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Study demonstrates major economic health benefit of PromarkerD - PromarkerD reimbursement update

- **Independent modelling estimates instigating PromarkerD testing could produce net savings for US payors of US$862 million over four years per million type 2 diabetes patients tested**
- **The study provides validation of the potential economic health benefit of PromarkerD in diabetic kidney disease management, which improves the likelihood that the test will be reimbursed by payors**
- **Results will be released online ahead of presentation at Virtual ISPOR 2021, the world's leading conference for health economics and outcomes research, from 17-20 May 2021**
- **Proteomics International to seek a CPT Proprietary Laboratory Analyses (PLA) code to facilitate the reimbursement of the innovative PromarkerD test by payors in the US**

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) is pleased to announce the results of an economic health benefit study for PromarkerD following comprehensive economic modelling and consultation with key industry stakeholders. The Company is set to seek a CPT Proprietary Laboratory Analyses (PLA) reimbursement code for its innovative PromarkerD test for diabetic kidney disease.

Independent consultant Boston Healthcare Associates modelled the budget impact of a proactive testing regime using PromarkerD for assessing diabetic kidney disease in patients with type 2 diabetes, compared to the current standard of care. The study found that, at US$150 a test, and over four years, PromarkerD produced estimated savings of up to US$2.4 billion against costs of US$1.5 billion for every million type 2 diabetes patients tested.

The modelling showed instigating PromarkerD testing produced estimated net savings for payors of US$862 million over four years per million patients tested. The savings primarily arise from slowing the progression of diabetic kidney disease against costs from increased testing and the use of preventative medications.

Proteomics International managing director Dr Richard Lipscombe said, "*With PromarkerD testing, patients may delay or avoid costly end outcomes such as dialysis and kidney transplants. Given there are approximately 31 million diabetics in the United States alone, the economic benefit of PromarkerD is clearly evident*."

Boston Healthcare Associates and Proteomics International will present the modelling at the annual conference of the Professional Society for Health Economics and Outcomes Research, Virtual ISPOR 2021, the world's leading conference for health economics, from 17-20 May 2021. The event is typically attended by global healthcare leaders, including policy makers, payors and health economists.

Proteomics International will now pursue a reimbursement code for PromarkerD based on its extensive engagement with expert panels representing physicians, laboratories and payors, including national and regional entities. Securing a reimbursement code will facilitate the reimbursement of the PromarkerD test by insurance companies and other payors in the US.

A CPT Proprietary Laboratory Analyses (PLA) code uniquely identifies a test for the laboratory and the payors. Reimbursement codes and payer coverage in the US are initiated through the American Medical Association (AMA) and its Current Procedural Terminology (CPT) Editorial Panel. The approval and acceptance of a PLA code follows assessment of the economic health benefit and clinical utility of a new test.

Dr Lipscombe said although securing a code is relatively straightforward, it is imperative that the code is covered and reimbursed by insurers. "*Our surveys indicate that a price between US$100 and US$300 per test would be considered reasonable, while US$550 or higher would be considered prohibitively expensive. The Company looks forward to updating shareholders when the final details have been determined for the reimbursement code.*"

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

ENDS

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 protein biomarkers, combined with three routinely available conventional clinical variables (age, 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 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 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.

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The following poster was presented at the The Professional Society for Health Economics and Outcomes Research (ISPOR) from May 17–20, 2021

Determination of Payer Budget Impact from Using an Innovative In Vitro Diagnostic in the Management of Diabetic Kidney Disease

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Background

- Up to 1 in every 3 adults with type 2 diabetes (T2D) also have chronic kidney disease, with over 95% of patients being asymptomatic.[1] Early detection and treatment of diabetic kidney disease (DKD) is essential to prevent further kidney injury.[2]
- Kidney disease costs the US Medicare system $114 billion annually.[3]
- PromarkerD is an innovative biomarker-based blood test that predicts risk of DKD and renal decline in T2D patients. Test scores are categorized as low-, moderate- or high-risk as determined by pre-specified cut-offs (set at 10% and 20%). PromarkerD helps predict the risk of DKD before kidney damage occurs.*

Aim

- To evaluate the budget impact from implementing a proactive testing regime using the PromarkerD test for assessing chronic kidney disease in patients with T2D versus current standard-of care (SOC) without PromarkerD.

Methods

- A hypothetical cohort of 1 million patients with T2D and no/mild DKD (eGFR >30mL/min/1.73m^2, KDIGO categories G1-3b)[4] were analyzed over 4 years (as shown by the blue box in Figure 1).
- The budget impact model evaluated potential net savings to US payers from covering the PromarkerD test versus standard-of-care (SOC) through: slower DKD stage progression; delayed or avoided dialysis and transplants; and reduction in dialysis crashes.
- The model also evaluated the potential relative costs associated with PromarkerD, including: PromarkerD test costs every 12, 8 or 6 months for low-, moderate-, and high-risk patients, respectively;[2]

Costs of preventative medications in high-risk PromarkerD patients (Table 1); Treatment costs for each DKD stage, including costs associated with dialysis and transplant (Table 1).

Figure 1. Prognosis of CKD by GFR and albuminuria category.

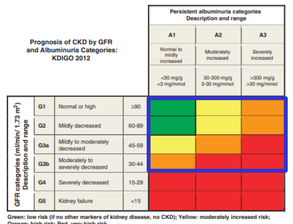


Table 1. Annual Costs per Patient at Each DKD Stage.[5, 6, 7, 8]

Cost per Patient at Each DKD Stage	Treatment Cost (USD)	Preventative Medications (PromarkerD High-Risk Patients) (USD)
Stage G1	$16,257	$1,031
Stage G2	$18,288	$1,421
Stage G3a	$21,068	$1,450
Stage G3b	$30,800	$2,082
Stage G4 (Non-Target)	$40,537	N/A
Stage G5 (Non-Target)	$70,219	N/A
ESRD		N/A
Treatment costs[8]	$109,783	
Dialysis[8]	$70,959	
Additional cost of dialysis crash[9]	$49,199 one time	
Transplant[10]	$262,000 one time	
Post-transplant care[10]	$40,000	

Methods

Model assumptions and parameters were derived from prior literature and PromarkerD clinical studies.

- Rates of progression were taken from prior PromarkerD clinical studies.[11]
- Only high-risk patients were prescribed preventative medications, with 80% adherence assumed.[12]
- 20% decline in progression through DKD stages due to PromarkerD implementation compared to SOC.[13] In sensitivity analyses, a range of progression rates (5-35%) were assessed, for provisional test costs of $150 as well as $100 and $200.
- Preventative medication costs were derived from the difference in medication costs between SOC and recommended medications for high-risk PromarkerD patients.
- Proportion of patients insured by Medicare vs. Commercial insurance was 60% vs. 40%.
- All savings and costs were inflation-adjusted to 2021 USD. A discount rate of 3% was used.[14]

Results

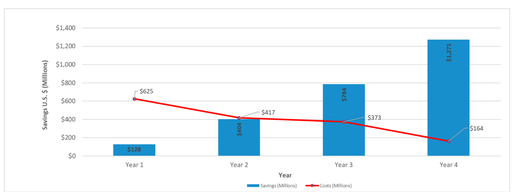
- Of the 1 million patients tested, 220,000 were predicted to be 'high-risk' and received additional preventative treatment.
- PromarkerD testing could produce savings for US payers of $2.4 billion over 4 years, against costs of $1.5 billion, resulting in **net savings of $862 million per million T2D patients over 4 years** (Table 2).

Table 2. Comparative savings and costs of using PromarkerD over SOC.

Budget Impact Model (Over 4 years)	Costs (USD)
Savings	$2.4 billion
Costs	$1.5 billion
Net Savings	**$862 million**

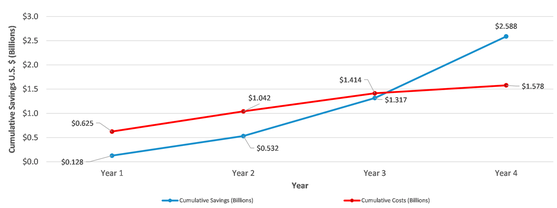
- The **total annual savings provided by PromarkerD equal the costs after 2 years**. Savings increase exponentially in subsequent years, far outweighing the associated costs compared to the current SOC without PromarkerD (Figure 2).

Figure 2. Annual (undiscounted) Savings for PromarkerD.



- The **breakeven point occurs at year 3**, after which the total savings are greater than the total costs (Figure 3).

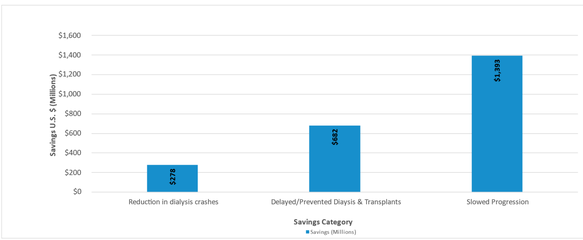
Figure 3. Cumulative (undiscounted) Savings versus Cost of PromarkerD implementation over 4 years.



Results

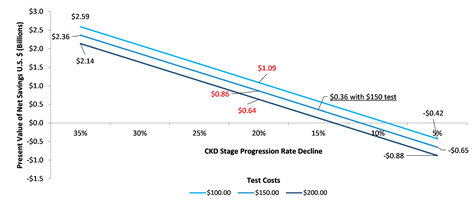
- Over 4 years, **most savings are associated with slowing the progression of DKD** ($1.4 billion, 59% of total savings), compared to the savings from delaying or preventing dialysis ($682 million, 29%), or reduction in dialysis crashes ($278 million, 12%) (Figure 4).

Figure 4. Gross Present Value of Savings over 4 years by Category.



- In sensitivity analysis, different progression rates and costs of the PromarkerD test were assessed. Using a 15% decline in progression would still result in a significant net savings over 4 years ($360 million with a $150 test). Net savings were also achieved using a PromarkerD test price of $100 (>$1 billion) and $200 ($640 million) (Figure 5).

Figure 5. Net Present Value of Savings (discounted) from PromarkerD Implementation over 4 years.



Conclusions

- Changing SOC by implementing an alternative PromarkerD testing regime in T2D patients could enable early intervention for high-risk patients, thereby slowing progression and lessening the need for expensive dialysis and transplants, as well as reducing unnecessary adoption of new and costly therapeutic interventions in low-risk patients.
- This study demonstrates substantial near-term savings ($862 million per million T2D patients) to US payers in the treatment of DKD, through early, accurate and cost-effective prognosis with the PromarkerD test.

References

* Defined as incident diabetic kidney disease (eGFR <60mL/min/1.73m²) in the next four years. If the eGFR level at the time of the test is already <60mL/min/1.73m², then the risk of a further decline in kidney function is defined as an eGFR decline ≥30% in the next four years.

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Boston Healthcare Associates was paid to conduct this study as an independent consultant to Proteomics International.