Bright Minds Biosciences and Firefly Neuroscience to Collaborate After the BREAKTHROUGH Study: A Phase 2 Trial of BMB-101 in Absence Epilepsy and Developmental Epileptic Encephalopathy for Full Analysis of EEG Data

NEW YORK AND VANCOUVER, October 21, 2024 – Bright Minds Biosciences Inc. (Bright Minds or the Company) (NASDAQ: DRUG), a biotechnology company focused on developing novel therapies for neurological and neuropsychiatric disorders, today announced that it is once again collaborating with Firefly Neuroscience, Inc. (Firefly) (NASDAQ: AIFF), an Artificial Intelligence (AI) company developing innovative solutions that improve brain health outcomes for patients with neurological and mental disorders, to provide a full analysis of the electroencephalogram (EEG) data in the Company's BREAKTHROUGH study, an open-label Phase 2 clinical trial evaluating the safety, tolerability, and efficacy of BMB-101, a highly selective 5-HT_{2C} receptor agonist, in adult patients with classic Absence Epilepsy and Developmental Epileptic Encephalopathy (DEE).

Bright Minds and Firefly have previously collaborated successfully to analyze the data of the Company's first-in-human Phase 1 study of BMB-101 using Firefly's advanced artificial intelligence, FDA-cleared BNA™ technology platform.

The BREAKTHROUGH study is designed as a basket clinical trial that will include patients diagnosed with either Absence Epilepsy (with or without Eyelid Myoclonia) or DEE. This group of disorders consists of a range of rare epilepsy disorders, including Epilepsy with Eyelid Myoclonia (known as Jeavons Syndrome). These conditions are characterized by refractory seizures that are often resistant to current treatments. The BREAKTHROUGH study is targeting enrollment of 20 adult participants aged from 18 to 65 years old.

"After successful use of the BNA platform to analyze the data from our Phase 1 study, we look forward to once again collaborating with the Firefly team at the conclusion of our Phase 2 program for our lead compound, BMB-101, to provide valuable insights into the EEG recordings during the study," said Ian McDonald, Chief Executive Officer of Bright Minds Biosciences. "We believe BMB-101 has the potential to be a best-in-class 5-HT_{2C} agonist. This compound is not only poised to make a significant impact in both the DEE and Absence Epilepsy communities, but also has broad applicability across the 30% of all epilepsy patients who experience drug resistance."

About BMB-101

BMB-101 is a novel scaffold 5-HT_{2C} Gq-protein biased agonist developed using structure-based drug design. It was explicitly designed for chronic treatment of neurological disorders where tolerance and drug resistance are common issues. Biased agonism at the 5-HT_{2C} receptor is one of its key features and adds another layer of functional selectivity within a well-validated target. BMB-101 works exclusively via the Gq-protein signaling pathway and avoids beta-arrest in activation, which is crucial to minimize the risk of receptor desensitization and tolerance development. This provides a novel mechanism, anti-epileptic drug designed to provide sustained seizure relief in hard-to-treat patient populations. In preclinical studies, BMB-101 has demonstrated efficacy in animal models of Dravet Syndrome and numerous models of generalized seizures.

In Phase 1 clinical studies, BMB-101 was given to 64 healthy volunteers in a Single Ascending Dose (SAD), Multiple Ascending Dose (MAD) and food-effects study. BMB-101 was demonstrated to be safe and well tolerated at all doses. No Serious Adverse Events (SAEs) were observed, and Adverse Events (AEs) were mild in nature and in line with on-target effects for serotonergic drugs.

An extensive target-engagement study was conducted using both fluid biomarkers (transient prolactin release) and physical biomarkers (Quantitative Electroencephalogram, qEEG). Both methods confirmed robust central target engagement. A qEEG signature typical for anti-epileptic drugs was observed, with a selective depression of EEG power at frequencies observed during epileptic seizures. Furthermore, a potentiation of frontal gamma-power was observed in this study which could indicate the potential for improved cognition.

About Bright Minds Biosciences

Bright Minds Biosciences is a biotechnology company developing innovative treatments for patients with neurological and psychiatric disorders. Our pipeline includes novel compounds targeting key receptors in the brain to address conditions with high unmet medical need, including epilepsy, depression, and other CNS disorders. Bright Minds is focused on delivering breakthrough therapies that can transform patients' lives.

Bright Minds Biosciences has developed a unique platform of highly selective serotonergic agonists exhibiting selectivity at different serotonergic receptors. This has provided a rich portfolio of NCE programs within neurology and psychiatry.

About Firefly
Firefly (NASDAQ: AIFF) is an Artificial Intelligence ("AI") company developing innovative solutions that improve brain health outcomes for patients with neurological and mental disorders. Firefly's FDA-510(k) cleared Brain Network Analytics (BNA™) technology revolutionizes diagnostic and treatment monitoring methods for conditions such as depression, dementia, anxiety disorders, concussions, and ADHD. Over the past 15 years, Firefly has built a comprehensive database of brain wave tests, securing patent protection, and achieving FDA clearance. The Company is now launching BNA™ commercially, targeting pharmaceutical companies engaged in drug research and clinical trials, as well as medical practitioners for clinical use.

Brain Network Analytics was developed using artificial intelligence and machine learning on Firefly's extensive proprietary database of standardized, high-definition longitudinal electroencephalograms (EEGs) of over 17,000 patients representing twelve disorders, as well as clinically normal patients. BNA™, in conjunction with an FDA-cleared EEG system, can provide clinicians with comprehensive insights into brain function. These insights can enhance a clinician's ability to accurately diagnose mental and cognitive disorders and to evaluate what therapy and/or drug is best suited to optimize a patient's outcome.

Please visit https://fireflyneuro.com/ for more information.

Forward-Looking Statements
This news release contains "forward-looking information". Often, but not always, forward-looking statements can be identified by the use of words such as "plans", "expects", "is expected", "budget", "scheduled", "estimates", "forecasts", "intends", "anticipates", or "believes" or variations (including negative variations) of such words and phrases, or state that certain actions, events or results "may", "could", "would", "might" or "will" be taken, occur or be achieved. Forward-looking statements in this news release include design, progress, and completion of the BREAKTHROUGH*Study, future clinical development of BMB-101, and future intended use or therapeutic benefit of BMB-101 to treat refractory epilepsy disorders. A variety of factors, including known and unknown risks, many of which are beyond our control, could cause actual results to differ materially from the forward-looking information in this news release. These factors include the company's financial position and operational runway, regulatory risk to operating in the pharmaceutical industry, and inaccuracies related to the assumption made by management relating to general availability of resources required to operate the studies noted in this news release. Additional risk factors can also be found in the Company's public filings under the Company's SEDAR+ profile at www.sedarplus.ca. Forward-looking statements contained herein are made as of the date of this news release and the Company disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or results or otherwise. There can be no assurance that forward-looking statements will prove to be accurate, as actual results and future events could differ materially from those anticipated in such statements. The Company undertakes no obligation to update forward-looking statements if circumstances, management's estimates or opinions should change, except as required by securities legislation. Accordingly, the reader is cautioned not to place undue reliance on forward-looking statements.*

The Canadian Securities Exchange has neither approved nor disapproved the information contained herein and does not accept responsibility for the adequacy or accuracy of this news release.

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