syndrome and other medical indications. The Phase I 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-time in-human studies.

BMB-101, a next-generation, 5-HT_{2C} selective and biased agonist, exhibits compelling behavioral and preclinical pharmacology and safety data with the potential to be the best-in-class drug. In well established, predictive animal models, BMB-101 demonstrated a significant reduction in both the number and intensity of epileptic seizures.

"BMB-101 was designed with the aim of improving the safety profile relative to earlier medications in this class, and we are excited about the potential to deliver an improved therapeutic to address this rare and devastating disease. Based on the strength of BMB-101's preclinical data and encouraging scientific rationale of 5-HT_{2C} agonism in the treatment of Dravet Syndrome, we are enthusiastic to advance our lead product into clinical trials," stated Dr. Revati Shreeniwas, Chief Medical Officer of Bright Minds Biosciences.

The Phase I clinical trial is a three-part (single ascending dose, food effects, multiple ascending dose) randomized, placebo-controlled study of BMB-101 in approximately 76 healthy volunteers, that is being conducted in Australia. The trial aims to evaluate the safety, tolerability and other pharmacokinetics of BMB-101 for use in Phase II clinical trials.

"Dosing the initial subject in the first-in-human trial of BMB-101 is an exciting milestone for Bright Minds. After several years of discovery and early development of next-generation, best-in-class serotonergic investigational drugs, we are delighted to progress into human trials. We are hopeful that our efforts result in more efficacious and safer drugs for patients suffering from Dravet Syndrome, which remains an area of high unmet medical need," stated Ian McDonald, CEO and Co-founder of Bright Minds Biosciences.

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 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 (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 potentially superior drugs to first-generation compounds, such as psilocybin.

Forward-Looking Information and Additional Cautionary Language

This news release contains statements and information that, to the extent that they are not historical fact, may constitute "forward-looking information" within the meaning of applicable securities legislation. Forward-looking information may include financial and other projections, as well as statements regarding future plans, objectives or economic performance, or the assumption underlying any of the foregoing. Forward looking information in this news release contains information related to the Phase I clinical trial and the future therapeutic potential of BMB-101. This news release uses words such as "may," "would," "could," "likely," "expect," "anticipate," "believe," "intend," "plan," "forecast," "project," "estimate," "outlook," and other similar expressions to identify forward-looking information.

Forward-looking information involves significant risks, assumptions, uncertainties and other factors that may cause actual future results or anticipated events to differ materially from those expressed or implied in any forward-looking statements and accordingly, should not be read as guarantees of future performance or results. Assumptions used to develop the forward-looking information in this news release includes assumptions related to completion of the Phase I drug trial as intended by the Company, the continuation of all participants in the trial for the duration of the trial, and continued positive results in relation to BMB-101 as a medication, including in respect of its safety.

Actual results, performance or achievement could differ materially from that expressed in, or implied by, any forward-looking information in this news release and, accordingly, readers should not place undue reliance on any such forward-looking information. Further, any forward-looking statement speaks only as of the date on which such statement is made. New factors emerge from time to time, and it is not possible for management to predict all of such factors and to assess in advance the impact of each such factor on the Company's business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. The Company does not undertake any obligations to update any forward-looking information to reflect information, events, results, circumstances or otherwise after the date hereof or to reflect the occurrence of unanticipated events, except as required by law.

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