



Albert Labs signs Letter of Intent (LOI) with iNGENū CRO for First In-Human Clinical Studies

VANCOUVER, BC, Nov. 17, 2022 /CNW/ - [Albert Labs International Corp.](#) (Albert Labs (CSE: ABRT) (FSE: VB50), the "Company"), a pharmaceutical drug development company focused on gaining regulatory approval for novel medicines to treat various mental health conditions, signs a Letter of Intent (LOI) with full-service Contract-Research Organisation (CRO), iNGENū, to carry out the Company's first in-human study of its primary drug target, KRN-101.

This randomised, double-blind study will evaluate the safety and tolerability of KRN-101 in study participants and determine its full pharmacokinetic characterization. As a unique, natural medicine containing a range of bioactives, KRN-101 is required to have its own pharmacokinetic profile despite an extensive background of safety data to support psilocybin-based medicines. Profiling KRN-101 through this study will allow the Company to reap the long-term potential of having a differentiated product through extensive opportunities for intellectual property protection.

This study will take place in Melbourne, Australia, and including the collection of all clinical outputs, will be carried out over 8 weeks with an expected completion in Q3 2023. Upon completion, KRN-101 will be available for use in late-stage clinical trials, allowing the Company to proceed with its Real World Evidence trial in the United Kingdom, which will establish the efficacy of the treatment for cancer-related distress. This first in-human study also allows the Company to collect valuable data which will enable a future Investigational New Drug (IND) Application to be filed with the FDA, thus taking KRN-101 to the largest pharmaceutical market in the world.

The Company will also benefit from the Australian Federal Government's Research & Development incentive programme which will provide cash rebates for 43.5% of all eligible costs relating to the study.

The study will be carried out by iNGENū, a full-service CRO specialising in clinical trials for psychoactive pharmaceuticals, who work with a network of specialist consultants and research facilities across the South-East Pacific region to facilitate high quality and cost-effective research.

Dr. Sud Agarwal, CEO of iNGENū: "It's a privilege to have been selected as the CRO by Albert Labs' team of highly credentialed research experts to take the KRN-101 investigational product into first-in-human studies in Australia."

"This study will be conducted by iNGENū CRO at a globally renowned research unit in Melbourne, and will yield critical data to help characterise the pharmacokinetics of KRN-101 and establish a recommended late-stage dose for future clinical trials."

Dr. Michael Raymont, CEO of Albert Labs: "We have carefully considered a range of partners for our first in-human study and are delighted to come to this agreement with iNGENū. We have been impressed by their capabilities and see a strong alignment with our core values as a company. We also greatly appreciate the assistance of the Australian Government for carrying out this research. Through this partnership we will provide the highest standard of clinical due diligence, and risk mitigation for planned late-stage trials in the UK through expansion into the United States. We feel that this is a significant step forward in value creation for our shareholders."

Business of Albert Labs International Corp.

Albert Labs is a pharmaceutical drug development company, focused on gaining regulatory approval for novel medicines for the treatment of mental health, and providing rapid access to effective prescription medicines for people suffering from mental health disorders. Its team of experts leverage advanced culture technology and natural extraction, coupled with a comprehensive regulatory approach, to accelerate the development of mental health drugs, for which the needs are both urgent and unmet. Albert Labs looks to develop solutions through an approved, fast track clinical pathway focusing on Real World Evidence (RWE). RWE studies are an increasingly recognized clinical route, heavily used in oncology and recently, in the successful development of COVID-19 vaccines.

Through collaborations with research institutions, hospital centres and government agencies, Albert Labs uses existing clinical infrastructure to deliver and improve patient access to its treatment. Albert Labs' first drug target, KRN-101, is a potential solution for cancer-related anxiety, a market of over 15 million people with roughly 1 million new sufferers each year. From this initial focus, Albert Labs will address broader mental health concerns, reported to affect over a billion people worldwide.

Albert Labs (CSE: ABRT) (FSE: VB50) is publicly [listed on the Canadian Securities Exchange \(CSE\)](#)

You can find more details about Albert Labs on our website [here](#).

ON BEHALF OF THE BOARD OF DIRECTORS

Albert Labs International Corp.

Dr. Michael Raymont

Chief Executive Officer & Chairman


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This news release includes forward-looking statements that are subject to assumptions, risks, and uncertainties. Statements in this news release that are not purely historical are forward-looking statements, including without limitation any statements concerning the Company's intentions, plans, estimates, beliefs, or expectations regarding the future. Although the Company believes that any such intentions, plans, estimates, beliefs, and expectations in this news release are reasonable, there can be no assurance that any such intentions, plans, beliefs, and expectations will prove to be accurate.

The Company cautions readers that all forward-looking statements, including without limitation those relating to the Company's future operations and business prospects, are based on assumptions none of which can be assured, and are subject to certain risks and uncertainties that could cause actual events or results to differ materially from those indicated in the forward-looking statements. Readers are advised to rely on their evaluation of such risks and uncertainties and should not place undue reliance on forward-looking statements.

Any forward-looking statements are made as of the date of this news release, and the Company assumes no obligation to update the forward-looking statements or to update the reasons why actual events or results could or do differ from those projected in the forward-looking statements. The Company assumes no obligations to update any forward-looking statements, whether as a result of new information, future events, or otherwise unless required by the applicable securities laws.

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CNW 08:30e 17-NOV-22