



ASX Release

16 July 2021

ASX code: PIQ

Proteomics International

LABORATORIES LTD

Diabetes treatment lowers PromarkerD risk score: Results to be presented at Australasian Diabetes Conference

- Collaborative study with Janssen finds the diabetes drug canagliflozin lowers PromarkerD risk scores in patients with type 2 diabetes
- Average PromarkerD score was statistically lower in patients taking the drug in a retrospective analysis of samples from the completed CANVAS clinical trial and statistically higher in patients taking a placebo
- Greatest improvements seen in people at high risk of developing diabetic kidney disease
- Results to be presented at the Australasian Diabetes Congress from 11-13 August 2021

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) today announces that its collaborative study with Janssen Research & Development, LLC (Janssen) has found a significant reduction in the PromarkerD risk scores of patients with type 2 diabetes taking canagliflozin, an SGLT2-inhibitor diabetes drug.

PromarkerD is a biomarker-based blood test that predicts renal function decline in type 2 diabetes (T2D). PromarkerD is the only available test capable of reliably predicting the onset of diabetic kidney disease (DKD) in patients with T2D. Canagliflozin is a sodium-glucose co-transporter 2 (SGLT2) inhibitor class drug used in the treatment of diabetes, and was the first diabetes medicine with an indication to slow the progression of diabetic nephropathy (also known as DKD) in patients with type 2 diabetes and DKD [FDA: 27 Sept 2019].

The present study was the second stage of the collaboration between Proteomics International and Janssen [ASX: 31 Mar 2020; 15 Jun 2020] in which the companies examined the association between canagliflozin, an approved diabetes therapy with additional renal benefits, and change in PromarkerD score (Δ score) over a three-year period in T2D patients in the completed CANagliflozin cardioVascular Assessment Study (CANVAS)*. Under the collaboration, Janssen provided samples from its completed clinical trial and Proteomics International performed the sample testing, with joint analysis of the study results undertaken.

This post-hoc analysis of data from CANVAS successfully confirmed the study's hypothesis that canagliflozin would be associated with significantly lowered PromarkerD risk scores, with the effect greatest in those T2D patients who were classified at study entry by the PromarkerD predictive test as at high risk of a subsequent decline in renal function.

The study retrospectively measured PromarkerD scores in blood samples from 2,008 patients taken at the start of the trial and again three years later. Patients were randomly allocated to canagliflozin treatment or placebo groups. The study found the average PromarkerD risk score of patients taking canagliflozin dropped during the trial, while the average risk score of patients taking a placebo rose. The most significant reductions were seen in the patients classified by PromarkerD at the start of the trial as at high risk of developing DKD. Each of these results was statistically significant.

* CANVAS: <https://clinicaltrials.gov/ct2/show/NCT01032629>

These results will be presented at the Australasian Diabetes Congress in Brisbane, from 11-13 August 2021. The conference abstract detailing the key findings of the study (design, results and conclusion) have been released online by the conference organisers in advance of the event (see below/copy attached).

Proteomics International managing director Dr Richard Lipscombe said the first stage of the collaboration provided additional validation for PromarkerD as a predictive test for diabetic kidney disease [ASX: 15 Jun 2020]. *“Now, for the first time, we are confirming that the SGLT2 inhibitor class of diabetes drug is associated with lowering a patient's PromarkerD risk score, and that there is a potential treatment for the at-risk patients identified by the test,” he said.*

“Excitingly, these latest findings further illustrate the benefits of the PromarkerD test by showing that we can also identify patients who are asymptomatic for diabetic kidney disease, and that canagliflozin improves their renal risk profile as well.”

Australasian Diabetes Congress poster presentation (ID: 27; Track: ADS Clinical ePosters[†])

[see attached Abstract]

Titled: *Canagliflozin attenuates PromarkerD diabetic kidney disease risk prediction scores*

Kirsten E. Peters^{1,2}, Katrina Spilsbury¹, Jialin Xu³, Scott D. Bringans¹, Timothy M.E. Davis², Norman Rosenthal³, Michael K. Hansen³, Richard J. Lipscombe¹

¹Proteomics International, Perth, WA, Australia; ²Medical School, University of Western Australia, Crawley, WA, Australia; ³Janssen Research & Development, LLC, Spring House, PA, USA.

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.

[†] www.xcdsystem.com/adc/program/vPZbWzx/index.cfm

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.

For further information please contact:

Dr Richard Lipscombe
Managing Director
Proteomics International Laboratories Ltd
T: +61 8 9389 1992
E: enquiries@proteomicsinternational.com

Dirk van Dissel
Corporate Advisor & Investor Relations
Candour Advisory
T: +61 408 326 367
E: dirk@candouradvisory.com.au

Kyle Moss
Corporate Advisor
Euroz Hartleys
T: +61 8 9488 1400
E: kmoss@euroz.com

Australasian Diabetes Congress

11-13 August 2021 (Virtual)

Reference ID: 27

Track: ADS Clinical ePosters

Program Category: Clinical Science

ADS Category: Group 7: Complications I

Abstract:

Canagliflozin attenuates PromarkerD diabetic kidney disease risk prediction scores

Authors

Kirsten E. Peters^{1,2}, Katrina Spilsbury¹, Jialin Xu³, Scott D. Bringans¹, Timothy M.E. Davis², Norman Rosenthal³, Michael K. Hansen³, Richard J. Lipscombe¹

Affiliations

¹Proteomics International, Perth, Western Australia, Australia.

²Medical School, University of Western Australia, Crawley, Western Australia, Australia.

³Janssen Research & Development, LLC, Spring House, PA, USA.

Aim

PromarkerD is a biomarker-based blood test that predicts renal function decline in type 2 diabetes (T2D). This study examined the association between canagliflozin, an approved diabetes therapy with additional renal benefits, and change in PromarkerD score (Δ score) over a three-year period in T2D patients in the CANagliflozin cardioVascular Assessment Study (CANVAS).

Study Design

PromarkerD scores were measured at baseline and Year 3 in 2,008 participants with a baseline eGFR ≥ 60 mL/min/1.73m². Protein biomarker concentrations (CD5L, ApoA4, IGFBP3) were combined with clinical data (age, serum HDL-cholesterol, eGFR) to provide PromarkerD scores (0 to 100%). Scores were categorised as low-, moderate- or high-risk as determined by pre-specified cut-offs. Generalized estimating equations were used to assess the effect of canagliflozin versus placebo on PromarkerD scores.

Results

At baseline, the participants (mean age 62 years, 69% males, median diabetes duration 12 years) had a mean PromarkerD score of 10.1%, with 67% categorised low-risk, 14% moderate-risk and 19% high-risk for renal function decline. After accounting for the known acute drop in eGFR following canagliflozin initiation, there was a significant treatment by time interaction ($p < 0.001$) whereby patients on canagliflozin had decreased mean PromarkerD scores from week 6 to year 3 (Δ score: -1.0% [95% CI: -1.9%, -0.1%]; $p = 0.038$), while those on placebo increased over the three-year period (Δ score: 3.9% [2.5%, 5.3%]; $p < 0.001$). When stratified by PromarkerD risk category, patients with high-risk scores at baseline who were randomised to canagliflozin had significantly lower scores at Year 3 (Δ score: -5.6% [-8.6%, -2.6%]; $p < 0.001$), while those on placebo remained high (Δ score: 3.2% [-1.3%, 7.7%]; $p = 0.17$) (Time*TRT $p = 0.002$).

Conclusion

This post-hoc analysis of data from CANVAS showed that canagliflozin significantly lowered PromarkerD risk scores, with the effect greatest in those T2D patients who were classified at study entry as at high-risk of a subsequent decline in renal function.