



## Bright Minds Biosciences Provides Scientific Update

**Lead program, BMB-101, advances to IND-enabling toxicology studies with the aim of commencing human trials in 1H 2022**

VANCOUVER, British Columbia, Sept. 22, 2021 (GLOBE NEWSWIRE) -- Bright Minds Biosciences ("Bright Minds," "BMB" or the "Company") (CSE: DRUG) (OTCQB: BMBIF), a biotechnology company focused on developing novel drugs for targeted treatment of neuropsychiatric disorders, epilepsy and pain, today provided an update of significant scientific developments.

Bright Minds is focused on advancing its promising lineup of best-in-class serotonergic ("5-HT") drug candidates that target the 5-HT<sub>2C</sub>, 5-HT<sub>2A/C</sub>, and 5-HT<sub>2A</sub> receptors, eliminating the toxicity associated with 5-HT<sub>2B</sub>. Leveraging the extensive drug discovery experience of the Bright Minds team, the Company aims to use its proprietary next-generation serotonin agonists to target abnormalities in neurocircuitry that lead to dysfunctional behaviors, while providing improved efficacy, safety and tolerability.

### Recent Scientific Developments:

- Established collaborative agreements with the National Institutes of Health for two programs: (1) preclinical screening program for chronic pain indications; and (2) the treatment of epilepsy.
- Expanded scientific and leadership capabilities with the additions of Dr. Emer Leahy to the Board of Directors; Krista Lanctot, Ph.D., to the Company's Scientific Advisory team; Jianmin Duan, Ph.D., as Vice President of Pharmacology; and Thomas Grizzle, as Vice President of Toxicology.

"Over the past few months, we have dramatically improved BMB's competitive position with our therapeutic categories, as well as our broader capital markets strategy," stated Ian McDonald, CEO of Bright Minds. Mr. McDonald continued, "With regard to our R&D developments, we continue to make significant progress in advancing our pipeline of novel transformative psychedelic drug candidates that improve on existing compounds and address significant unmet clinical needs in mental health, impulsivity and central nervous system disorders. Our compounds are in the late preclinical stage and have demonstrated compelling data in well-accepted animal models for Dravet syndrome, a rare childhood form of epilepsy, opioid withdrawal, binge eating disorder, and Alzheimer's disease psychosis. Looking ahead, we plan to initiate our first-in-human trial of BMB-101 early next year to investigate the possible use of this novel, patented drug to treat Dravet Syndrome."

### Pipeline Update

- **5-HT<sub>2C</sub> Program for the Treatment of Dravet Syndrome and Selected Behavioral Disorders:**
  - Selected BMB-101, a novel, well-characterized highly selective compound with high 5-HT<sub>2C</sub> agonist potency and receptor subtype selectivity versus 5-HT<sub>2A</sub> and 5-HT<sub>2B</sub> as lead 5-HT<sub>2C</sub> clinical pipeline drug candidate. BMB-101 is a New Chemical Entity ("NCE") with exceptionally strong intellectual property protection, which we believe differentiates its overall competitive position. This compound and its analogues were first invented by Bright Minds' Chief Scientific Officer, Dr. Alan Kozikowski and Dr. Jianjun Cheng at the University of Illinois in Chicago.
  - Identified Dravet Syndrome as lead indication for BMB-101. The Company demonstrated compelling efficacy signals with BMB-101 in well-established zebrafish models, with lower seizure duration and frequency.
  - Advanced Investigational New Drug ("IND") enabling safety and toxicology studies, which bolster our confidence in commencing human trials in 1H 2022.
  - Identified other indications for BMB-101, which include Opioid Use Disorder and Binge Eating Disorder:
    - Preclinical studies of BMB-101 established efficacy in validated rat models for the treatment of opioid use disorder. These studies were conducted in collaboration with expert research laboratory of Professor Kathy Cunningham at the University of Texas Medical Branch, Galveston.
- Additional animal models demonstrated a clear dose response, as well as a reduction in binge eating episodes in rats of 50%.
- The Company commenced the manufacture of high purity cGMP API, which will satisfy our requirements for our forthcoming clinical studies.

- Currently, the Phase I studies are slated to begin in 1H 2022; Phase IIa targeted for 2H 2022.
- **5-HT<sub>2A</sub> Program for Treatment of Depression and other Neuropsychiatric Disorders:**
  - The Company's 5HT<sub>2A</sub> program is currently screening several potential drug candidates as improved next-generation psychedelics, with the goal of expanding therapeutic scope and market potential versus psilocybin and other first-generation psychedelic drugs in the treatment of depression and other mental health disorders.
  - The Company is conducting *in vitro* and *in vivo* assays in collaboration with the well-known academic laboratories of Professor John McCorvy of the Medical College of Wisconsin and Professor Adam Halberstadt of the University of California, San Diego.
  - Novel drug compound discovery and optimization efforts are under way. Structure activity relationships ("SAR") and lead compounds identified, with drug discovery and optimization program accelerated with medicinal chemist expansion to 22 full-time equivalents. Clinical trials are targeted for 2H 2022.
- **5-HT<sub>2A</sub> + 5-HT<sub>2C</sub> Mixed Agonist Profile:**
  - The Company's novel 5-HT<sub>2A</sub> + 5-HT<sub>2C</sub> compound is in early preclinical development for several chronic pain disorders/neuropathic pain syndromes, including cluster headaches and chemotherapy-induced peripheral neuropathy.

## Other Events

Bright Minds Biosciences Inc. (the "Company") has engaged In-Site Communications Inc. ("In-Site"), previous service provider of the Company, for a 12-month term ending on March 30, 2022. Pursuant to the terms of the services agreement with "In-Site", In-Site had provided services from January 4, 2021, and had extended the term of the services agreement such that it will now be providing services until March 31, 2022. The 12-month term will be compensated in cash for an aggregate of US\$216,000. The Services consist of communications materials development (e.g. press releases, earnings call scripts, investor slide presentation), institutional outreach and investor marketing activities, and overall messaging and positioning of Bright Minds, and do not occur on any web platform. The service provider, on behalf of In-Site, is Lisa Wilson, an arm's length third party to the Company, and may be contacted at the information provided at the bottom of this release. The Company plans to issue In-Site 8,807 options (the "Options") to acquire common shares in the capital of the Company at an exercise price of \$7.64 per option for a period of three years. 25% of the Options will vest every three months from the distribution date, being September 21, 2021.

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

## Forward Looking Statements

This news release contains forward-looking statements, including statements regarding the scientific findings of Company's drug development program, and other statements that are not historical facts. Forward-looking statements are often identified by terms such as "will", "may", "should", "anticipate", "expects" and similar expressions. All statements other than statements of historical fact included in this release are forward-looking statements that involve risks and uncertainties. There can be no assurance that such statements will prove to be accurate and actual results and future events could differ materially from those anticipated in such statements.

The reader is cautioned that assumptions used in the preparation of any forward-looking information may prove to be incorrect. Events or circumstances may cause actual results to differ materially from those predicted, as a result of numerous known and unknown risks, uncertainties, and other factors, many of which are beyond the control of the Company, and which are described in the Company's public filings available under its profile at [www.sedar.com](http://www.sedar.com). The reader is cautioned not to place undue reliance on any forward-looking information. Such information, although considered reasonable by management at the time of preparation, may prove to be incorrect and actual results may differ materially from those anticipated. Forward-looking statements contained in this news release are expressly qualified by this cautionary statement. The forward-looking statements contained in this news release are made as of the date of this news release and the Company does not intend to update any of the included forward-looking statements except as required by Canadian securities laws.

## Investor Contact:

Judy DiClemente  
 E: [jdiclemente@insitecony.com](mailto:jdiclemente@insitecony.com)  
 T: (212) 452-2793

Lisa Wilson  
 E: [lwilson@insitecony.com](mailto:lwilson@insitecony.com)

T: (917) 543-9932