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US FDA provides 513(g) response for PromarkerD

- **The US Food & Drug Administration (FDA) 513(g) application sought to determine the best product classification and regulatory path for PromarkerD in the USA**
- **FDA advises that an application through the De Novo classification pathway is appropriate**
- **The primary and immediate route to market for PromarkerD in the US remains the LDT (Laboratory Developed Test) path through CLIA (Clinical Laboratory Improvement Amendments) certified labs**

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) is pleased to report that it has received notification from the United States Food and Drug Administration (FDA) that its PromarkerD test system for diabetic kidney disease should follow a De Novo classification pathway for regulatory approval.

This guidance follows the Company's 513(g) application to the FDA made in April 2021 [ASX: 29 April], with the response delayed due to COVID-19 related resource limitations.

The De Novo pathway for medical device marketing in the US was added by the FDA to address novel devices of low to moderate risk, such as blood tests, that do not have a valid predicate device, i.e. there is no similar device already approved[1]. The FDA advised that PromarkerD was considered closest to the Acute Kidney Injury Test System, but found that the 510(k) product classification route was not available because currently there was no substantially equivalent device.

The FDA also commented that the use of multiple markers, a proprietary algorithm, and the predictive result output were each considered novel in relation to diabetic kidney disease. Consequently, the FDA advised that PromarkerD is suitable for the De Novo classification. The Company considers that the De Novo classification recognises the novel attributes of PromarkerD and will have marketing advantages upon successful approval from the FDA.

The Company will now prepare a full product application to the FDA proposing the PromarkerD test system as a Class IIa IVD (In Vitro Diagnostic). It is expected the Company will submit this application in Q1 CY22, with the FDA timeline for review of such applications being approximately 12 months. The timing of the product application will enable the inclusion of Proteomics International's new ISO 13485 contract manufacturing capability [ASX: 12 August] and its Janssen Stage 2 data [ASX: 16 July].

Whilst the Company is pursuing FDA approval, the primary and immediate route to market for PromarkerD in the US remains the LDT (Laboratory Developed Test) path through CLIA (Clinical Laboratory Improvement Amendments) certified labs, which allows sales to commence prior to any FDA approval. Proteomics International is in advanced discussions with several parties regarding bringing PromarkerD to the US market.

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

ENDS

[1] www.fda.gov/medical-devices

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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 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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