

NeonMind Provides Integrated Drug Development Plan Update for NEO-001 to Treat Obesity

- ***Target Product Profile and Clinical Phase 1/2 Study Aim To Address Deficiencies In Chronic Weight Management***
- ***Pre-IND Meeting in the U.S. and Pre-CTA Consultation Meeting in Canada Targeted for 4Q2021***
- ***Initiation of Phase 1/2 Clinical Proof of Concept Study in Obese Patients Anticipated in 1H2022***

VANCOUVER, BC / ACCESSWIRE / July 21, 2021 / NeonMind Biosciences Inc.

(CSE:NEON)(OTQBC:NMDBF)(FFE:6UF) ("NeonMind" or the "Company"), an integrated drug development and wellness company focused on the potential therapeutic uses of psilocybin for treating obesity and weight management conditions, announced today its R&D Working Group has completed an integrated drug development plan for its lead drug candidate targeting obesity, NEO-001, a high-dose psilocybin treatment coupled with behavior therapy and lifestyle intervention, which aims to improve the efficacy of chronic weight management in adults. The Company has identified a regulatory strategy, including a target indication and product profile; it believes will best position NeonMind as it advances its first lead candidate through development.

The Company is targeting a Pre-IND meeting with the U.S. Food and Drug Administration (FDA) in Q4 2021 to confirm potential to expedite development via the appropriate regulatory pathway and a Pre-CTA Consultation Meeting with Health Canada during the same timeframe. NeonMind anticipates initiating a Phase 1/2 proof-of-concept study in obese patients in the first half of 2022.

NEO-001, the Company's high-dose psilocybin treatment, is intended for use as an adjunct to behavioral therapy and to accompany a reduced-calorie diet and increased physical activity for adults with an initial body mass index (BMI) of 30 kg/m² or greater, or a BMI of 27 kg/m² or greater and at least one weight-related, comorbid condition. The Company's target product profile aims to best address the psychological and behavioral deficiencies in the current standard of care for chronic weight management.

It has been demonstrated that one of the most prevalent and often forgotten drivers of weight management issues is psychological and behavioral shortcomings. In clinical studies, psilocybin has shown promising results in addressing these shortcomings in other indications. In addition, improving weight management has many benefits in addressing highly burdensome and detrimental comorbidities particularly in those individuals with hypertension, dyslipidemia, type 2 diabetes, and psychiatric disorders. These additional indications are available to the Company's program and provide potential opportunities to expand the range of clinical targets.

"Growing evidence supports the therapeutic promise of psilocybin as a psychiatric tool that can help facilitate cognitive flexibility and behavioral plasticity. Recent clinical and neuroimaging data suggest persisting changes in patterns of brain function after a single high dose of psilocybin, which are associated with enhanced mood and changes in emotional processing and anxiety. These shifts have been hypothesized to work as a sort of 'mental reset' that could have significant therapeutic potential for other health conditions like obesity," said Dr. Albert Garcia-Romeu, Assistant Professor of Psychiatry and Behavioral Sciences at the Johns Hopkins Center for Psychedelic & Consciousness Research and advisor to NeonMind. "NeonMind's research approach will add meaningfully to our knowledge of psilocybin as a medical tool, and I'm excited by the prospects of NeonMind's program for expanding therapeutic psilocybin research to novel areas such as weight management, where innovative treatments are needed."

"Our innovative obesity drug candidate has the potential to generate durable weight loss in adults, which has been a long-standing gap in the current landscape of weight management methods and treatments," said Robert Tessarolo, President & CEO of NeonMind. "NeonMind's ultimate mission is to help people change their lives by changing their minds, through novel treatments with psychedelics. We are eager to embark on this regulatory journey, as we move one step closer to bringing psilocybin to patients who need it most. Our psilocybin-assisted treatment program has significant potential, and we believe it is going to bring a new therapeutic modality to the broader healthcare industry for the treatment of obesity and related comorbidities."

About NeonMind Biosciences Inc.

NeonMind is engaged in preclinical research to develop potential clinical treatments and wellness products to address obesity and weight management conditions and to promote health and wellness. The Company operates three divisions: (i) a pharmaceutical division engaged in drug development of psychedelic compounds with two lead psilocybin-based drug candidates targeting obesity; (ii) a medical services division focused on launching specialty mental health clinics that integrate psychedelic therapeutics into traditional psychotherapy settings; and (iii) a consumer products division that currently sells mushroom-infused products to promote health and wellness.

In its pharmaceutical division, NeonMind has two distinct psilocybin drug development programs targeting obesity. NeonMind's first drug candidate employs psilocybin as an agonist at the serotonin 5-HT_{2A} receptor, which is involved in the hallucinogenic effect of psychedelics. The Company's second drug candidate employs low-dose psilocybin as an agonist at the 5-HT_{2C} receptor, which controls appetite.

NeonMind established a medical services division with the goal of launching NeonMind-branded specialty mental health clinics in Canada that incorporate evidence-backed innovative treatments to address a variety of mental health needs.

NeonMind's consumer division currently sells NeonMind-branded coffee products in the United States and Canada through NeonMind's direct to consumer e-commerce platform.

For more information on NeonMind, go to www.NeonMindBiosciences.com.

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