



Proteomics International

LABORATORIES LTD

ASX Release
14 January 2020

ASX code: PIQ

CE Mark for PromarkerD Hub

- **CE Mark registration received for the PromarkerD Hub - a software tool used to calculate the risk of kidney disease in patients with type 2 diabetes**
- **Registration complements the recent CE Mark for PromarkerD (MS)[#] giving a complete package of approvals for PromarkerD in the EU and a significant foundation for future regulatory approvals in other jurisdictions, specifically US FDA registration**
- **The proprietary PromarkerD Hub software algorithm provides another level of IP protection on top of the Company's granted biomarker patents**
- **Proteomics International now to seek CE Mark registration of the PromarkerD immunoassay, which successfully completed stability testing in December**
- **CE Mark registration anticipated to expedite execution of the licensing and sales of PromarkerD throughout Europe, where 60 million adults have diabetes and 1 in 3 currently have chronic kidney disease**

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) announces it has secured CE Mark registration for the PromarkerD Hub as an IVD medical device (in vitro diagnostic). PromarkerD Hub is a software tool used to calculate the risk of kidney disease in patients with type 2 diabetes. It 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).

CE marking of the PromarkerD Hub complements the recent CE registration of the mass spectrometry version of the test, PromarkerD (MS) [ASX: 12 November 2019].

Dr Richard Lipscombe, Managing Director of Proteomics International said, *"This is an exciting time for our Company as we pursue licensing and sales of PromarkerD throughout Europe - with CE Mark registration of both PromarkerD Hub and our pioneering PromarkerD (MS) test, we now have a complete package of approvals in the EU. We also have a significant foundation for future regulatory approvals in other jurisdictions, with the next target beyond CE Mark being US FDA registration."*

Proteomics International will now prepare a datapack for CE Mark registration of the PromarkerD immunoassay, which was recently validated [ASX: 17 September], and in December successfully completed stability testing. It is anticipated that the PromarkerD immunoassay CE Mark application will be lodged in the current quarter.

The CE Mark provides assurance to potential licensing partners and consumers in the EU that the product has been developed and manufactured to meet EU safety, health and environmental protection requirements.

The PromarkerD Hub is an integral component of the PromarkerD test system and processes data obtained from the PromarkerD mass spectrometry (MS) or immunoassay (IA) technology platforms.

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It provides a flexible portal for uploading test results and generating reports of prognosis and diagnosis risk scores for patients anywhere in the world.

Achieving CE Mark registration for the PromarkerD test system and in particular PromarkerD (IA)[#] will build a solid case for PromarkerD to receive US FDA approval. Proteomics International intends to lodge the US FDA application by mid-year 2020.

The PromarkerD Hub was granted TGA regulatory approval for export use last year [ASX: 29 July 2019]. The hub's proprietary software algorithm provides another level of IP protection on top of the Company's biomarker patents already granted in multiple jurisdictions (including the EU, USA, Japan and China).

The World Health Organisation estimates the European Region is home to 60 million adults with diabetes, and currently approximately 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.

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

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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. PromarkerD recently launched in Spain through Proteomics International's partnership with Patia Europe.

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.

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