



Australia Allows Prescription of MDMA and Psilocybin in Groundbreaking Regulatory Change

PharmAla Biotech is the only company in the world with the ability to ship GMP MDMA and Psilocybin today

VANCOUVER, British Columbia, Feb. 03, 2023 -- PharmAla Biotech Holdings Inc. ("PharmAla")(CSE: MDMA) applauds the Australian Therapeutic Goods Administration (TGA) in [allowing for specially-licensed psychiatrists to prescribe MDMA and Psilocybin](#). PharmAla is the only publicly-traded company currently manufacturing and exporting clinical-grade MDMA, and the only entity in the world that offers its customers GMP MDMA and GMP Psilocybin.

"This is a critically important announcement by the TGA, allowing for the direct prescription and treatment of patients with PTSD and Treatment-Resistant Depression with Psychedelic molecules," said Nick Kadysh, CEO of PharmAla. "As the registered supplier to three different Australian clinical trials using MDMA – more than any other Psychedelics API supplier - PharmAla is the only company which has both GMP MDMA and Psilocybin in inventory, and stands ready to ship these molecules to Australia."

PharmAla is the first publicly traded company to manufacture GMP MDMA, and is the first company to make available to customers two clinical-grade Psychedelic APIs. Before being authorised by the TGA under this scheme, psychiatrists must obtain approval for the use of the substances for patients under their care by a human research ethics committee (HREC) that is registered by the National Health and Medical Research Council (NHMRC). PharmAla has already been contracted to supply several HREC-approved trials.

"The TGA decision absolutely sets a new global standard for treatment with molecules like MDMA and Psilocybin," said Dr. Shane Morris, COO of PharmAla Biotech. "Allowing specially-licensed psychiatrists to prescribe these molecules directly to patients is an excellent approach, and will certainly help drive other countries to re-assess how they regulate these molecules to meet patients' medical needs."

Customers interested in acquiring MDMA or Psilocybin for human use under the new TGA guidance should contact PharmAla's Head of Sales, David Purcell, at sales@pharmala.ca

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.

For more information, please contact:

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