



Proteomics International

LABORATORIES LTD

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PromarkerD international validation study results published in Journal of Clinical Medicine

Medical Technology company Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) is pleased to announce the publication of the successful validation results from a major multi-centre clinical study confirming the effectiveness of PromarkerD as a predictive test for diabetic kidney disease.

The findings have been published online as an early version of the internationally peer-reviewed Journal of Clinical Medicine in a paper titled '*PromarkerD Predicts Renal Function Decline in Type 2 Diabetes in the Canagliflozin Cardiovascular Assessment Study (CANVAS)*'¹. These results were first presented at the world's leading diabetes conference, the 80th Scientific Sessions of the American Diabetes Association (ADA) [ASX: 15 June].

The joint publication between Proteomics International, The University of Western Australia Medical School and Janssen Research and Development is the first external validation study of PromarkerD which confirms the prognostic utility of the test for incident chronic kidney disease (CKD).

PromarkerD scores were measured at baseline ('Year 0') in 3,568 patients with type 2 diabetes with pre-existing high-risk of cardiovascular disease from the completed four-year phase 3 CANVAS clinical trial. The primary finding of the publication is that PromarkerD accurately predicted which patients in the trial would develop clinically significant CKD during the four-year period.

The participants in the study had a median PromarkerD score of 2.9%, with 70.5% categorised as low-risk, 13.6% as moderate-risk and 15.9% as high-risk for developing CKD. Patients predicted by PromarkerD to be at high-risk of CKD were 13.5 times more likely than the low-risk group to develop the disease, with the results showing high statistical significance ($P = 1.3 \times 10^{-104}$).

In addition, the Authors observed that the results from this group of diabetes patient at high-risk of cardiovascular disease showed differences from previous publications in community-based diabetes patients². This highlights pathways that can be explored to refine the renal decline algorithm for such patients and forms part of the Company's on-going collaboration with Janssen [ASX: 31 March].

Proteomics International managing director Dr Richard Lipscombe, also senior author on the paper, said this was a pivotal study for the Company. "*Peer-reviewed publications form an essential component of PromarkerD's adoption by Key Opinion Leaders and the wider diabetes community. The clinical data will now form an important part of the evidence in an application for FDA regulatory approval of the PromarkerD test system,*" he said.

Authorised by Terry Sweet (Chair) on behalf of the Board of PIQ.

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¹ J. Clin. Med. (2020) 9, 3212; doi.org/10.3390/jcm9103212

² J. Diabetes Complic. (2019) 33, 107406; doi.org/10.1016/j.jdiacomp.2019.07.003

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About PromarkerD (www.PromarkerD.com)

PromarkerD is a predictive test for the early detection of chronic kidney disease (CKD) in patients with type-2 diabetes. CKD is one of the major complications arising from diabetes and if unchecked can lead to dialysis or kidney transplant.

The patented PromarkerD test system uses a simple blood test to detect a unique 'fingerprint' of the early onset of disease by measuring three serum proteins (ApoA4, CD5L and IGFBP3), combined with three routinely available conventional clinical variables (age, high-density lipoprotein (HDL)-cholesterol and estimated glomerular filtration rate (eGFR)).

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. The PromarkerD immunoassay, the PromarkerD mass spectrometry assay, and the PromarkerD software hub have each achieved CE Mark registration in the European Union.

Further information is available through the PromarkerD web portal.

To visit the PromarkerD ADA virtual booth please see: www.PromarkerD.com/product

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 high-speed, low cost predictive 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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