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PharmAla Submits Pre-IND Dossier for Novel MDMA Analog to FDA

ALA-002 is PharmAla's lead drug candidate, showing exceptional safety and efficacy in preclinical rodent models

VANCOUVER, BC, November 2, 2022 /Globe Newswire/ PharmAla Biotech (CSE:MDMA) is pleased to announce that it has submitted its pre-IND data meeting package to the US Food and Drug Administration (USFDA) in advance of its pre-IND meeting scheduled for later this month. PharmAla will be requesting FDA feedback on the nonclinical and CMC development plan to support the initial clinical trial for ALA-002.

"As a 'regulatory-first' organization, we know that regulators like FDA are rightly concerned with safety of novel medicines. One of the key goals for PharmAla was the development of MDXX compounds that show an improved safety profile compared to generic MDMA," said Nick Kadysh, CEO of PharmAla Biotech. "We hope that USFDA will see the same potential in our pre-clinical results which we do."

PharmAla's goal is to bring ALA-002 into the clinic as a treatment for disorders in adults diagnosed with Autism Spectrum Disorder (ASD). As such, ALA-002 was tested not only in general population research, but also in generally accepted autism mouse models.

"ALA-002 is the first molecule of which we are bringing to USFDA, and we believe it will be an incredibly valuable tool to treat conditions commonly occurring alongside ASD," said Dr. Harpreet Kaur, Vice President of Research for PharmAla Biotech. "However, we are hard at work identifying new molecules in the MDXX class that also have clinical promise. Using our proprietary MDXX drug discovery algorithm, we believe we will have even more molecules to bring to regulators in the near future – including the ABA series of non-controlled molecules."

For more information, please visit www.PharmAla.ca, where you can sign up to receive regular new updates.

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. Our team of dedicated professionals includes regulatory experts, scientists, and biomanufacturing professionals. For more information, visit www.PharmAla.ca.

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