PharmAla Contracts with Clerkenwell to bring safer MDMA analogue to US, UK

PharmAla, the world's first publicly-traded manufacturer of GMP MDMA, has contracted with Clerkenwell Health, a UK-based CRO and Clinical Trial site, to provide regulatory support for both US FDA and UK MHRA applications

VANCOUVER, BC, Oct. 11, 2022 /CNW/ - PharmAla Biotech (CSE: MDMA) is pleased to announce that it has retained Clerkenwell Health, a UK-based Contract Research Organization, to assist PharmAla in regulatory proceedings with both the US Food and Drug Administration (FDA) and the UK Medicines and Health Regulatory Authority (MHRA). PharmAla intends to bring ALA-002, its leading Novel Chemical Entity (NCE), to both jurisdictions. ALA-002 was designed to provide the same efficacy as MDMA, has an improved safety profile, including Cardio- and Neuro-tox, and fewer adverse events.

"PharmAla have a unique and exciting strategy, which could present real improvements to clinical development and application of empathogens" said Dr Henry Fisher, Co-founder and Chief Scientific Officer at Clerkenwell Health. "Engaging with both the MHRA and the FDA on their behalf is also an important milestone for us as we widen our clinical research footprint."

Clerkenwell will provide regulatory support for ALA-002 in both the UK and USA. The agreement also countenances the potential to drive more molecules through the pharmaceutical regulatory approvals pathway. PharmAla continues to develop additional molecules, including its ABA series of non-controlled MDMA analogues, and further NCEs still under development.

"Clerkenwell represents an excellent partner to push forward our regulatory efforts," said Dr. Harpreet Kaur, Vice President of Research at PharmAla Biotech. "They have brought not only excellent experience with regulatory affairs in two different key jurisdictions, but also represent the capability to execute clinical research at their UK facility. We're incredibly pleased to have them as partners."

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 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. PharmAla has built what it believes to be North America's first cGMP MDMA value chain, encompassing GMP manufacturing of Active Pharmaceutical Ingredient (API), and drug product formulation. PharmAla's research and development unit has also begun preclinical research into two patented Novel Chemical Entities (NCEs) based on MDXX class molecules, with proof-of-concept research currently ongoing at the University of Arkansas School for Medical Sciences in the United States and at InterVivo Solutions in

Canada. For more information, visit www.PharmAla.ca.

About Clerkenwell Health

Clerkenwell Health is a specialist clinical research organisation, focused on supporting clients with the design and delivery of psychedelic-assisted therapy trials. They facilitate psychedelic research at scale through commercial centres of excellence which allow organisations to run clinical trials, co-develop drugs and be at the forefront of clinical innovation. They offer companies a full suite of clinical trial support: scientific advisory, trial design, regulatory approvals, provision of suitable trial sites, and the monitoring and management of trials.

The team brings together decades of international regulatory affairs, clinical development strategy, clinical operations, and market access expertise. They support clients by identifying suitable indications, engaging regulators, designing clinically sound and scientifically robust study protocols and delivering trials through their own facilities and those of their wide partnership network. More information about Clerkenwell Health can be found on their website.

Neither the Canadian Securities Exchange nor its Regulation Services Provider have reviewed or accept responsibility for the adequacy or accuracy of this release.

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This press release contains 'forward-looking information' within the meaning of applicable Canadian securities legislation. These statements relate to future events or future performance. The use of any of the words "could", "intend", "expect", "believe", "will", "projected", "estimated" and similar expressions and statements relating to matters that are not historical facts are intended to identify forward-looking information and are based on PharmAla's current belief or assumptions as to the outcome and timing of such future events. Forward-looking information is based on reasonable assumptions that have been made by PharmAla at the date of the information and is subject to known and unknown risks, uncertainties, and other factors that may cause actual results or events to differ materially from those anticipated in the forward-looking information. The forward-looking information contained in this press release is made as of the date hereof, and PharmAla is not obligated to update or revise any forward-looking information, whether as a result of new information, future events or otherwise, except as required by applicable securities laws. Factors that could cause actual results to differ materially from those anticipated in 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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