

World's First Observational Trial to Assess Real-World Efficacy of MDMA Treatment

PharmAla, University of Calgary, and Heroic Hearts Canada to partner on a groundbreaking observational trial

VANCOUVER, British Columbia, Nov. 09, 2023 -- PharmAla Biotech Holdings Inc. ("**PharmAla**") (CSE: MDMA) (OTC:PMBHF), the University of Calgary ("**UC**"), and Heroic Hearts Canada ("**HHC**", and collectively, the "**Parties**") are pleased to announce that they have completed a Letter of Intent ("**LOI**"), and received initial Ethics Board Approval, to initiate an Observational Trial (the "**Trial**") on patients treated with 3,4-Methylenedioxymethamphetamine ("**MDMA**") through Health Canada's Special Access Program (SAP). The Parties will each play an important role in the execution of this trial:

- PharmAla Biotech is currently the only manufacturer of GMP MDMA for clinical use in Canada. PharmAla will provide drug product to physicians under SAP through its licensed distribution partners, and connect clinicians and patients with UC researchers for voluntary data collection.
- The University of Calgary, under the direction of Dr. Leah Mayo, Parker Research Chair in Psychedelics, will assess data pertaining to efficacy of MDMA in the treatment of PTSD under real-world circumstances. The University of Calgary will have full rights to publication of data generated by the trial, with no limitation by the Parties.
- Heroic Hearts Project Canada, a charity supporting veteran mental health by facilitating access to psychedelic-assisted therapy, will offer its future program participants who receive MDMA-assisted therapy via the SAP the option to participate in the Trial and thereby contribute RWE.

The announcement of the Trial comes following the release yesterday of the Senate of Canada's Subcommittee on Veterans report, [The Time is Now: Granting equitable access to psychedelic-assisted therapies](#), which urged Veterans Affairs Canada to increase research into the treatment of veterans' "moral injuries" such as Post-Traumatic Stress Disorder with psychedelic molecules, including MDMA. This trial will generate Real World Evidence ("**RWE**") on the efficacy of MDMA in the treatment of Post-Traumatic Stress Disorder which may be submitted to Health regulators, including Health Canada and Veterans Affairs Canada. The Parties hope that data collected in the Trial will add to the knowledge base of both regulators and the scientific community on the real-world evidence of efficacy and safety of these treatments.

The Parties' initial submission to the Review Ethics Board has been approved, and the parties intend to proceed to data gathering immediately. Subsequent Ethics Review Board submissions are contemplated in the LOI. As the trial is Observational in nature, no patients will be dosed as part of the trial's protocol. The goal of the trial is to gather data on the efficacy of treatment for patients who are already qualified for treatment under the Special Access Program.

Quotes:

"Our ability to treat patients through SAP, while imperfect, remains a credit to Canadian regulators and an incredibly valuable tool for the collection of evidence of MDMA's efficacy in real-world clinical outcomes. We're incredibly pleased to work with Dr. Mayo and Heroic Hearts to bring together patients, clinicians, and scientists," said Nick Kadysh, CEO, PharmAla Biotech. "We are already seeing amazing results in patients, and we believe we are currently the only company in the world that can generate evidence from SAP which can be shared directly with regulators, as well as the scientific community."

"While clinical evidence in the form of trial data on the efficacy of MDMA as a treatment for PTSD has been published – and is encouraging – this is a global first: an assessment of the efficacy of MDMA in treating PTSD outside the bounds of a clinical trial," said Dr. Leah Mayo, Parker Psychedelics Research Chair, University of Calgary. "This observational trial is only possible due to the unique partnership of the 3 groups represented here, and the data gathered should significantly add to the body of knowledge around MDMA-assisted therapies."

"Heroic Hearts Canada is committed to making MDMA-assisted therapy and other innovative psychedelic-assisted therapies accessible to veterans, who experience disproportionately high rates of trauma and mental illness after service," said David Fascinato, Executive Director, Heroic Hearts Canada. "This partnership is an important opportunity to add to the body of knowledge and support Health Canada and stakeholders such as Veterans Affairs Canada, in understanding the potential of MDMA-assisted therapy, with the goal of eventual approval so that it is accessible to all in need through approved healthcare channels."

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 several IP families, including ALA-002, its lead drug candidate. 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

About the University of Calgary:

UCalgary is Canada's entrepreneurial university, located in Canada's most enterprising city. It is a top research university and one of the highest-ranked universities of its age. Founded in 1966, its 35,000 students experience an innovative learning environment, made rich by research, hands-on experiences and entrepreneurial thinking. It is [Canada's leader in the creation of start-ups](#).

For more information, please contact:

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Media inquiries can be sent to Senior Communications Specialist Kelly Johnston kelly.johnston2@ucalgary.ca and research inquiries can be directed to the Psychedelic and Cannabinoid Therapeutics Lab Research Coordinator, Kaitlin O'Grady (kaitlin.ogrady@ucalgary.ca)

About Heroic Hearts Canada:

Heroic Hearts Canada is a registered Canadian charity whose sole purpose is to empower veterans on their healing journey by connecting them with safe, effective, and transformative psychedelic-assisted therapies in Canada and abroad. Our programs facilitate access to vetted clinics providing psychedelic-assisted therapies and contribute to the growing base of evidence and research on the impacts of psychedelic-assisted therapies in Canada and abroad.

For more information, please contact:

David Fascinato
Executive Director
Heroic Hearts Canada
Email: david@heroicheartsproject.ca
Website: www.heroicheartsproject.ca

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