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MediPharm Labs Receives First GMP Certification, Now Permitted to Serve Global Medical Cannabis Market

BARRIE, Ontario, Dec. 13, 2019 (GLOBE NEWSWIRE) -- MediPharm Labs Corp. (TSX: LABS) (OTCQX: MEDIF) (FSE: MLZ) ("MediPharm Labs" or the "Company") a global leader in specialized research-driven cannabis extraction, distillation and purification, today announced that the Australian Therapeutic Goods Administration (the "TGA") has notified the Company that its Canadian manufacturing facility meets the requirements for Good Manufacturing Practice for Medicinal Products ("GMP"), a key business breakthrough that increases MediPharm Labs' global manufacturing capabilities.

The TGA is the branch of the of the Australian Government's Department of Health responsible for regulating therapeutic goods including prescription medicines, vaccines and medical devices, and is one of 52 regulatory authority members of the Pharmaceutical Inspection Co-operation Scheme (PIC/S), an international co-operative that harmonizes GMP standards and quality systems of inspectorates in the field of medicinal products.

During an intensive audit under the TGA's clearance program for the overseas manufacture of medicine and Active Pharmaceutical Ingredients ("APIs") for supply to Australia, MediPharm Labs demonstrated that its state-of-the-art Canadian facility met the PIC/S GMP requirements as a Medicines Manufacturer of both Cannabis as a Medicine (oral liquids) in accordance with Part I of the PIC/S GMP guide and Cannabis as an API in accordance with Part II of the PIC/S GMP. The site was also successfully audited for chemical testing and analysis of cannabis as a medicine.

GMP Status: A Catalyst for Global Growth

MediPharm Labs received its certification less than 60 days from its TGA inspection, which was completed between October 14-16, 2019. While the certificate was issued by Australia's TGA to permit MediPharm Labs' Canadian facility to deliver APIs and final medicinal products to the Australian medical cannabis market, upon MediPharm Labs' Australian production facility receiving its GMP certificate, the Company will be positioned to leverage a global supply chain to sell cannabis APIs and finished products to countries across the EU, including Germany, due to a Mutual Recognition Agreement between Australia and the EU.

"I cannot overstate the importance and prestige of earning our first GMP certification," said Pat McCutcheon, Chief Executive Officer of MediPharm Labs. "GMP certification is *the* ticket to gaining access to the rapidly growing global medical cannabis market. And it is *the*

recognized standard by which pharmaceutical manufacturers and consumer packaged goods companies worldwide judge their supply partners. We thank the TGA for being the first to formally recognize the quality of our facilities and processes. Although this certification specifically applies to the Australian market, it adds to a body of evidence that will assist us in our quest to obtain the EU-GMP certification to directly sell into the EU market.”

First for An Extraction-Only Company in Canada

With the formal certificate now issued, MediPharm Labs is the first Canadian extraction-only cannabis company to announce TGA GMP certification, reflecting that the Company’s Canadian facility was purpose-built to GMP standards. This internationally recognized certification is only granted to companies that can demonstrate consistency, precision and quality in all stages of production and are able to comply with GMP principles for manufacturing Active Pharmaceutical Ingredients and final medicinal products.

Industry-Leading Capabilities

MediPharm Labs’ 70,000 square foot Canadian production facility in Canada features ISO standard built clean rooms, critical environments laboratories, commercial-scale distillation and chromatography R&D as well as multi-phase supercritical CO₂ primary extraction lines. The facility was built to be scalable and to serve markets inside and outside Canada. MediPharm Labs is permitted to conduct controlled human administration trials of dried cannabis, cannabis extracts and concentrates, distillates, oil, edibles, topicals and terpenes before they are used in the downstream formulation process as a result of receiving its Cannabis Research Licence under Health Canada’s Cannabis Act and Cannabis Regulations in October 2019.

“Today’s announcement is a key business breakthrough for MediPharm Labs that reflects the tremendous scientific and production knowledge resident in our workforce and our rigorous design, monitoring and production control environments,” said Mr. McCutcheon. “This is a well-earned achievement shared by all members of our team and one that sets us up for the next era of international growth as a competitively advantaged company.”

About the Pharmaceutical Inspection Co-operation Scheme

PIC/S seeks to harmonize inspection procedures worldwide by developing common standards in the field of GMP and by providing training to inspectors. It also aims at facilitating co-operation and networking between competent authorities, regional and international organizations, thus increasing mutual confidence. This is reflected in PIC/S’ mission, which is to lead the international development, implementation and maintenance of harmonised GMP standards and quality systems of inspectorates in the field of medicinal products. For more information, visit www.picscheme.org

About MediPharm Labs Corp.

Founded in 2015, MediPharm Labs specializes in the production of purified, pharmaceutical-like cannabis oil and concentrates and advanced derivative products utilizing a Good Manufacturing Practices certified facility and ISO standard built clean rooms. MediPharm Labs has invested in an expert, research driven team, state-of-the-art technology,

downstream purification methodologies and purpose-built facilities with five primary extraction lines for delivery of pure, trusted and precision-dosed cannabis products for its customers. Through its wholesale and white label platforms, they formulate, process, package and distribute cannabis extracts and advanced cannabinoid-based products to domestic and international markets. As a global leader, MediPharm Labs has completed commercial exports to Australia and is nearing commercialization of its Australian extraction facility. MediPharm Labs Australia was established in 2017.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING INFORMATION:

This news release contains “forward-looking information” and “forward-looking statements” (collectively, “forward-looking statements”) within the meaning of the applicable Canadian securities legislation. All statements, other than statements of historical fact, are forward-looking statements and are based on expectations, estimates and projections as at the date of this news release. Any statement that involves discussions with respect to predictions, expectations, beliefs, plans, projections, objectives, assumptions, future events or performance (often but not always using phrases such as “expects”, or “does not expect”, “is expected”, “anticipates” or “does not anticipate”, “plans”, “budget”, “scheduled”, “forecasts”, “estimates”, “believes” or “intends” or variations of such words and phrases or stating that certain actions, events or results “may” or “could”, “would”, “might” or “will” be taken to occur or be achieved) are not statements of historical fact and may be forward-looking statements. In this news release, forward-looking statements relate to, among other things, execution of the Company’s business strategy (including sale into the global medical market and sale of APIs or sale of finished goods), GMP certification of the Australian facility and leveraging of a global supply chain. Forward-looking statements are necessarily based upon a number of estimates and assumptions that, while considered reasonable, are subject to known and unknown risks, uncertainties, and other factors which may cause the actual results and future events to differ materially from those expressed or implied by such forward-looking statements. Such factors include, but are not limited to: general business, economic, competitive, political and social uncertainties; the inability of MediPharm Labs to obtain adequate financing; the delay or failure to receive regulatory approvals; and other factors discussed in MediPharm Labs’ filings, available on the SEDAR website at www.sedar.com. There can be no assurance that such statements will prove to be accurate, as actual results and future events could differ materially from those anticipated in such statements. Accordingly, readers should not place undue reliance on the forward-looking statements and information contained in this news release. Except as required by law, MediPharm Labs assumes no obligation to update the forward-looking statements of beliefs, opinions, projections, or other factors, should they change.



Source: MediPharm Labs Corp.