



Proteomics International

LABORATORIES LTD

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Proteomics International to resubmit application for PromarkerD listing on Australian Medicare Benefits Schedule

- **Australia's Medical Services Advisory Committee (MSAC) denies initial application for the PromarkerD test for diabetic kidney disease to be included in the Medicare Benefits Schedule**
- **In reaching its decision not to support public funding of PromarkerD testing, MSAC acknowledged its introduction could save the healthcare system money in the long term**
- **MSAC were primarily concerned about the cost of the test and the lack of sufficient data on how use of PromarkerD would change clinical practice, which the Company will now work to address**
- **Decision comes after UK's National Institute for Health and Care Excellence (NICE) published a briefing supporting PromarkerD's effectiveness and the American Medical Association issued a new dedicated CPT Proprietary Laboratory Analyses (PLA) reimbursement code for PromarkerD**
- **Independent application for regulatory approval of PromarkerD by the Australian Therapeutic Goods Administration (TGA) remains on-going**
- **Peer-reviewed studies have demonstrated PromarkerD is effective and that, if available, clinicians would use the test to help manage their diabetes patients**

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) announces that it will resubmit its application to have the PromarkerD predictive test for diabetic kidney disease (DKD) included in the Australian Medicare Benefits Schedule (MBS) after its initial application was denied. The MBS review relates to having the cost of the test reimbursed in Australia and does not relate to the regulatory approval process.

The application for listing PromarkerD testing on the MBS was denied at first instance by Australia's Medical Services Advisory Committee (MSAC). Proteomics International notes that the majority of first-time submissions to the MBS and Pharmaceutical Benefit Scheme (PBS) are denied^{1,2} and therefore, it intends to resubmit its application for PromarkerD to be covered under the MBS after completing a debriefing with MSAC and preparing any necessary new documentation.

The Company believes there is strong evidence that PromarkerD testing can both improve patient quality of life and deliver significant savings for health care systems, through fewer patients requiring dialysis and kidney transplants and is looking forward to re-engaging with MSAC to respond to its queries.

The MSAC decision not to support public funding of PromarkerD testing in Australia comes after key bodies in the Company's target markets of the USA and UK moved towards endorsing the test.

The American Medical Association recently approved a new dedicated CPT® Proprietary Laboratory Analyses (PLA) reimbursement code for PromarkerD, which is a critical step towards the test being covered

¹ Parliament of Australia Medical Services Advisory Committee

² Medicines Oncology Industry Taskforce (2013) Deloitte Access Economics

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by both Medicare & Medicaid and private health insurers in the USA, and thereby enabling affordable access and broad adoption of the test in the USA [ASX: 3 January].

In December, the UK's National Institute for Health and Care Excellence (NICE) published a Medtech Innovation Briefing reporting that PromarkerD is effective at predicting renal function decline in people with type 2 diabetes. The briefing, known as NICE advice is an important stepping stone towards inclusion in the NICE Guidelines and broad adoption of the test in the UK [ASX: 14 December 2022].

In reaching its decision, Australia's MSAC were primarily concerned about the cost of the test and the lack of sufficient data on how the use of PromarkerD would change clinical practice and improve outcomes for patients. The Company is confident it can provide the necessary information to address these items, along with addressing specific technical queries which the Committee also raised.

Despite these concerns, the MSAC commentary identified a potential wide uptake of the test, and that "In the long term (likely greater than 6 years), the use of PromarkerD was predicted to lead to lower PBS and MBS costs due to the prevention or delay of onset of DKD, primarily through the avoidance of procedures such as dialysis and kidney transplants along with associated medication costs". Proteomics International also notes that the calculated incremental cost-effectiveness ratio (ICER) for introducing PromarkerD was estimated to be \$3,615 per quality-of-life year (QALY) gained, which is well below accepted cost thresholds for adoption of new treatments^{3, 4}.

Proteomics International has assembled a comprehensive body of evidence to support its first-in-class test and has published multiple clinical studies covering over 4,000 patients demonstrating the strong performance of PromarkerD for predicting DKD and that the test outperforms current standard-of-care. Clinician engagement surveys in the USA and Australia have also been highly positive, with the clinical utility survey submitted with the application indicating that 98% of Australian doctors were likely to order the test for their type 2 diabetes patients.

Proteomics International Managing Director Dr Richard Lipscombe said the Australian decision was frustrating for the Company. *"This home grown innovation has traction in both the US and UK, and whilst Australia is not a major market for us in terms of size, we do not want to see the Australian public forced to either pay for PromarkerD out of their own pockets or miss out on the potentially life-saving test. Consequently, we look forward to re-engaging with MSAC to address concerns and to clarify any misunderstandings which may have detracted from the Committee approving the application."*

Proteomics International completed the 'pre-assessment' phase of its application to MSAC in February 2022 [ASX: 22 February 2022] and submitted a full application in June 2022 for the 'assessment' stage of the process, which includes evaluation by a second sub-committee and consideration from the full MSAC. The MSAC meeting was held on 24-25 November 2022 to consider the proposal to include PromarkerD on the MBS, and the official outcome was released today⁵.

The Company notes that MSAC's decision on reimbursement is not linked to the separate application for regulatory approval of the PromarkerD immunoassay kit by the Australian Therapeutic Goods Administration which is still ongoing [ASX: 2 June 2022].

Authorised by the Board of Proteomics International Laboratories Ltd (ASX:PIQ).

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About PromarkerD (www.PromarkerD.com)

Diabetic kidney disease (DKD) is a serious complication arising from diabetes which if unchecked can lead to dialysis or kidney transplant. PromarkerD is a prognostic test that can predict future kidney function decline in patients with type 2 diabetes and no existing DKD. The patented PromarkerD test system uses a simple blood test to detect a unique 'fingerprint' of the early onset of the disease by measuring three serum

³ www.pbs.gov.au/info/general/working-groups/amwg

⁴ Lew (2019); doi.org/10.17061/phrp2921913

⁵ www.msac.gov.au/internet/msac/publishing.nsf/Content/1691-public

protein biomarkers, combined with three routinely available conventional clinical variables (age, HDL-cholesterol and estimated glomerular filtration rate (eGFR)). A cloud-based algorithm integrates the results into a patient risk report. In clinical studies published in leading journals PromarkerD correctly predicted up to 86% of otherwise healthy diabetics who went on to develop diabetic kidney disease within four years. The PromarkerD test is CE Mark registered in the European Union.

Further information is available through the PromarkerD web portal.

To visit the PromarkerD 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. Proteomics International's mission is to improve the quality of lives by the creation and application of innovative tools that enable the improved treatment of disease.

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