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US Medicare sets reimbursement price for PromarkerD and Australian regulatory decision

- **Centers for Medicare & Medicaid Services (CMS) list PromarkerD predictive test for diabetic kidney disease and assign payment rate of US$390.75 in the United States**
- **CMS is the single largest payer for health care in the United States, with Medicare and Medicaid collectively responsible for 42 per cent of healthcare spending and providing health coverage to more than 100 million Americans**
- **The Australian Therapeutic Goods Administration (TGA) advises decision not to include the PromarkerD test in the Australian Register of Therapeutic Goods (ARTG) due primarily to change of manufacturer**
- **TGA decision does not affect Proteomics International's activities in its primary markets of the United States and Europe**
- **Approximately 32 million adults live with diabetes in the United States and 61 million in Europe, as compared to 1.5 million in Australia**

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) is pleased to announce a major milestone in the commercialisation of its predictive test for diabetic kidney disease, PromarkerD, with the US Centers for Medicare & Medicaid Services (CMS) setting a national reimbursement price for the test in the United States.

Centers for Medicare & Medicaid Services (US)

The CMS is the federal agency in the United States that is responsible for providing health coverage to more than 100 million Americans through Medicare and Medicaid. The reimbursement rate set by CMS applies to all patients accessing government-funded healthcare in the United States. Medicare covers health care costs for people over the age of 65, while Medicaid covers eligible low-income Americans. CMS is the single largest payer for health care in the United States, with Medicare and Medicaid collectively responsible for 42 per cent of healthcare spending[1].

In its preliminary pricing determination CMS has assigned a payment rate of US$390.75 for PromarkerD, which is to be delivered through Sonic Healthcare USA [ASX: 10 May 2023]. The rate, set by the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests, is expected to become final after a 30 day period of public comment, and then become effective from 1 January 2024.

Proteomics International Managing Director Dr Richard Lipscombe said, *"We thank our licence partner, Sonic Healthcare USA for their leading role in attaining this CMS list pricing, which is a key milestone under our agreement. CMS reimbursement will enable affordable access to PromarkerD for millions of Americans and help drive broad adoption of the test. As we prepare for the US launch of PromarkerD, the CMS price is an essential component of the roll-out strategy, both because of the number of people it covers, and because many private payers follow CMS pricing."*

[1] www.kff.org/mental-health/issue-brief/10-things-to-know-about-medicaid/

The reimbursement price comes after the American Medical Association (AMA) approved a unique CPT® Proprietary Laboratory Analyses (PLA) code 0385U for PromarkerD earlier this year [ASX: 3 January].

Therapeutic Goods Administration (Australia)

Separately, Proteomics International has been advised by the Australian Therapeutic Goods Administration (TGA) of its decision not to include the PromarkerD test in the Australian Register of Therapeutic Goods (ARTG).

The TGA decision temporarily impacts the ability of the Company to sell its test in Australia but does not affect the Company's activities in the United States, where the test is using the CLIA Laboratory Developed Test (LDT) framework, or Europe, where PromarkerD is CE Mark registered.

Proteomic International's request for Australian registration was for the Company's immunoassay version of the PromarkerD test which was originally manufactured in Australia, and has since been transferred to an ISO 13485 manufacturer in Europe [ASX: 16 June 2022]. The application was based upon data collected using the Company's mass spectrometry analytical platform, with supplementary data being provided from its Australian manufactured immunoassay. The Company submitted its application to the TGA in May 2022 and responded to two requests for additional information.

In reaching its decision the TGA indicated that the submitted information did not contain adequate detail to enable the registration of the product that is intended for sale, and primarily that the clinical and analytical data needed to be predominately collected on the currently manufactured version of the test (i.e. immunoassay version manufactured in Europe). These issues were not advised to the Company during the review process and thus it did not have the opportunity to address them prior to receiving the notification.

Proteomics International is confident in the robustness of its published data on PromarkerD and from its current immunoassay manufacturing process. The immunoassay version of PromarkerD has also been used successfully to generate results, in collaboration with Janssen Research & Development, to demonstrate the beneficial effect of canagliflozin treatment on reducing PromarkerD risk scores [ASX: 3 May 2023]. Consequently, the Company will now consider its alternatives to address the items that the TGA has raised. The outcome of the TGA's decision does not affect the Company's commercialisation efforts in its primary markets of the USA and Europe.

In the United States an estimated 32 million people—or 11 per cent of the adult population—live with diabetes and in Europe there are 61 million (7%), in contrast, Australia has 1.5 million adults (6.4%) living with diabetes[2]. The total cost of diabetic kidney disease (DKD) is USD 130 billion per year in the US alone[3], according to the US Renal Data System.

Proteomics International Managing Director Dr Richard Lipscombe said, *"The Company's immediate focus is firmly on the major markets of the USA and Europe. The CMS pricing of US$390 per test in the US is testament to the clear value the PromarkerD test can deliver to the US health system, whilst our existing CE Mark registration underpins our plans to access the European market."*

Early diagnosis of DKD using PromarkerD can help inform doctors' treatment decisions to improve clinical outcomes for patients [ASX: 2 August 2022], whilst published research shows early intervention with an SGLT2-inhibitor class drug leads to a significant reduction in the PromarkerD risk scores for developing DKD (SGLT2-inhibitors are a widely used diabetes drug, now also indicated for the treatment of DKD) [ASX: 3 May 2023]. Reducing or delaying the progression of the disease would reduce the incidence of dialysis and kidney transplant, improving quality of life for patients and saving healthcare systems millions of dollars.

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

ENDS

2 International Diabetes Federation Diabetes Atlas 10th edition, 2021

3 US Renal Data System 2020

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 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.

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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