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MediPharm Labs Australia Granted GMP Certificate and Licence to Manufacture Therapeutic Goods; On Track to Ramp Up and Fulfill New Supply Agreements

BARRIE, Ontario, May 07, 2020 (GLOBE NEWSWIRE) --**MediPharm Labs Corp.**, (TSX: LABS) (OTCQX: MEDIF) (FSE: MLZ) (“MediPharm Labs” or the “Company”) a global leader in specialized, research-driven pharmaceutical-quality cannabis extraction, distillation and derivative products, is delighted to announce that its subsidiary, **MediPharm Labs Australia Pty. Ltd.** (“MediPharm Labs Australia”) has been granted its GMP Certification and Licence to Manufacture Therapeutic Goods, a key milestone in the advancement of the Company’s global supply chain strategy and a catalyst for revenue generation in Australia.

The Licence was granted by the Australian Therapeutic Goods Administration (the “TGA”) – the branch of the Australian Government’s Department of Health responsible for regulating therapeutic goods including prescription medicines, vaccines and medical devices. The TGA is one of 53 regulatory authority members of the [Pharmaceutical Inspection Co-operation Scheme \(PIC/S\)](#), an international co-operative arrangement among regulatory authorities in the field of Good Manufacturing Practice (“GMP”) for medicinal products. The PIC/S mission is to lead the development, implementation and maintenance of harmonised GMP standards and quality systems of inspectorates in the field of medicinal products. Many PIC/S members, such as the TGA, also enter into mutual recognition agreements with other PIC/S members whereby each regulatory authority specifically recognizes certain processes and procedures of the other country to expedite the international flow of goods.

The Licence confirms that MediPharm Labs Australia complies with the internationally recognized GMP requirements of the PIC/S Guide for Medicinal Products and allows the manufacture of therapeutic goods intended for export or which are exempt from registration and listing on the Australian Register of Therapeutic Goods under the provisions of Section 18(1) or Section 19 (1)(a) of the Therapeutic Goods Act.

Under the Licence, MediPharm Labs Australia may store cannabis resin as an Active Pharmaceutical Ingredient (“API”) and may engage in packaging, storage and release for supply as a Medicine Manufacturer of Oral Liquids within its specialized facility in Wonthaggi, Victoria.

“As a GMP-compliant company situated in the emerging Asia-Pacific cannabis market, this is a milestone achievement and essential licence that clears the way for MediPharm Labs

Australia to further accelerate supply opportunities, at home and abroad, and begin fulfilling our pipeline of customer orders for finished, formulated products,” said Warren Everitt, Chief Executive Officer, Asia Pacific, MediPharm Labs. “This Licence is also emblematic of the tremendous duty of care we took in building our capabilities to the high standards required of GMP. MediPharm Labs Australia can now serve as a key link in the Company’s international GMP-compliant supply chain complementing our state-of-the-art GMP certified facility in Canada.”

In 2020, MediPharm Labs Australia has secured several medicinal cannabis supply agreements for both Australia and New Zealand reflecting the growing commercial opportunity in these markets. With this licence in place, it expects to ramp up supply of GMP-compliant products and begin fulfilment of new and upcoming supply agreements upon receiving final product approvals.

“We set out to make MediPharm Labs Australia the first mover in Australia and other quickly emerging Asian-Pacific markets for the production of pharma-quality cannabis products. With this new Licence, we have achieved that and more,” said Pat McCutcheon, CEO of MediPharm Labs. “This Licence gives us an invaluable edge in the domestic Australian market by signalling to customers that our Company is the one to align with for the highest quality production. From a global market perspective, the TGA has mutual recognition agreements with various other PIC/S members, which means that products we make in Australia will satisfy certain requirements in those other jurisdictions where we intend to seek import permits for our products. Accordingly, this development has wide-reaching implications for our business.”

Construction of the MediPharm Labs Australia facility began in 2018 and was completed in December 2019. Also in December 2019, MediPharm Labs Australia received State Licences for cannabis substances from the Department of Health and Human Services in Victoria, Australia. Under these State Licences, MediPharm Labs Australia is allowed to manufacture, store, and supply cannabis products and medicines and, for research purposes, test cannabis at its facility. MediPharm Labs Australia also has its Cannabis Manufacturing Licence from the Australian Office of Drug Control (ODC) under the Narcotic Drugs Act 1967. MediPharm Labs Australia holds ODC Import and Export Licences, allowing import and export of cannabis resin and extracts, bulk medicinal cannabis oil and finished medicinal cannabis products.

MediPharm Labs Australia was designed to replicate the high-quality standards of the Company’s Canadian production facility. It features multi-phase supercritical CO₂ extraction equipment, softgel capsule manufacturing equipment, clean rooms and testing laboratories and has TGA manufacturing approval for labelling and packaging lines.

About GMP

Good Manufacturing Practices are defined by the Quality Systems that relate to: Premises and Equipment; Personnel; Production Systems (Processing and Sanitation); Laboratory Controls; Materials System; Packaging & Labeling System; and the Overall Quality Management System. As such, MediPharm Labs Australia has been proactively working towards receiving its GMP certification since its inception in June 2017 through the specialized design and construction of its facility, by the hiring of its expert team with experience operating in pharmaceutical GMP environments, and through the selection of

manufacturing technology which has been validated as meeting GMP requirements. Achieving GMP certification has been a complex, multi-year project with a series of milestones that involved multijurisdictional licenses and permits, building and documenting internal control systems, validating suppliers and equipment, and finally, successfully completing audits from regulators.

About MediPharm Labs

Founded in 2015, MediPharm Labs specializes in the production of purified, pharmaceutical-quality cannabis oil and concentrates and advanced derivative products utilizing a Good Manufacturing Practices certified facility with 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, MediPharm Labs formulates, develops (including through sensory testing), processes, packages and distributes 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.

For further information, please contact:

Laura Lepore, VP, Investor Relations and Communications

Telephone: 416-913-7425 ext. 1525

Email: investors@medipharmlabs.com

Website: www.medipharmlabs.com

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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, revenue generation in Australia; expediting the international flow of goods under mutual recognition agreements; accelerating supply opportunities in Australia and abroad; fulfilling a pipeline of customer orders for finished products; ramping up supply of GMP-compliant product; and satisfaction of Company products of requirements under mutual recognition agreements and application of related import permits. 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.