



NeonMind Announces Successful Completion of Pre-IND Consultation with FDA on Clinical Path for Obesity Drug Candidate NEO-001

- *FDA feedback provides clear clinical path for NEO-001, the first obesity drug therapy focused on neuropharmacological and behavioral changes for sustainable weight loss*
- *Company plans to file an IND application for a Phase 1/2 clinical study anticipated to start in H1'2022*

Vancouver, B.C. – November 23, 2021: NeonMind Biosciences Inc. (CSE: NEON) (OTCQB: NMDBF) (FRA: 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 it successfully completed a pre-Investigational New Drug (IND) consultation with the U.S. Food and Drug Administration (FDA), regarding proposed clinical trials for NeonMind's lead obesity drug candidate, NEO-001. The Company expects to initiate a Phase 1/2 clinical study in the first half of 2022.



"We are extremely pleased with the FDA's feedback and the outcome of the pre-IND consultation, which validated the scientific hypothesis and clinical approach developed by the NeonMind team. The FDA provided helpful feedback and constructive recommendations for the next steps in our development plan. We appreciate the FDA's guidance and are on track to bring the first and only psychedelic-based treatment for obesity into clinical trials," said Robert Tessarolo, President & CEO of NeonMind. "In parallel with an



IND submission, we plan to engage with a Contract Research Organization and qualify clinical sites to move expeditiously into a Phase 1/2 Proof-of-Concept study.”

The pre-IND consultation offered feedback for NeonMind to execute on measurable clinical development milestones for its NEO-001 clinical program. The FDA acknowledged the study rationale and potential therapeutic opportunity of NEO-001 for the treatment of obesity, and the justification to advance into human clinical trials. NeonMind will incorporate the FDA’s recommendations and does not expect any impact on the timing of the proposed NEO-001 clinical program. NeonMind’s proprietary therapy will be the first psychedelic program in humans to target a large population of patients struggling with sustainable weight management.

NEO-001, the Company’ lead drug candidate targeting obesity, is a high-dose psilocybin treatment coupled with behavioral 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, which it believes will best position NeonMind as it advances its first lead candidate through development.

About NeonMind Biosciences Inc.

NeonMind operates two divisions: (i) a pharmaceutical division engaged in drug development of psychedelic compounds with two lead psilocybin-based drug candidates targeting obesity; and (ii) a medical services division focused on launching specialty mental health clinics that integrate psychedelic therapeutics into traditional psychotherapy settings.

In its pharmaceutical division, NeonMind has two distinct psilocybin drug development programs targeting obesity. NeonMind’s lead candidate, NEO-001, 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, NEO-002, employs low-dose psilocybin as an agonist at the 5-HT_{2C} receptor, which controls appetite.

NeonMind, and its strategic medical services partner, SRx Health Solutions, expect to launch NeonMind-branded specialty mental health clinics in Canada that incorporate evidence-backed innovative treatments to address a variety of mental health needs. For more information on NeonMind, go to www.NeonMindBiosciences.com.

Rob Tessarolo, President & Chief Executive Officer, NeonMind Biosciences Inc.

rob@neonmind.com

Tel: 416-750-3101



Investor Relations:

KCSA Strategic Communications

Scott Eckstein/Tim Regan

neonmind@kcsa.com

Tel: 212-896-1210

The Canadian Securities Exchange has not reviewed, approved nor disapproved the contents of this news release.

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