Patent Allowance Granted for ALA-002 Composition by US Patent and Trademark Office

Novel Composition of MDMA Enantiomers leading to next-generation MDMA possibilities

TORONTO, March 27, 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 extremely pleased to announce that the US Patent and Trademark Office (USPTO) has indicated it is issuing an allowance for the granting of a patent for ALA-002, the company's lead investigational MDXX Novel Chemical Entity (NCE). This provides the Company a strong basis for ongoing protection of this intellectual property (IP).

ALA-002 is a novel mixture of MDMA enantiomers, consisting of 70-80% R-MDMA and 20-30% S-MDMA. Preclinical testing has shown that the administration of ALA-002 results in significantly lowered incidence of hyperthermia, the major adverse event elicited by racemic generic MDMA. The Composition also showed improved indication of pro-social effect in both C57 (General Population) and BTBR (Autism-Like) mouse models, and a reduced "abuse liability" (addiction) potential.

PharmAla's patent application included *in-vivo* experimental animal data, which is generally held to be stronger evidence than computational, or *in-silico*, modeling.

"MDMA is relatively unique in that it has two enantiomers that are active, but are active in dramatically different ways. In the brain, these two variants of the molecule have a synergistic effect. In short, the sum of these parts is greater than the whole," said Dr. Harpreet Kaur, Vice President of Research at PharmAla Biotech. "Viewed this way, it becomes obvious that the effects of racemic MDMA should be viewed not as one active, but as a combination effect – and as such, it is open to optimization. With ALA-002, we believe we have done that difficult work, and have created an improved, novel, next generation MDMA drug substance formulation."

ALA-002 is considered by the US Food and Drug Administration (FDA) to be a Novel Chemical Entity (NCE), and in the opinion of the Company it is a different *Active Moiety* than racemic MDMA. As such, the Company believes that should it be approved by the FDA for use as a treatment for any disorder, it should be granted its own Data Exclusivity period.

The Company intends to pursue its own clinical research with the novel composition, either alone or with an out-licensing partner. It has completed a Phase 2 protocol for the research of ALA-002 as a treatment for Social Anxiety symptoms in patients with Autism Spectrum Disorder (ASD) in conjunction with researchers at the University of Sydney. The Company believes that this is an Orphan Indication, in that there are no FDA-approved treatments currently available for social anxiety in autistic patients. However, the Company also believes that ALA-002 could be useful in the treatment of a number of neurological and neuropsychiatric disorders.

"We are incredibly pleased that USPTO has issued an allowance for the granting of the Composition of Matter patent for ALA-002. This is the culmination of years of pre-clinical and intellectual property work, and represents a significant achievement in a relatively crowded IP environment," said Nick Kadysh, Founding CEO, PharmAla Biotech. "PharmAla's IP team has already begun working towards patenting this composition in a number of relevant global markets, with the support of Intellectual Property Ontario (IPON), and we are excited to both defend and build on what we believe is an exceptionally valuable piece of intellectual property."

PharmAla intends to use this landmark USPTO allowance to accelerate allowance in other jurisdictions through all practicable means.

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.

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