



Proteomics International

LABORATORIES LTD

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CE Mark for PromarkerD Immunoassay Kit

- **CE Mark registration received for the PromarkerD Immunoassay - the high-throughput version of the PromarkerD test system used to predict the onset of kidney disease in patients with type 2 diabetes**
- **The PromarkerD[#] test system is the only test available in the Europe Union (EU) for predicting the onset of diabetic kidney disease (DKD)**
- **In Europe 60 million adults have diabetes and 1 in 3 currently have chronic kidney disease, representing a significant public health issue**
- **Registration complements the recent CE Mark for the PromarkerD software Hub and PromarkerD (MS)[#] giving a comprehensive package of EU approvals and a foundation for future regulatory approvals in other jurisdictions, specifically US FDA registration**
- **CE Mark registration anticipated to expedite execution of the licensing and sales of PromarkerD throughout Europe**

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ), a pioneer in predictive diagnostics, announces it has secured CE Mark registration for its PromarkerD Immunoassay kit as an IVD medical device (in vitro diagnostic).

PromarkerD (IA)[#] forms part of the PromarkerD[#] test system which is the only test available in the Europe Union (EU) for predicting the onset of diabetic kidney disease (DKD). The PromarkerD Immunoassay is the high-throughput version of the already CE Marked PromarkerD (MS) Mass Spectrometry test system. This will allow a greater number of prospective laboratories to process much higher numbers of samples at a more cost effective rate.

PromarkerD was registered for use in the EU as part of the Company's program of regulatory and reimbursement registrations.

The PromarkerD test system assesses the risk of DKD in patients with type 2 diabetes. Chronic kidney disease is one of the major complications arising from diabetes and if unchecked can lead to dialysis or kidney transplant.

PromarkerD is a simple, low-cost blood test that uses a unique protein 'fingerprint' to detect the onset of disease up to four years before clinical symptoms appear. The early detection and prevention or treatment of DKD is a major focus of both global pharmaceutical companies and government health departments.

The CE Mark is a significant commercialisation step for Proteomics International providing, as it does, assurance to potential licensing partners and consumers that the product has been developed and manufactured to meet EU safety, health and environmental protection requirements.

Dr Richard Lipscombe, Managing Director of Proteomics International said, *"The CE Mark is another important milestone for PromarkerD as we move forward with new deals in the region. With CE*

Proteomics International Laboratories Ltd

ABN 78 169 979 971

Box 3008, Broadway, Nedlands, WA 6009, Australia

T: +61 8 9389 1992 | E: enquiries@proteomicsinternational.com | W: www.proteomicsinternational.com

Mark the immunoassay offers a higher-throughput option for testing laboratories who want access to our ground-breaking test for predicting diabetic kidney disease - one that could enable earlier therapeutic intervention to minimise the effect of this crippling disease."

CE marking of the PromarkerD Immunoassay complements the recent CE registration of the mass spectrometry version of the test, PromarkerD (MS) [ASX: 12 November 2019] and software hub [ASX: 14 January 2020].

Achieving CE Mark registration for the PromarkerD (IA)[#] provides a strong foundation for PromarkerD to receive US FDA approval. Proteomics International intends to lodge the US FDA application in mid-year 2020.

The World Health Organisation estimates the European Region is home to 60 million adults with diabetes, and currently 1 in 3 have chronic kidney disease. PromarkerD could aid clinical decision-making by identifying at-risk individuals for earlier therapeutic intervention to help to minimise the effect of the disease, and potentially save healthcare systems billions of dollars.

Authorised by Dr Richard Lipscombe (Managing Director) on behalf of the Board of PIQ.

Definitions:

"Promarker" - the proprietary technology used to discover and evaluate proteins for use as diagnostics

"PromarkerD/PromarkerD test system" - the patented predictive diagnostic test for Diabetic Kidney Disease

"PromarkerD (MS)" - the predictive diagnostic test for Diabetic Kidney Disease using Mass Spectrometry

"PromarkerD (IA)" - the predictive diagnostic test for Diabetic Kidney Disease using ImmunoAssay

"PromarkerD Hub" - the proprietary software tool used to calculate the risk of Diabetic Kidney Disease in diabetes patients

ENDS

About PromarkerD (www.PromarkerD.com)

The PromarkerD test system assesses the risk of diabetic kidney disease (DKD) in patients with type 2 diabetes. Chronic kidney disease is one of the major complications arising from diabetes and if unchecked can lead to dialysis or kidney transplant. PromarkerD is a simple blood test that uses a unique protein 'fingerprint' to provide an early detection of the onset of disease. In clinical studies published in leading journals PromarkerD correctly predicted 86% of otherwise healthy diabetics who went on to develop chronic kidney disease within four years.

Further information is available through the PromarkerD web portal.

About Proteomics International Laboratories (PILL) (www.proteomicsinternational.com)

Proteomics International (Perth, Western Australia) is a wholly owned subsidiary and trading name of PILL (ASX: PIQ), a medical technology company at the forefront of predictive diagnostics and bio-analytical services. The Company specialises in the area of proteomics – the industrial scale study of the structure and function of proteins. It received the world's first ISO 17025 laboratory accreditation for proteomics services, and operates from state-of-the-art facilities located on Perth's QEII Medical Campus.

Proteomics International's business model is centred on the commercialisation of the Company's world-leading test for diabetic kidney disease, PromarkerD. The Company offsets the cash burn from R&D and product development through provision of specialist analytical services, whilst using its proprietary Promarker™ technology platform to create a pipeline of novel diagnostic tests.

For further information please contact:

Dr Richard Lipscombe
Managing Director
Proteomics International Laboratories Ltd
T: +61 8 9389 1992
E: enquiries@proteomicsinternational.com

Dirk van Dissel
[Corporate Advisor & Investor Relations]
Adelaide Equity Partners
T: +61 408 326 367
E: dvandissel@adelaideequity.com.au

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