USFDA Approves LaNeo MDMA for Clinical Trial Use in the United States

Approved Study to Examine Tolerability of MDMA in Schizophrenia at UCLA

VANCOUVER, British Columbia, June 09, 2023 -- PharmAla Biotech Holdings Inc. (“PharmAla”)(CSE: MDMA)(OTC:PMBHF), a biotechnology company focused on the research, development, and manufacturing of MDXX class molecules (including MDMA), is pleased to report that the US Food and Drug Administration (USFDA) has approved a clinical trial utilizing PharmAla’s LaNeo MDMA Investigational Medical Product (IMP) capsules (40mg). This is the first time that PharmAla’s IMP has been approved for trial use in the United States.

"While we’ve had great success with many regulators around the world, it’s still a major milestone to receive a stamp of approval from USFDA for our investigational drugs,” said Dr. Harpreet Kaur, Vice President of Research at PharmAla Biotech. “As with any IMP supplier, there are always questions about Chemistry, Manufacturing and Control - even for well-known molecules. We believe that this announcement should confirm that our IMP conforms to the high levels of quality and documentation that one of the preeminent regulators in the world requires.

PharmAla supports numerous researchers around the world who are studying MDMA for a diverse series of indications. The company also provides Psilocybin to researchers through their partnership with Mindset Pharma. In Australia, which is allowing treatment of patients with both MDMA and Psilocybin through the Authorized Prescriber Program as of July 1st, PharmAla has formed a Joint Venture with Vitura Health (ASX:VIT) in order to distribute its products, called *Cortexa*.

“We found that the FDA scrutinized our materials and processes in a rigorous but fair fashion,” said Nick Kadysh, CEO, PharmAla Biotech. “As with all of our clients, we worked hard to support UCLA Researchers in their application to USFDA. We hope that they are pleased with the results, and look forward to providing them with their IMP as soon as DEA and Health Canada issue the relevant permits.”

The PharmAla team, led by Sales Director David Purcell, will be hosting a booth for potential customers at Psychedelic Science 2023 Conference in Denver for the week of June 19-23. Researchers interested in information regarding PharmAla’s IMP can visit www.PharmAla.ca.

About PharmAla

PharmAla Biotech Holdings Inc. (CSE: MDMA) 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, and to develop novel drugs in the same class. PharmAla is the first publicly-traded company to manufacture clinical-grade MDMA. PharmAla’s research and development unit has completed proof-of-concept research into ALA-002, PharmAla’s 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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these forward-looking statements are described under the caption “Risk Factors” in PharmAla’s management’s discussion and analysis which is available on PharmAla’s profile at www.sedar.com.

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