Bright Minds Biosciences Provides Update About Planned Study with BMB-101 in Developmental and Epileptic Encephalopathies

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NEW YORK, Nov. 02, 2026 (GLOBE NEWSWIRE) -- **Bright Minds Biosciences Inc. (CSE: DRUG) (NASDAQ: DRUG)** (“**Bright Minds**” or the “ **Company**”) announces that the U.S. Food and Drug Administration (“ **FDA**”) has notified the Company via email that its investigational new drug application (“**IND**”) for Developmental and Epileptic Encephalopathies (“ **DEEs**”) and related Protocol BMB-101-105 has been placed on a partial clinical hold following the FDA’s review.

The proposed trial related to this IND is a randomized, placebo-controlled, double-blind Phase 2 study designed to evaluate the efficacy and safety of ascending doses of BMB-101, up to a maximum tolerated dose, for the treatment of seizures associated with DEEs.

The Company believes that the partial clinical hold covers only the planned Phase 2 trial of BMB-101 in DEE in the United States, and the partial clinical hold does not affect the Company’s other ongoing clinical trials.

The primary reason given by the FDA relates to identified toxicity in mice, and inadequate pharmacokinetic and juvenile toxicity data to support the proposed pediatric enrollment.

The Company believes that the FDA’s observation of toxicity in mice was not seen in any other species. The Company further believes, based on its toxicity reports, peer reviewers, and multiple independent toxicology expert opinions, that the adverse mouse findings were incidental and not drug-related. These are the Company’s beliefs and should not be understood as the FDA findings or as resolving the FDA’s stated concerns.

The Company is awaiting the FDA’s full Partial Clinical Hold Letter. The FDA stated that it would provide the letter within 30 days, including additional details, non-hold recommendations, and study-design recommendations.

Bright Minds intends to immediately request further clarification from the FDA. The Company plans to review the FDA’s Partial Clinical Hold Letter and refine the study in accordance with the FDA’s recommendations with the objective of addressing the identified issues and advancing future U.S. clinical trials. Additional data or studies may be required, and there can be no assurance as to when or whether the partial clinical hold will be lifted or future U.S. trials will be permitted to proceed.

About BMB-101

BMB has completed two clinical trials with BMB-101. To date approximately 90 subjects have received BMB-101 across all the Company’s clinical programs.

Phase 1: In a placebo-controlled single-ascending-dose, multiple-ascending-dose and food-effect studies conducted in 64 healthy volunteers, BMB-101 was well tolerated at all doses tested. There were no serious adverse events, and adverse events were mild and consistent with on-target serotonergic effects. There were no drug-related serious adverse events.

On January 6, 2026, the Company announced the topline data from its Phase 2 BREAKTHROUGH trial. In 24 adults with drug-resistant absence seizures or DEE, most of whom were taking three to five other anti-seizure medications, 79.6% of treatment-emergent adverse events were mild and 17.2% were moderate. No drug-related serious adverse events occurred. Six DEE patients completed the main study treatment with median reduction of motor seizures of 63.3%. All five DEE patients who entered the open label extension remain on therapy with BMB-101.

About Bright Minds

Bright Minds 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 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.

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Forward Looking Information

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, without limitation statements concerning the anticipated scope of the partial clinical hold and its expected impact on the Company's other ongoing clinical trials; receipt and timing of the FDA's full Partial Clinical Hold Letter, the Company's intended response and study refinements, potential additional data or studies, whether or when the partial clinical hold may be lifted or future U.S. trials may be permitted to proceed, and the advancement and timing of future U.S. clinical trials. Such statements represent the Company's current views with respect to future events and are necessarily based upon a number of assumptions and estimates that, while considered reasonable by the Company, are inherently subject to significant business, economic, competitive, political and social risks, contingencies and uncertainties. Many factors, both known and unknown, could cause results, performance, or achievements to be materially different from the results, performance or achievements that are or may be expressed or implied by such forward-looking statements. Material assumptions include that further FDA communications will be consistent with the Company's current understanding of the scope of the partial clinical hold and its impact on other ongoing clinical trials, that the FDA will provide further feedback as indicated, that an acceptable regulatory path can be identified, and that the Company can obtain the data, funding and other resources necessary to implement any required changes. Actual outcomes may differ materially because of differences between the Company's current understanding and the FDA's further communications regarding the scope or impact of the partial clinical hold, the FDA's assessment of mouse toxicity and pediatric data, additional regulatory requirements, adverse nonclinical or clinical findings, delays in generating data or revising the study, insufficient funding or resources, and the possibility that the partial clinical hold will not be lifted. 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, except as required by applicable securities legislation. 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. 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.