



PharmAla Received Guidance on ALA-002 from MHRA; Launches Clinical Program with University of Sydney

Utilizing Advice from the UK's Medicines and Healthcare Regulatory Agency, PharmAla to move forward on Clinical Trials

VANCOUVER, British Columbia, July 20, 2023 -- PharmAla Biotech Holdings Inc. ("**PharmAla**" or the "**Company**") (CSE: MDMA) (OTC:PMBHF), a biotechnology company focused on the research, development, and manufacturing of novel MDXX class molecules (including MDMA), is thrilled that – following pre-submission meetings held in Q1 of 2023 – it has received written guidance from the UK's Medicines and Healthcare products Regulatory Agency's (MHRA). The guidance constitutes, in part, advice that ALA-002 does not require further preclinical data in order for clinical trials to proceed.

"While this result took a bit longer to receive than we anticipated, it did conform with our expectations," said Dr. Harpreet Kaur, Vice President of Research, PharmAla Biotech. "We are now prepared to move into the clinical phase of ALA-002's development with full confidence that we have a range of competent and well-regulated jurisdictions to choose from. Our intent is to move rapidly, with the expectation of moving into a Phase 2 trial."

Following receipt of this guidance, PharmAla is further pleased to announce that it has entered into a clinical development agreement with the University of Sydney, under the leadership of Dr. Adam Guastella, the Michael Crouch Chair in Child and Youth Mental Health at the University.

"Dr. Guastella is highly expert in the specific area of research in which we wish to engage, and we are very pleased to formalize our relationship with him – and to continue deepening our ties to Australia," said Nick Kadysh, CEO, PharmAla Biotech. "We believe that ALA-002 represents one of PharmAla's most promising IP assets. Not only is it viable as a treatment for fear disorders – much like generic MDMA – but with its improved toxicology, we are hopeful that clinical trials will bear out its viability for treating another orphan indication. PharmAla intends to treat the symptoms of social anxiety in Autism patients – we couldn't imagine a better partner than Dr. Guastella to move forward on this exciting research."

About PharmAla

PharmAla 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.

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Cautionary Note Regarding Forward-Looking Statements

*This news release contains forward-looking statements and forward-looking information (collectively, "**forward-looking statements**") within the meaning of applicable Canadian securities legislation. These statements relate to matters that identify future events or future performance. Often, but not always, forward looking information can be identified by words such as "could", "pro forma", "plans", "expects", "may", "will", "should", "budget", "scheduled", "estimates", "forecasts", "intends", "anticipates", "believes", "potential" or variations of such words including negative variations thereof, and phrases that refer to certain actions, events or results that may, could, would, might or will occur or be taken or achieved. The forward-looking statements contained herein include, but are not limited to statements regarding: the Company's objectives and goals; the shipment of MDMA to the University of Sydney and the Company's contract with the University of Sydney; the Company refiling an amended and restated offering document and corresponding news release to relaunch the LIFE Offering; and the results of the Sydney trial and further research into MDMA based on these results.*

These forward-looking statements are based on certain assumptions and estimates of management of the Company at the time such statements were made, including: the Company's ability to attract and retain qualified members of management to grow the Company's business and its operations; the Company's ability to raise any necessary additional capital on reasonable terms to advance the development of the Company's products; the Company's ability to effectively manage unanticipated costs and expenses; the Company retaining and supplementing its board of directors and management, or otherwise engaging consultants and advisors having knowledge of the industries (or segments thereof) within which the Company may from time to time participate; current and future members of management abiding by the Company's business objectives and strategies from time to time established by the Company; the Company's ability to generate cash flow from operations; future prices and demand for MDXX class molecules and MDMA; the Company's ability to procure equipment and operating supplies in sufficient quantities and on a timely basis; future currency exchange rates and interest rates; operating conditions being favourable such that the Company is able to operate in a safe, efficient and effective manner; the Company's ability to attract and retain skilled personnel; political and regulatory stability; the receipt of governmental, regulatory and third-party approvals, licenses and permits on favourable terms; obtaining required renewals for existing approvals, licenses and permits on favourable terms; requirements under applicable laws; sustained labour stability; stability in financial and capital goods markets; results of operations and performance; industry trends; the market for MDXX class molecules and MDMA will continue to strengthen; the Company having sufficient funds to meet its administrative overhead expenses for the next twelve months; the Authorized Prescriber Program in Australia coming into effect on July 1, 2023; the Company's ability to fulfil the shipment to the University of Sydney; the Company's ability to refile an amended and restated offering document and news release to relaunch the LIFE Offering; and the Company's ability to view the results of the Sydney trial. While the Company considers these assumptions to be reasonable, based on information currently available, they may prove to be incorrect. Readers are cautioned not to place undue reliance on forward-looking statements.

Actual future results may differ materially as forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements expressed or implied by such forward-looking statements. Such factors include, without limitation: risks associated with general economic conditions; adverse industry events; income tax and regulatory matters; the Company not utilizing the use of proceeds to expand its operations and products; additional financing may not be available to the Company when required or, if available, the terms of such financing may not be favourable to the Company; fluctuations in demand of MDXX class molecules and MDMA; the Company may not be able to identify, negotiate or finance any future acquisitions successfully, or to integrate such acquisitions with its current business; the Company's research and development activities are dependent upon the grant of appropriate licenses, concessions, leases, permits and regulatory consents, which may be withdrawn or not granted; the Company's operations could be adversely affected by possible future government legislation, policies and controls or by changes in applicable laws and regulations; the Company and/or its directors and officers may be subject to a variety of legal proceedings, the results of which may have a material adverse effect on the Company's business; the Company may be adversely affected if potential conflicts of interests involving its directors and officers are not resolved in favour of the Company; dilution from future equity financing could negatively impact holders of the Company's securities; employee relations; ongoing uncertainties relating to the COVID-19 pandemic; the Authorized Prescriber Program in Australia not coming into effect on July 1, 2022; the Company's inability to fulfil the shipment to the University of Sydney; the Company's inability to access the results of the University of Sydney trials; the Company's inability to refile an amended and restated offering document and news release to relaunch the LIFE Offering; and those factors described under the heading "Risks and Uncertainties" in the Company's management's discussion and analysis for the fiscal year ended August 31, 2022, available under the Company's profile on SEDAR.

Readers are cautioned that the foregoing list is not exhaustive. Readers are further cautioned not to place undue reliance on forward-looking statements as there can be no assurance that the plans, intentions or expectations upon which they are placed will occur. Such information, although considered reasonable by management at the time of preparation, may prove to be incorrect and actual results may differ materially from those anticipated. Forward-looking statements contained in this news release are expressly qualified by this cautionary statement and reflect our expectations as of the date hereof, and thus are subject to change thereafter. The Company does not undertake to release publicly any revisions for updating any voluntary forward-looking statements, except as required by law.