



Proteomics International

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Proteomics International achieves CE Mark for world's first predictive test for diabetic kidney disease PromarkerD (MS)[#]

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ), a pioneer in predictive diagnostics, announces it has secured CE Mark registration for PromarkerD (MS) as an IVD medical device (in vitro diagnostic). PromarkerD is the world-leading test for predicting the onset of diabetic kidney disease. PromarkerD was registered for use in the European Union (EU) as part of the company's program of future asset registration.

The PromarkerD test system assesses the risk of diabetic kidney disease 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 detect the onset of disease up to four years before clinical symptoms appear.

CE marking provides a significant step for Proteomics International to license and sell PromarkerD throughout the European Union. The registration is for the mass spectrometry version of the test, PromarkerD (MS), and lays the groundwork for future CE marking of PromarkerD on other technology platforms such as the recently validated PromarkerD immunoassay [ASX: 17 September]. The CE Mark provides assurance to EU consumers that the product has been developed and manufactured to meet EU safety, health and environmental protection requirements.

"The CE Mark is another important milestone for PromarkerD as we move forward with new deals in the region," said Dr Richard Lipscombe, Managing Director of Proteomics International. "CE Mark registration reflects the strength of the clinical and technical data that we have collected in developing our ground-breaking test that could help save healthcare systems billions of dollars".

The CE Mark registration follows the launch of PromarkerD in Spain, where diabetes affects 10 per cent of the adult population or 3.6 million people [ASX: 13 September]. The PromarkerD (MS) test was launched in September in partnership with clinical diagnostics provider Atturos (Ireland) [ASX: 12 September] and under an exclusive two-year licence agreement with Patia Europe for the region of Spain.

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 and help to minimise the effect of the disease.

Definitions:

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

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

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

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

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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

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 8 8232 8800
E: dvandissel@adelaideequity.com.au