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Proteomics International

LABORATORIES LTD

Proteomics and Dimerix partner to improve the treatment of kidney disease

Medical technology company Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ), a leader in providing predictive diagnostics, is pleased to announce that it has partnered with innovative drug developer Dimerix Limited (ASX:DXB) to improve the treatment of chronic kidney disease (CKD).

- **422 million people have diabetes and 1 in 3 adult diabetics have chronic kidney disease**
- **Kidney disease is the ninth leading cause of death in the United States, accounting for 48,000 deaths a year, with related healthcare spending exceeding US\$50 billion annually**
- **PromarkerD has been shown in clinical studies on diabetic kidney disease to predict rapid decline in kidney function up to four years in advance**
- **DMX-200 has shown positive results for the treatment of chronic kidney disease in early phase clinical trials**
- **PromarkerD has the potential to serve as a Companion Diagnostic test (CDx) to DMX-200 to monitor the effectiveness of the drug and to shorten the clinical trials process**
- **Initial work will confirm the effect of DMX-200 on the PromarkerD panel in healthy volunteers, and will be expanded in clinical studies of patients with chronic kidney disease**
- **Results will be announced as they are available during 2018**

Proteomics International (PI) has developed PromarkerD, a predictive and diagnostic test for diabetic kidney disease that measures a protein biomarker panel in the blood. Dimerix has developed a candidate drug therapy for chronic kidney disease, known as DMX-200.

The DMX-200 therapeutic showed promising efficacy signals in a recent Phase 2a clinical trial, particularly in patients with diabetic kidney disease, whilst PromarkerD has been shown in clinical studies to predict rapid decline in kidney function up to four years in advance.

Proteomics International and Dimerix will evaluate the performance of PromarkerD alongside DMX-200 in early phase clinical trials for chronic kidney disease. The condition is referred to as a 'silent disease' because it often has no symptoms in its early stages and can go undetected until it is very advanced.

PromarkerD has the potential to serve as a Companion Diagnostic test (CDx) in clinical trials to help measure and monitor the effectiveness of a drug. The FDA states a CDx provides information that is essential for the safe and effective use of a corresponding drug. A CDx can help identify at risk patients who might benefit from taking the drug, enable more accurate dosing, and help monitor clinical end points and side effects. In combination, a validated CDx can improve the success rate of drug candidates.

It is expected the PromarkerD test will be used to explore the response of healthy volunteers to treatment in the Dimerix Phase 1 pharmacokinetic (PK) study currently underway at Linear Clinical Research (Perth, Australia), and in its upcoming Phase 2 trial program.

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PromarkerD has been rated the world's leading diagnostic test for diabetic kidney disease by global market research firm Frost & Sullivan. Early disease detection with PromarkerD allows early therapeutic intervention with drugs such as DMX-200 and may enable the onset of disease to be delayed or prevented altogether, with potentially dramatic savings for global healthcare systems.

In the United States 30 million people suffer from chronic kidney disease, with currently 44% of cases attributed to diabetes. Medicare spending for patients with chronic kidney disease aged 65 and older exceeded US\$50 billion in 2013, and represented 20% of all Medicare spending in this age group.

If PromarkerD proves successful as a Companion Diagnostic test to support the use of DMX-200 as treatment for chronic kidney disease then Dimerix will have the option to licence PromarkerD for on-going use. Preliminary results will be available during 2018.

CEO of Dimerix, Kathy Harrison said "Chronic Kidney Disease is a massive and rapidly growing issue. Many patients are diagnosed too late and the existing treatments can have little to no effect. Having a test which can predict disease progression will undoubtedly be beneficial to both controlling disease and treating it with new drugs like DMX-200."

Proteomics International's Managing Director, Dr Richard Lipscombe added "It's great to see Australian innovation leading the world in the treatment of kidney disease and diabetes. The era of precision medicine is here and we're delighted to be working with Dimerix to try to improve the speed of drug development. This could benefit patients around the world."

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About Proteomics International Laboratories (PILL) (www.proteomicsinternational.com)

Proteomics International is a wholly owned subsidiary and trading name of PILL (ASX: PIQ), a medical technology company focused on proteomics – the industrial scale study of the structure and function of proteins. PILL is recognised as a global leader in the field of proteomics. It received the world's first ISO 17025 laboratory accreditation for proteomics services, and operates from state-of-the-art facilities located on the QEII Medical Campus in Perth, Western Australia. The Company's business model uses its proprietary Promarker™ technology platform across three integrated areas of diagnostics, drug discovery and analytical services.

About Dimerix Bioscience

Dimerix Limited's (ASX: DXB) wholly owned subsidiary Dimerix Bioscience Pty Ltd is a clinical-stage biotechnology company committed to discovering and developing new therapeutic models identified using its proprietary assay platform, Receptor-HIT. The technology was used to identify DMX-200 in an internal drug development program for the treatment of patients with chronic kidney

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disease. In addition to its own therapeutic programs, the company also earns revenue by providing this technology to global pharmaceutical companies.

About Chronic Kidney Disease

Chronic Kidney Disease (CKD) is a disorder in which patients show progressive loss of kidney function usually accompanied by excess protein in the urine (proteinuria). Levels of proteinuria indicate decline of kidney function (higher levels = more decline). In part, this is believed to reflect direct toxicity or damage to the kidneys by proteinuria itself. This establishes a cycle of worsening kidney function leading in turn to increasing proteinuria and further kidney damage. Many CKD patients progress to need a kidney transplant or dialysis and/or experience other diabetes complications such as cardiovascular disease. The prevalence of CKD is rising and as such there is urgent need for treatments that can benefit CKD patients.