



## **Biomind Labs Doses First Subject in Phase I/IIa Clinical Trial of Its DMT-Based Inhaled Formulation BMND01 for Treatment-Resistant Depression**

April 26, 2022 08:38 AM Eastern Daylight Time

TORONTO--(BUSINESS WIRE)--Biomind Labs Inc. (“**Biomind Labs**” or the “**Company**”) (NEO: BMND) (OTC: BMNDF) (FSE: 3XI), a leading biotech company focused on developing the next generation of pharmaceuticals to treat patients suffering from neurological and psychiatric disorders by scientifically harnessing the medicinal power of psychedelic molecules, announced today that it has commenced dose administration of the first subject in a Phase I/IIa clinical trial of the Company’s novel drug candidate BMND01, for treatment-resistant depression with inhaled administration.

The Phase I/IIa clinical trial on Biomind’s first innovative formulation of N,N-Dimethyltryptamine (“**DMT**”) is evaluating the safety, pharmacokinetics, behavioral and brain effects of BMND01, for inhaled administration. The trial has commenced on time and as scheduled and is being administered by superior medical practices at Biomind’s new clinical psychedelic research facility in the University Hospital Onofre Lopes. Led by Dr. Dráulio Araújo, Biomind’s Scientific and Clinical advisor, the team is a renowned group of scientists that conducted the first randomized placebo-controlled trial with ayahuasca for treatment-resistant depression.

This study is the world’s first clinical trial to test an inhaled formulation of DMT, Biomind’s novel drug candidate BMND01. The trial is designed with a fixed ascending two dose, concentration-response study, initially in healthy volunteers, followed by the Phase IIa portion of the study that will administer the formulation in psychedelic-naïve patients with treatment-resistant depression. This first phase of the study includes up to thirty healthy patients and dosing is expected to be completed in approximately four months.

"An inhaled formulation could allow DMT to be rapidly delivered directly into the systemic circulation, bypassing the first-pass metabolism, recognized as a major problem for some routes of DMT administration. Due to the chosen inhaled route of administration, the DMT is likely to exert plenty of its potency in approximately ten minutes, which will allow more affordable interventions to be designed and implemented," commented Dr. Dráulio Araújo.

Alejandro Antalich, CEO of Biomind Labs, said: “The Company’s new psychedelic therapeutic model, as a psychiatry intervention-based approach, may allow a rapid and feasible merge of DMT therapy into clinical practices. Our intervention model has the capacity to be more easily integrated into existing mental health clinics worldwide, which will democratize the access to significantly more patients than the traditional psychedelic assisted therapy model.”

**About Biomind Labs Inc.**

Biomind Labs is a biotech research and development company aimed at transforming biomedical sciences knowledge into novel pharmaceutical drugs and innovative nanotech delivery systems for a variety of psychiatric and neurological conditions. Through its acceleration platform, Biomind Labs is developing novel pharmaceutical formulations of the main psychedelic molecules, DMT, 5-MeO-DMT and mescaline for treating a wide range of therapeutic indications. Biomind Labs' focus is to provide patients access to affordable and modern-day treatments.

### **Cautionary Note Regarding Forward-Looking Statements**

This press release contains statements that constitute "forward-looking information" ("forward-looking information") within the meaning of the applicable Canadian securities legislation. All statements, other than statements of historical fact, are forward-looking information and are based on expectations, estimates and projections as at the date of this news release. Any statement that discusses predictions, expectations, beliefs, plans, projections, objectives, assumptions, future events or performance (often but not always using phrases such as "expects", or "does not expect", "is expected", "anticipates" or "does not anticipate", "plans", "budget", "scheduled", "forecasts", "estimates", "believes" or "intends" or variations of such words and phrases or stating that certain actions, events or results "may" or "could", "would", "might" or "will" be taken to occur or be achieved) are not statements of historical fact and may be forward-looking information. Forward-looking statements in this document include, among others, statements relating to the Company's ability to scientifically harness the medicinal power of psychedelic molecules to treat patients suffering from neurological and psychiatric disorders, any timeframes and possible results of the Phase I/IIa clinical trial of the Company's novel drug candidate BMND01, the Company's ability to produce affordable interventions, the rapid and feasible merge of DMT therapy into clinical practices, the Company's intervention model to be more easily integrated into existing mental health clinics worldwide, the Company's ability to democratize the access to significantly more patients than the traditional psychedelic assisted therapy model, and other statements that are not historical facts.

By their nature, forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements, or other future events, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Such factors and risks include, among others: (a) the Company may require additional financing from time to time in order to continue its operations which may not be available when needed or on acceptable terms and conditions acceptable; (b) compliance with extensive government regulation; (c) domestic and foreign laws and regulations could adversely affect the Company's business and results of operations; (d) the stock markets have experienced volatility that often has been unrelated to the performance of companies and these fluctuations may adversely affect the price of the Company's securities, regardless of its operating peers; (e) adverse changes in the public perception of tryptamine-based treatments and psychedelic-based therapies; (f) the impact of COVID-19; and (g) general business, economic, competitive, political and social uncertainties. Accordingly, readers should not place undue reliance on the forward-looking information contained in this press release.

The Company makes no medical, treatment or health benefit claims about the Company's proposed products. The U.S. Food and Drug Administration, Health Canada or other similar regulatory authorities have not evaluated claims regarding tryptamine-based treatments, psychedelic-based therapies or other psychedelic compounds. The efficacy of such products has not been confirmed by approved research. There is no assurance that the use of psychedelic tryptamines, tryptamine derivatives or other psychedelic compounds can diagnose, treat, cure or prevent any disease or condition. Vigorous scientific research and clinical trials are needed. The Company has not yet completed commercial clinical trials for the use of its proposed products. Any references to quality, consistency, efficacy and safety of potential products do not imply that the Company verified such in commercial clinical trials or that the Company will complete such trials. If the Company cannot obtain the approvals or research necessary to commercialize its business, it may have a material adverse effect on the Company's performance and operations.

The forward-looking information contained in this news release represents the expectations of the Company as of the date of this news release and, accordingly, is subject to change after such date. Readers should not place undue importance on forward-looking information and should not rely upon this information as of any other date. The Company undertakes no obligation to update these forward-looking statements in the event that management's beliefs, estimates or opinions, or other factors, should change.

The Neo Exchange Inc. has neither approved nor disapproved the contents of this news release and is not responsible for the adequacy and accuracy of the contents herein.

## Contacts

For more information, please contact:

Biomind Labs Inc.

Alejandro Antalich

Chief Executive Officer

Email: [info@biomindlabs.com](mailto:info@biomindlabs.com)

Tel: + 598 97 702500