PharmAla Comments on USFDA Decision regarding MDMA-Assisted Therapy and Announces Patent Granting for ALA-002

TORONTO, Aug. 09, 2024 -- PharmAla Biotech Holdings Inc. ("**PharmAla**" or the "**Company**") (CSE: MDMA) (OTC:MDXXF), a biotechnology company focused on the research, development, and manufacturing of LaNeo™ MDMA and novel derivatives of MDMA (MDXX class molecules) is disappointed in the decision made by the US Food and Drug Administration (USFDA) to request that Lykos Therapeutics complete a third confirmatory Phase 3 trial prior to allowing the approval of MDMA assisted therapy (MDMA-AT) for the treatment of Post Traumatic Stress Disorder.

"PharmAla does not operate in the US except as a clinical trial supplier, and as such this decision will have a limited impact on our operations in the near-term. USFDA has an important responsibility to get things right, and we believe that they are acting in good faith, however there is a vitally important patient need for novel PTSD treatments which must be balanced with that prudency," said Nicholas Kadysh, CEO, PharmAla Biotech. "MDMA is not only supported by a significant evidence base of published clinical trial research, but is also being actively used in patient treatments in 2 jurisdictions, Canada and Australia, entirely supplied by PharmAla. There is a growing body of evidence of its efficacy in the real world, to which we are pleased to have contributed. We must re-commit ourselves to ongoing research which will convince even the most sceptical regulators that this medicine is both safe and effective."

PharmAla produces its LaNeo MDMA capsules in Canada, under GMP conditions. They are distributed in Canada under the Health Canada Special Access Program, to qualified patients, and in Australia under the Therapeutic Goods Administration (TGA)'s Authorized Prescriber Scheme. In Australia, distribution and sales are performed by Cortexa, PharmAla's Joint Venture (JV) with Vitura Ltd.

"As a result of this decision, we anticipate clinical research on MDMA to increase; PharmAla is an important supplier of MDMA for that research, with over a dozen human clinical trials contracted globally, and we will continue to support our partners in their efforts," said Dr. Shane Morris, COO, PharmAla Biotech.

ALA-002 Patent Issuance

PharmAla is pleased to announce that its patent for the composition of matter for its novel, non-racemic mixture of MDMA enantiomers, internally deemed ALA-002, has been issued by the US Patent and Trademark Office (USPTO), under patent No. 12,053,452.

"We believe that the issuance of this patent represents an incredibly valuable cornerstone of PharmAla's research and development program. Numerous researchers have indicated concern with several elements of racemic MDMA, including both acute and chronic cardiotoxicology, as well as adverse events such as hyperthermia," said Dr. Harpreet Kaur, VP of Research, PharmAla Biotech. "Our preclinical research, now published, has proven that we have significantly addressed these concerns. By addressing these safety issues, we believe that PharmAla's ALA-002 development program is exceptionally positioned to gain favourable approval by regulators."

About PharmAla

PharmAla Biotech Holdings Inc. (CSE: MDMA) (OTCQB: MDXXF) is a biotechnology company focused on the research, development, and manufacturing of MDXX class molecules, including MDMA. PharmAla was founded with a dual focus: alleviating the global backlog of generic, clinical-grade MDMA to enable clinical trials as well as commercial sales in selected jurisdictions, and to develop novel drugs in the same class. PharmAla is the only company currently provisioning clinical-grade MDMA for patient treatments outside of clinical trials. PharmAla's research and development unit has completed proof-of-concept research into several IP families, including ALA-002, its lead drug candidate. PharmAla is a "regulatory first" organization, formed under the principle that true success in the psychedelics industry will only be achieved through excellent relationships with regulators.

For more information, please contact:
Nicholas Kadysh
Chief Executive Officer
PharmAla Biotech Holdings Inc.
Email: press@PharmAla.ca
Phone: 1-855-444-6362
Website: www.PharmAla.ca

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