Bright Minds Biosciences Initiates New Prader-Willi Syndrome (PWS) Program; KOL Event Scheduled for November 6TH

November 6, 2025

-- Company will host a webcast at 10am ET on November 6, 2025, to discuss its Phase 2a study to assess efficacy, safety and tolerability of BMB-101 (NOVA Study) for the treatment of patients with Prader-Willi Syndrome --
-- Key Opinion Leaders (KOLs) participating on the call will include Theresa V. Strong, PhD., Jennifer L. Miller, MD, and Elizabeth Roof, H.S.P., M.A. --
-- Strong pre-clinical and clinical rationale supports potential of BMB 5-HT_{2C} agonists to be the first on-target mechanism addressing both neuropsychiatric symptoms and hyperphagia --

NEW YORK and VANCOUVER, British Columbia, Nov. 06, 2025 (GLOBE NEWSWIRE) -- Bright Minds Biosciences Inc. (CSE: DRUG) (NASDAQ: DRUG) ("**Bright Minds**" or the " **Company**") today announced the initiation of its Prader-Willi Syndrome (PWS) program, and nomination of BMB-105 as a new clinical candidate. As part of the development program, Bright Minds will commence:

- A Phase 2a (NOVA) study to assess the efficacy, safety and tolerability of BMB-101 for the treatment of patients with PWS. This study is designed as a proof-of-pharmacology study to demonstrate that 5-HT_{2C} agonism will address symptom complex in PWS patients.

- A randomized Phase 1 placebo-controlled study to evaluate the safety, tolerability, pharmacokinetics and food effect of BMB-105 in healthy volunteers.

Following completion of the ongoing Phase 2a proof-of-pharmacology study with BMB-101, Bright Minds plans to select and advance a 5-HT_{2C} molecule (BMB-105) as the dedicated compound for the PWS program. This approach will reduce the time to market by approximately one year.

Operational Update for BMB-101 in Absence Seizures (AS) and Developmental and Epileptic Encephalopathies (DEE)

- To date, BMB-101 has been well tolerated, with no drug-related Serious Adverse Events nor any safety signals requiring any protocol adjustments.

- Exposure levels and tolerability achieved are consistent with expectations from Phase 1 study, supporting dose selection for future studies.

- Participation in the open-label extension is proceeding well, with nearly all eligible patients electing to remain on therapy under investigator supervision.

- Top-line data will be released in early January 2026

- The Company is planning a Ph 2/3 in AS and DEE in 2026.

"The initiation of our PWS program and NOVA clinical study are exciting next steps as we continue our development efforts to serve patients with rare diseases," said Ian McDonald, CEO and Co-founder of Bright Minds Biosciences. "The current therapeutic landscape is inadequate. 5-HT_{2C} agonism offers a novel mechanism for PWS by targeting the underlying aspects of the disease. This proof-of-pharmacology clinical study is designed to evaluate BMB-101's utility in addressing both hyperphagia and the behavioral/neuropsychiatric symptoms of PWS. We believe it will pave the way forward for a pivotal study with BMB-105, our dedicated compound, and expedite the development of the drug that aims at directly targeting the pathophysiology of PWS. As we continue to develop our pipeline and extensive portfolio of next-generation serotonergic agents, we believe that our 5-HT_{2C} selective agonists provide a unique approach with the potential to deliver a novel and effective treatment option that PWS patients and their families desperately need."

"We are pleased to host world-renowned experts on PWS who share our passion for discovering improved treatments for this complex and challenging neurodevelopmental disorder," concluded McDonald.

The KOLs will provide an overview of PWS, the unmet medical need and limitations of current treatments, the quality-of-life challenges for patients and their families, and the clinical assessment tools used in drug development.

Invited speakers include:

Dr. Jennifer Miller is a professor in the division of Pediatric Endocrinology at University of Florida. She received her medical degree from the University of Florida in 1998, and an M.S. in Clinical Investigation from the University of Florida in 2005. Dr. Miller specializes in the care and treatment of individuals with Prader-Willi syndrome and other genetic causes of early-onset excessive weight gain. Her research focuses on investigation of the etiology and possible treatment for obesity and metabolic abnormalities in individuals with PWS and early-onset obesity. For the past 12 years, Dr. Miller's work has focused on achieving an appropriate treatment for hyperphagia. She currently follows more than 500 patients with PWS from around the world, and over 100 patients with early-onset obesity due to other genetic causes. She is working on clinical treatment trials to treat hyperphagia in individuals with PWS and early-onset obesity.

Theresa V. Strong, Ph.D., received a B.S. from Rutgers University and a Ph.D. in Medical Genetics from the University of Alabama at Birmingham (UAB). After postdoctoral studies with Dr. Francis Collins at the University of Michigan, she joined the UAB faculty, leading a research lab focused on gene therapy for cancer and directing UAB's Vector Production Facility. Theresa is one of the founding members of the Foundation for Prader Willi Research (FPWR) and has directed FPWR's grant program since its inception. In 2016, she transitioned to a full-time position as Director of Research Programs at FPWR. She remains an Adjunct Professor in the Department of Genetics at UAB. She and her husband Jim have four children, including a son with PWS.

Elizabeth Roof, H.S.P., M.A., Senior Research Specialist, Research Lab Director, has worked with children and teens with PWS for almost 30 years at Vanderbilt University. Ms. Roof has been licensed since 1994 as a Health Service Provider in Psychology in the state of Tennessee and has been conducting research with Elisabeth Dykens since 2003, focused on the psychiatric, behavioral and adaptive strengths in PWS and WS. Ms. Roof has personally evaluated over 450 individuals with PWS and WS. She has trained 27 research staff over the years, who take that expertise with them to graduate, medical, and nursing school, and out into the real world. Ms. Roof also works with residential and clinical professionals and schools to provide best practices for those living with PWS and WS. She has managed five NIH trials and 11 clinical trials in PWS since 2014 and works with sponsors to identify best outcome measures, study designs, and logistics that best suit PWS families. Ms. Roof has spoken at PWS and WS conferences across the US, Canada, Europe, and Australia.

Members of Bright Minds' leadership team will provide an update and status of the ongoing clinical study in epilepsy. The team will also review the therapeutic rationale for the proprietary 5-HT_{2C} agonists in PWS and discuss the Company's study to assess efficacy, safety and tolerability of BMB-101 for the treatment of patients with PWS. Attendees will have the opportunity to ask questions at the conclusion of the program.

Webcast Information

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

Date & Time:	November 6, 2025, 10 am ET
Webcast Access:	https://app.livestorm.co/bright-minds-biosciences/announcement-of-pws-program

NOVA Clinical Study Design

The NOVA clinical study is a double-blind, randomized, Phase 2a study lasting up to 16 weeks. There will be a 4-week screening period, during which hyperphagia and PWS-related behavioral testing will establish the presence and degree of PWS symptoms. Following the screening period, participants will be randomized in a 1:1 ratio to either BMB-101 or placebo. Participants will enter into a weekly ascending Maximum Tolerated Dose (MTD) titration phase of 4 weeks followed by a maintenance phase of 8 weeks. There will be 5 clinic visits and 4 telephone visits. Following completion of the maintenance phase, participants at the discretion of the Investigator may elect to continue into an unblinded, open label phase to receive BMB-101 for up to 9 months (extendable beyond that time). Participants who do not elect to continue into the open label phase will be tapered from assigned study treatment over 4 weeks following completion of the maintenance phase.

- Primary Objective:
  - To assess the effect of BMB-101 on hyperphagia-related behaviors in patients with PWS.
- Secondary Objectives:
  - To assess the effect of BMB-101 on various associated behavioral disorders in PWS.
  - To assess the safety and tolerability of BMB-101 in patients with PWS.

- Primary Endpoint:
    - Hyperphagia. Change from Baseline in Hyperphagia Questionnaire for clinical trials (HQ-CT) scores over time.
- Secondary Endpoints:
    - Hyperphagia. Change from baseline in hyperphagia severity score as measured by the Caregiver Global Impression of Severity (CaGI-S) 7-point scale over time.
    - Hyperphagia. Change from baseline in hyperphagia severity score as measured by the Clinician Global Impression of Severity (CGI-S) 7-point scale over time.
    - Global Impression. Change from baseline in severity and improvement of PWS disease scores as measured by the Clinician Global Impression of Severity and Improvement (CGI-S and CGI-I) 7-point scale over time.
    - Behaviors. Change from baseline in PWS-associated behavioral issues such as symptoms measured by the PWS Profile over time.

About Prader-Willi Syndrome

Prader-Willi syndrome (PWS) is a rare genetic neurodevelopmental disorder resulting from abnormal gene expression on chromosome 15. According to the Prader-Willi Syndrome Association USA, the condition affects approximately one in every 15,000 live births. The hallmark feature of PWS is hyperphagia – a chronic, life-threatening condition marked by an unrelenting feeling of hunger, obsessive thoughts about food, an overwhelming drive to eat, and a lack of normal satiety. These symptoms can profoundly affect daily life, placing significant emotional and physical burdens on individuals with PWS and their families. Hyperphagia is associated with serious health risks, including acute complications such as stomach rupture, choking, and accidental death related to food-seeking behaviors, as well as long-term comorbidities such as obesity, type 2 diabetes, and cardiovascular disease.

Individuals with PWS also experience significant neurobehavioral challenges, including emotional dysregulation, compulsivity, temper outbursts, and cognitive impairment, which further impact daily functioning and quality of life. There are no drugs that can adequately address those issues

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-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, 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.

BMB-101 is currently being evaluated in a Phase 2a study in patients suffering from Developmental and Epileptic Encephalopathies and Absence Seizures.

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, 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 initiation of the PWS program, the selection and advancement of a 5-HT_{2C} molecule (BMB-105) as the dedicated compound for the PWS program, the initiation of the NOVA clinical study, and the Company’s plans for a Ph 2/3 in DEE and Ph 2/3 in 2026. 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.

Contact Information

Alex Vasilkevich
Chief Operating Officer
Bright Minds Biosciences Inc.
T: 414-731-6422
E: alex@brightmindsbio.com
Website: www.brightmindsbio.com

Investor Relations

Lisa M. Wilson
T: 212-452-2793
E: lwilson@insitecony.com