



# Bright Minds Biosciences Announces Positive Topline Results from Phase 2 Clinical Trial of BMB-101 in Patients with Absence Seizures and Developmental and Encephalopathic Epilepsies (DEE)

January 6, 2026

- BMB-101 demonstrated significant anti-seizure benefit in both cohorts with favorable safety and tolerability
  - Absence: 73.1% median reduction in the number of absence seizure  $\geq 3s$ ,  $p = 0.012$
  - DEE: 63.3% median reduction in major motor seizures
- REM sleep improvement in patients with Absence Seizures: mean 90% increase in REM sleep with no change in total sleep duration
- Company has initiated preparations for global registrational trials in both DEE and Absence Seizure patients
- Bright Minds to hold conference call and live webcast at 8AM ET today

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NEW YORK, Jan. 06, 2026 (GLOBE NEWSWIRE) -- Bright Minds Biosciences Inc. (CSE: DRUG) (Nasdaq: DRUG) ("Bright Minds" or the "Company"), a clinical-stage biotechnology company focused on developing highly selective 5-HT receptor agonists for neurological and psychiatric disorders, today announced positive and significant topline results from its Phase 2 BREAKTHROUGH clinical trial evaluating BMB-101, a selective 5-HT<sub>2C</sub> biased agonist, in adult patients with drug-resistant Absence Seizures and Developmental and Encephalopathic Epilepsies. The study met its primary efficacy endpoints in both cohorts, demonstrating robust seizure reduction with a favorable safety and tolerability profile.

## Phase 2 BREAKTHROUGH Study Overview

The Phase 2 open-label, multicenter study evaluated safety, tolerability and efficacy of BMB-101 in adults with drug-resistant Absence Seizures and DEE. A total of 24 patients were enrolled, exceeding the original target of 20. The study included a 4-week baseline, 4-week titration and maintenance period (2 weeks for Absence cohort, 4 weeks for DEE cohort).

### Primary Endpoints:

- Absence cohort: change from baseline in the number of Absence Seizures (lasting  $\geq 3s$ ) on 24h EEG, conducted by independent and blinded reviewers
- DEE cohort: change from baseline in major motor seizure frequency (seizure diary)

### Patient Profile

The study enrolled 24 patients (15 with Absence Seizures and 9 with DEE), with a mean age of 30 years. Participants were receiving a median of 3 concomitant anti-seizure treatments in the Absence cohort and 5 in the DEE cohort, having previously failed up to 16 treatments (with a failed mean of 3.7 antiseizure treatments for the Absence cohort, and a failed mean of 9.8 for antiseizure treatments for the DEE cohort). The population also included patients treated with neuromodulation: 2 with Vagus Nerve Stimulators (VNS) in the Absence cohort and 5 in the DEE cohort. At baseline, the median number of Absence Seizures  $\geq 3s$  was 22, and similarly, the median number of countable motor seizures for the DEE cohort was 22.

### Patient Disposition

A total of 24 patients were enrolled (Absence cohort:  $n=15$ ; DEE cohort:  $n=9$ ).

Absence cohort: 12/15 patients completed the maintenance period. Three patients discontinued during titration/early treatment. Reasons reported across discontinuations included taste intolerance (related; drug product formulation subsequently updated), flu-like symptoms with muscle ache/fatigue (possibly related), dizziness (possibly related) and with insufficient baseline seizure counts.

The prespecified efficacy-evaluable population comprised of 11 patients (including one DEE patient with atypical Absence Seizures) with analyzable paired baseline and maintenance 24-hour ambulatory EEG recordings. One enrolled patient was excluded from the efficacy analysis because the baseline EEG did not meet entry criteria, and one maintenance EEG was of

insufficient quality for reliable analysis.

DEE cohort: 6/9 patients completed the maintenance period. Three patients discontinued during titration/early treatment. Reasons reported across discontinuations included fluctuation in a pre-existing behavioral condition, lethargy (possibly related) and an intercurrent shoulder fracture with associated drowsiness/opiate use (not drug-related). The prespecified efficacy-evaluable population comprised of 6 patients. The DEE cohort included 4 Lennox-Gastaut Syndrome (LGS) patients, 1 Dravet syndrome and 1 Rett syndrome patient.

## **Efficacy Results**

### **Absence seizure Cohort (n=11):**

- 73.1% median reduction in the number of absence seizure  $\geq 3$ s.  $p = 0.012$  (Wilcoxon Signed Rank Test)
- 74.4% median reduction in total time in seizures lasting  $\geq 3$ s during 24h (Seizure Burden).  $p = 0.012$  (Wilcoxon Signed Rank Test)
- Patients achieved robust reduction of Absence Seizures regardless of seizure duration.

### **DEE Cohort (n=6):**

- Cohort included 4 LGS patients, 1 Dravet Syndrome (who previously failed fenfluramine for efficacy), and 1 Rett Syndrome patient
- 63.3% median reduction in major motor seizures
- 60.3 % median reduction in LGS patients, and 76.1% in other DEE patients
- Last observation carried forward applied to two patients.

## **Safety & Tolerability**

BMB-101 was generally well tolerated. Most treatment-emergent adverse events were mild (79.6%) or moderate (17.2%), with no treatment-related serious adverse events. Most common AEs ( $\geq 10\%$ ): respiratory infections (20.8%), fatigue (16.7%), constipation (16.7%), headache (12.5%), drowsiness (12.5%). There were three severe adverse events, including dry mouth (transient, no dose change, no discontinuation), and one patient who had fractured shoulder and opiate-related drowsiness (not related).

## **Additional Effects beyond Seizure Control**

The study explored the effects of BMB-101 on sleep. There was a 90% increase in REM sleep (56.2 min at baseline to 106.7 min on BMB-101) in patients, while overall sleep duration remained unchanged (9.1 h at baseline vs 8.9 h on BMB-101). This is crucial since REM sleep increase was not due to increased sleep duration. REM sleep is important for memory consolidation, emotional-behavior regulation and cognitive function.

## **Next Steps**

Bright Minds Biosciences has initiated preparations for global registrational trials in Absence Seizures and DEE. Additional data including long-term outcomes will be presented throughout the year. Bright Minds Biosciences will also be initiating a study in Prader Willi Syndrome, currently anticipated to begin in Q1 2026 ("PWS Program").

## **Conference Call/Webcast Information**

The Bright Minds virtual event will be webcast live by visiting the "Investors" section of the Company's website and selecting "Events and Presentations."

A replay of the webcast will not be available after the event.

**Date and Time:** January 6, 2026, 8AM ET

**Webcast:** <https://app.livestorm.co/bright-minds-biosciences/bmb-101-topline-data-announcement>

The call will include a discussion of the data followed by a Q&A session. Individuals who wish to ask questions should use the "Questions" tab available during the live webcast.

## **About BMB-101**

BMB-101 is a novel scaffold 5-HT<sub>2C</sub> 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<sub>2C</sub> 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-arrestin activation, which is crucial to minimize the risk of receptor desensitization and tolerance development.

In preclinical studies, BMB-101 has demonstrated efficacy in animal models of epilepsy, binge eating, aggression, substance use disorder, and cognitive decline which highlights its potential for the use in multiple neurological and neuropsychiatric disorders, including drug-resistant epilepsy, Prader-Willi Syndrome (PWS) and others.

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 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, PWS, 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.

### **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.

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 statements related to the impact of results of the Company's Phase 2 BREAKTHROUGH clinical trial evaluating BMB-101, the Company's preparations for global registrational trials in Absence Seizures and DEE in 2026, the initiation of the PWS Program in Q1 2026, and the future clinical development of BMB-101. 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. The Company also cautions that the data related to BMB-101 efficacy, safety and tolerability with regard to Phase 2 trials of BMB-101 are preliminary in nature, and may be subject to change with additional analysis and following the completion of audit and verification procedures. Additional risk factors can also be found in the Company's public filings under the Company's SEDAR+ profile at [www.sedarplus.ca](http://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.

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