Investor Teleconference at 11am today 15 June (AEST)
Conference ID: 10007885
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International study validates PromarkerD predictive test for diabetic kidney disease

Highlights

- **Proteomics International's PromarkerD predictive test for diabetic kidney disease successfully validated in major clinical study**

- **Results of analysis conducted on 3,000 patients from a completed multi-centre clinical trial (the CANVAS[1] study) presented over the weekend at the 80th Scientific Sessions of the American Diabetes Association (ADA)**

- **Data confirms previous findings that PromarkerD is able to correctly predict a clinically significant decline in kidney function up to four years in advance**

- **The results showed that patients predicted by PromarkerD to be at high-risk of chronic kidney disease were 13.5 times more likely than the low-risk group to develop the disease, with the results showing high statistical significance (P = 1.3×10^{-104})**

- **PromarkerD is the world's first and only predictive test for diabetic kidney disease to receive European CE Mark registration**

- **Proteomics International now focused on partnering with suitable organisations to bring PromarkerD to patients in the USA**

- **There are 463 million adults living with diabetes and currently 1 in 3 have diabetic kidney disease**

Medical Technology company Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ), announces a global multi-centre study of 3,000 people has confirmed the effectiveness of PromarkerD as a predictive test for diabetic kidney disease. The collaborative study applied the PromarkerD test system to patient samples from the CANVAS completed phase 3 clinical trial.

The findings were presented over the weekend at the world's leading diabetes conference, the 80th Scientific Sessions of the American Diabetes Association (ADA) in the Clinical Therapeutics/ New Technology—SGLT Inhibitors category, in a poster presentation (#1118-P) titled: '*Validation of the PromarkerD Test for Predicting Renal Decline in Type 2 Diabetes in the Canagliflozin Cardiovascular Assessment Study (CANVAS)*'.

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[1] The Canagliflozin Cardiovascular Assessment Study (CANVAS) phase 3 clinical trial

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The retrospective analysis of blood samples from the completed clinical trial showed that patients predicted by PromarkerD to be at high-risk of chronic kidney disease were 13.5 times more likely than the low-risk group to develop the disease, with the results showing high statistical significance (P = 1.3×10^{-104}).

Importantly, the current data confirms previous findings that PromarkerD is able to correctly predict a clinically significant decline in kidney function up to four years in advance.

The International Diabetes Federation estimates there are 463 million adults living with diabetes globally. Being able to correctly predict an early decline in kidney function in these people means that doctors and patients can take action to prevent patients going on to costly dialysis and eventual kidney transplant. The annual cost of diabetic kidney disease is estimated at USD50 billion per year in the USA alone.

Proteomics International Managing Director Dr Richard Lipscombe said the results were far-reaching for the commercial roll-out of the test because they substantiated the effectiveness of PromarkerD as a prognostic test for diabetic kidney disease in a globally recognised clinical cohort. Proteomics International is now focused on partnering discussions with suitable organisations to bring PromarkerD to patients in the USA.

"PromarkerD works, it's safe, and it can be run by accredited laboratories now as a laboratory developed test (LDT)," he said. *"This is really a green light for using this simple blood test globally."* The result also paves the way for future FDA approval of the test and complements the recent successful CE Mark registration of the new PromarkerD immunoassay in the European Union [ASX: 16 April].

"This technology has the ability to improve the lives of the 31 million Americans living with diabetes," Dr Lipscombe said. *"If patients know that they're on the path to diabetic kidney disease, they can intervene sooner to treat the condition."*

Further research is now being undertaken to determine whether patients display an improved prognosis after treatment, in the form of a lower PromarkerD risk score [ASX: 31 March]. This is a complex process, requiring extensive analysis of the large clinical data set. Future analysis will also examine the performance of PromarkerD in predicting cardiovascular disease.

The ADA's 80th Scientific Sessions run from June 12 to 16. This year the conference has been restructured as a virtual experience.

Study Details: Aim, Design, Analysis and Outcomes
A copy of the ADA conference presentation is attached, and summarised below.

Aim
To predict which patients who started with a healthy kidney function would experience a clinically significant decline in kidney function during the course of the four year clinical study.

The research was conducted by Proteomics International, The University of Western Australia Medical School, and Janssen Research and Development.

Study Design
- Baseline (Year 0) PromarkerD scores were measured in 2,976 CANVAS (NCT01032629) participants all with baseline eGFR ≥60 mL/min/1.73m^2 (n=982 placebo arm, n=1,994 treatment arm).

- The baseline characteristics of the clinical study were individuals with type-2 diabetes at high-risk of cardiovascular disease, with median age 62 years and diabetes duration 12 years.

- The PromarkerD test system measured protein biomarker concentrations (CD5L, ApoA4, IGFBP3) by immunoaffinity targeted mass spectrometry, combined with the age, serum HDL-

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cholesterol and eGFR of each subject at the baseline trial visit using a previously defined algorithm to provide prognostic test scores.

- The prognostic test score predicts incident chronic kidney disease (CKD) (defined as an eGFR drop <60 mL/min/1.73m^2) during the four years from randomisation. [An eGFR <60 mL/min/1.73m^2 is a globally recognised measure of CKD as per the Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group[2]].

- Statistical analysis used logistic regression modelling (Wald Chi-Squared Test) and ROC-AUC analysis to determine prognostic performance.

- The PromarkerD test score (predicted probability) ranges from 0% to 100% and implemented a 'traffic light' system to categorise patients as low-, moderate- or high-risk as determined by pre-specified cut-offs.

- During the follow-up period 926 (31.1%) individuals developed CKD.

Study Outcome - PromarkerD Predicts Incident Chronic Kidney Disease in CANVAS

The chart below illustrates the relationship between the PromarkerD prognostic score for each risk category versus the increased risk, or odds ratio (OR), of developing CKD. For example, the high risk group were 13.5 times more likely to develop CKD than the low risk group, with the 95% confidence interval (CI) being 10.7 to 17.1 times.

Chart 1: PromarkerD Prognostic Score vs Odds Ratios (increase in risk of CKD)
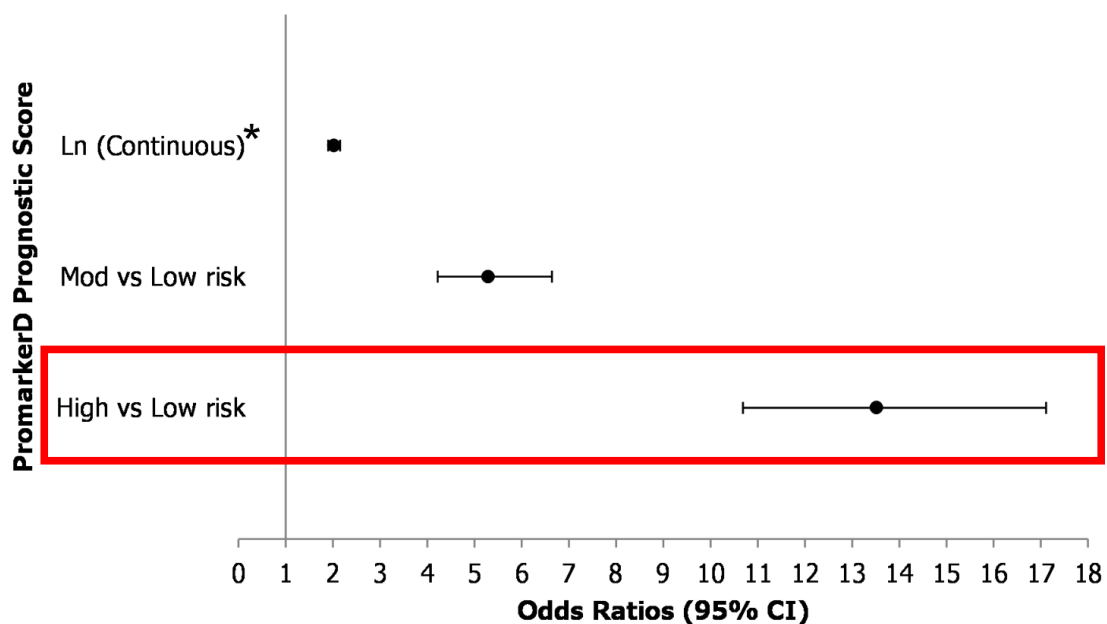
* The prognostic test score was natural logarithm (ln-transformed) due to a non-normal distribution.

- After adjustment for treatment, moderate and high-risk test scores were increasingly prognostic for incident CKD versus low-risk:

  - Moderate-risk scores: OR = 5.3 [95%CI 4.2-6.6], P =2.8x10^{-47}
  - High-risk scores: OR = 13.5 [95%CI 10.7-17.1], P =1.3x10^{-104}

- Using a standard ROC analysis the prognostic performance of PromarkerD in the CANVAS cohort of diabetes patients at high-risk of cardiovascular disease (AUC 0.81, Sensitivity 73%, Specificity 77%) compared well with previous published results from community-based diabetes patients (AUC 0.88, Sensitivity 86%, Specificity 78%)[3].

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[2]   https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4089693/

[3]   https://doi.org/10.2337/dc17-0911

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- PromarkerD achieved a positive predictive value (PPV) at the high-risk cut-off of 74%, and a negative predictive value (NPV) at the moderate-risk cut-off of 83%. These values again compared well with previous published test performance in community-based diabetes patients (PPV = 34%, NPV 98%) [ASX: 10 September 2019][4].

- The test score was also significantly associated with incident CKD when modelled as a continuous score (OR=2.0 [95% CI 1.9-2.2], P=2.3×10^{-109}) – meaning an increase in PromarkerD risk score was significantly associated with poor patient CKD outcomes during the four years of the clinical study.

Glossary

ACR and eGFR	*Albumin Creatinine Ratio (ACR)* is a urine test and the *estimated Glomerular Filtration rate (eGFR)* is a blood test, each used for the <u>diagnosis</u> of chronic kidney disease.
AUC/ROC curve	*Area Under the Curve* in a *receiver operating characteristic* curve, or *ROC* curve, is a graphical plot that illustrates the performance of a classifier system. The conventional interpretation of the clinical significance of the ROC curve AUC is: >0.7 acceptable discrimination; >0.8 excellent discrimination; > 0.9 outstanding discrimination.
Odds Ratio (OR)	A measure of association between two events. It can be used to determine whether a particular exposure is a risk factor for a particular outcome. In clinical research it gives direct information to doctors about which treatment approach has the best odds of benefiting the patient.
Negative Predictive Value (NPV)	The probability that people who get a negative test result truly do not have the disease. In other words, it is the probability that a negative test result is accurate.
Positive Predictive Value (PPV)	The probability that a patient with a positive (abnormal) test result actually has the disease.
Probability (P)	The *P* value, or calculated *probability*, that an observation is true. Most authors refer to statistically significant as P < 0.05 and statistically highly significant as P < 0.001 (less than one in a thousand chance of being wrong).
Sensitivity (true positive rate)	The ability of a test to correctly identify those with the disease.
Specificity (true negative rate)	The ability of the test to correctly identify those without the disease.

<u>Examples of the statistical performance of diagnostic tests in clinical use</u>

To give context to the high statistical significance of the performance of PromarkerD as a predictive test for whether a patient is at risk of diabetic kidney disease, set out below is the statistical performance of two common diagnostic tests:

Breast Cancer: BRCA1 and BRCA2 gene mutations (genetic test assessing hereditary breast cancer risk by measuring the presence of mutations in the BRCA1 and BRCA2 genes) [5].

- BRCA1 mutation present: OR = 5.91 [95% CI 5.25-6.67], P = 2.2×10^{-186}
- BRCA2 mutation present: OR = 3.31 [95% CI 2.95-3.71], P = 2.7×10^{-95}

Prostate Cancer: Prostate-Specific Antigen (PSA) levels (blood test measuring the concentration of the PSA protein for the diagnosis of prostate cancer) [6].

- Prostate cancer versus no cancer: AUC 0.68, P = <0.001
- PSA cut-off threshold 3ng/ml: Sensitivity 32%, Specificity 87%

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4   https://doi.org/10.1016/j.jdiacomp.2019.07.003
5   https://ascopubs.org/doi/pdfdirect/10.1200/PO.16.00066
6   https://pubmed.ncbi.nlm.nih.gov/15998892/

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About PromarkerD (www.PromarkerD.com)

The PromarkerD test system assesses the risk of diabetic kidney disease (DKD) in patients with type 2 diabetes. Chronic kidney disease is one of the major complications arising from diabetes and if unchecked can lead to dialysis or kidney transplant. PromarkerD is a simple blood test that uses a unique protein 'fingerprint' to provide an early detection of the onset of disease. 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.

ADA poster presentation (#1118-P) titled: '*Validation of the PromarkerD Test for Predicting Renal Decline in Type 2 Diabetes in the Canagliflozin Cardiovascular Assessment Study (CANVAS)*'.

To visit the PromarkerD ADA virtual booth please see: www.PromarkerD.com/product

Conference call details

Time: Monday 15 June 2020, 11:00am (AEST)

Led by Managing Director Richard Lipscombe

Conference ID: **10007885**

To access the call pre-register (preferred option) or dial-in direct (delays possible):

1. Pre-registration			
Participants can pre-register by navigating to: **https://s1.c-conf.com/diamondpass/10007885-invite.html** Registered participants will receive their dial in number upon registration to enter the call automatically on the day.			

2. Dial-in directly (toll free – early dial-in is encouraged as delays may be possible)			
AUSTRALIA:	1800 455 963	JAPAN:	0066 3386 8000
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Authorised by the Board of Proteomics International Laboratories Ltd (ASX.PIQ).

ENDS

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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 high-speed, low cost predictive 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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Validation of the PromarkerD Test for Predicting Renal Decline in Type 2 Diabetes in the CANagliflozin cardioVascular Assessment Study (CANVAS)

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Proteomics International

CANVAS Program

PromarkerD
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A new blood test for predicting diabetic kidney disease

Disclosures

- ▶ The PromarkerD biomarker concentrations were measured by Proteomics International, and the PromarkerD scores were calculated using a proprietary algorithm

- ▶ This analysis used archived samples from the CANVAS study and was funded by Proteomics International

- ▶ The CANVAS study was funded by Janssen Research & Development, LLC. Canagliflozin has been developed by Janssen Research & Development, LLC, in collaboration with Mitsubishi Tanabe Pharma Corporation

- ▶ Presenter disclosures: K. Peters is an employee and shareholder of Proteomics International Laboratories Ltd, which is the owner of a patent covering the use of the PromarkerD test. Consequently, K. Peters may receive financial benefit from the commercial use of the PromarkerD test

- ▶ Technical editorial support was provided by Alaina Mitsch, PhD, of MedErgy, and was funded by Janssen Research & Development, LLC

Introduction

- Diabetes is the leading cause of end-stage renal disease (ESRD)[1]

- Chronic kidney disease (CKD) develops in 1 in 3 people with type 2 diabetes (T2D)[2]

- The ability of baseline urinary albumin:creatinine ratio (uACR) or estimated glomerular filtration rate (eGFR) to predict onset and progression of CKD complicating diabetes is limited[3]

- PromarkerD is a novel blood test that can predict future renal function decline in people with T2D[4,5]

- This study sought to validate the prognostic utility of PromarkerD in individuals with T2D from CANVAS, a randomized controlled trial of canagliflozin vs. placebo (NCT01032629)[6]

[1] https://www.cdc.gov/kidneydisease/pdf/2019_National-Chronic-Kidney-Disease-Fact-Sheet.pdf, [2] https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf,
[3] Dunkler et al., JASN. 2015;10:1371-1379, [4] Peters et al., Diab Care. 2017;40:1548-1555, [5] Peters et al., J Diab Comp. 2019;33:107406, [6] Neal et al., N Eng J Med. 2017;377(7):644-657.

PromarkerD Test System

▶ The PromarkerD test system was developed and validated in community-based adults with T2D from the Fremantle Diabetes Study Phase II (FDS2) in Australia[4,5,7]

▶ PromarkerD is a simple blood test that combines the concentration of three plasma biomarkers (CD5L, ApoA4 and IGFBP3) with clinical factors (age, serum HDL-cholesterol, eGFR) to provide prognostic and diagnostic test scores

▶ In FDS2, PromarkerD predicted 86% of people with diabetes who developed CKD (eGFR <60 mL/min/1.73m^2) within four years (sensitivity 86%, specificity 78%, ROC-AUC=0.88)[4]

▶ PromarkerD also has excellent negative predictive value, or "rule-out" capability, of 98% for four-year risk of developing CKD[4]

[4] Peters et al., Diab Care. 2017;40:1548-1555, [5] Peters et al., J Diab Comp. 2019;33:107406, [7] Davis et al. Int J Epid. 2013;42(2):412-421.

PromarkerD Score x Outcome

▶ Baseline PromarkerD scores were measured prior to randomization in 2,976 CANVAS participants all with baseline eGFR ≥60 mL/min/1.73m^2 (n=982 placebo arm, n=1,994 canagliflozin arm)

▶ Biomarker concentrations (CD5L, ApoA4, IGFBP3) measured by immunoaffinity targeted mass spectrometry were combined with the age, serum HDL-cholesterol and eGFR of each subject at the baseline trial visit using a previously defined algorithm to provide prognostic test scores

▶ The prognostic test score predicts incident CKD (defined as an eGFR drop <60 mL/min/1.73m^2) during the four years from randomization

▶ During the follow-up period, 926 (31.1%) individuals developed CKD, 274 (27.9%) of the subjects on placebo and 652 (32.7%) of those on canagliflozin

Statistical Analyses

▶ The test score (predicted probability) ranges from 0% to 100% and is <u>categorized as low-, moderate- or high-risk</u> as determined by pre-specified cut-offs for optimal sensitivity and specificity

Prognostic

LOW RISK	MODERATE RISK	HIGH RISK
0% to <10% Low four-year risk of developing DKD.	10% to <20% Moderate four-year risk of developing DKD.	20% to 100% High four-year risk of developing DKD.

▶ A logistic regression model was used to fit incident CKD against PromarkerD score and treatment with canagliflozin, with odds ratios presented for PromarkerD scores adjusted for treatment

▶ PromarkerD scores were modeled as both continuous scores (from 0% to 100%) and as risk categories (moderate- or high-risk compared to the low-risk category as reference)

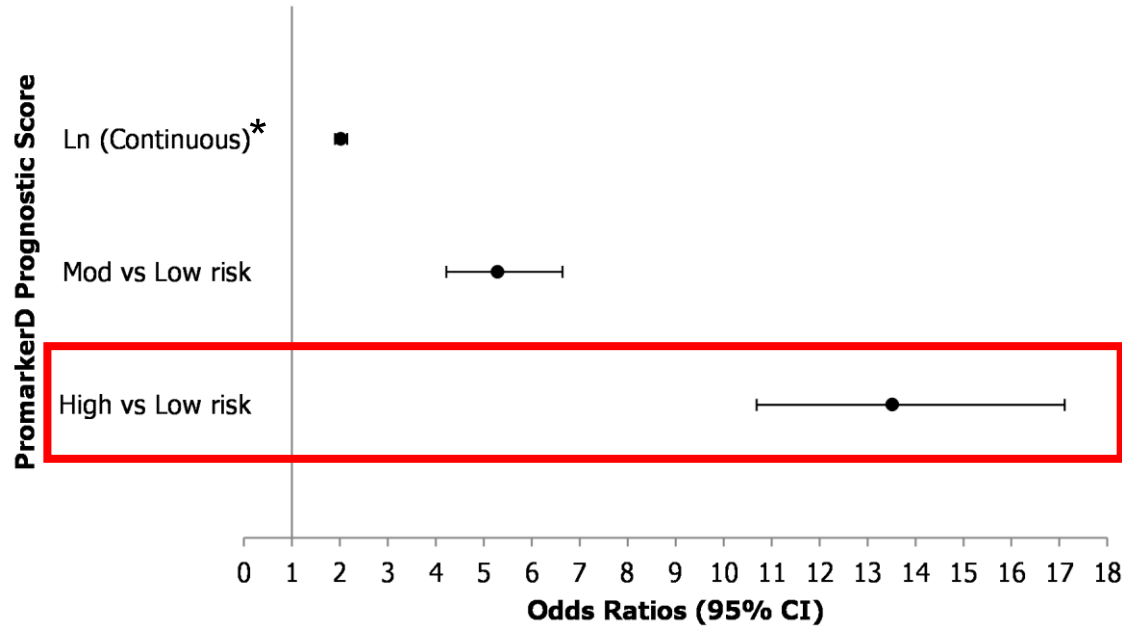▶ Prognostic performance was assessed by ROC-AUC analysis using the test scores

Baseline Characteristics

Characteristic	Canagliflozin (n = 1,994)	Placebo (n = 982)	Total (n = 2,976)
Age (years)	62.0±7.7	61.6±7.6	61.9±7.7
Female sex, n (%)	641 (32.1)	308 (31.4)	949 (31.9)
BMI (kg/m^2)	32.7±6.1	32.3±6.1	32.6±6.1
Diabetes duration (years)*	12.1 [8.0-17.0]	12.0 [8.0-16.8]	12.0 [8.0-17.0]
HbA$_{1c}$ (%)*	8.0 [7.5-8.7]	8.0 [7.5-8.8]	8.0 [7.5-8.7]
Serum total cholesterol (mmol/L)	4.3±1.1	4.4±1.2	4.3±1.2
Serum HDL-cholesterol (mmol/L)	1.20±0.32	1.20±0.31	1.20±0.32
Serum triglycerides (mmol/L)†	1.7 (1.0-2.8)	1.7 (1.0-2.9)	1.7 (1.0-2.8)
Systolic blood pressure (mmHg)	136±16	137±16	137±16
Diastolic blood pressure (mmHg)	78±10	79±10	78±10
eGFR (mL/min/1.73m^2)	82.3±15.3	82.4±15.7	82.3±15.5
uACR (mg/g)*	11.2 [6.4-30.6]	11.0 [6.1-32.6]	11.2 [6.3-31.6]
Microalbuminuria, n (%)	425 (21.3)	209 (21.3)	634 (21.3)
Macroalbuminuria, n (%)	76 (3.8)	56 (5.7)	132 (4.4)

All values are mean±SD (standard deviation) unless labeled otherwise; * Median [IQR – interquartile range];
† Geometric Mean (SD range). BMI, body mass index; eGFR, estimated glomerular filtration rate (CKDEPI); uACR, urine albumin to creatinine ratio; Microalbuminuria and macroalbuminuria were defined as uACR 30-300 mg/g and >300 mg/g, respectively.

- PromarkerD scores were measured in 2,976 participants at baseline
- Prognostic test score:
  - Overall median 2.9%
  - Number of subjects (%) by risk categories
    - Low-risk: 2,099 (70.5%)
    - Moderate-risk: 405 (13.6%)
    - High-risk: 472 (15.9%)
- No significant difference in test scores by allocated treatment (P=0.56)

PromarkerD Predicts Incident CKD in CANVAS

Ln (Continuous)*

Mod vs Low risk

High vs Low risk

PromarkerD Prognostic Score

Odds Ratios (95% CI)

0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18

* The prognostic test score was natural logarithm (ln-transformed) due to a non-normal distribution.

▶ After adjustment for canagliflozin, moderate- and high-risk test scores were increasingly prognostic for incident CKD versus low-risk

  ▶ Moderate-risk scores: OR=5.3 [95%CI 4.2, 6.6], P=2.8x10^{-47}

  ▶ **High-risk scores: OR=13.5 [95%CI 10.7, 17.1], P=1.3x10^{-104}**

▶ The test score was also significantly associated with incident CKD when modeled as a continuous score (OR=2.0 [95%CI 1.9, 2.2], P=2.3x10^{-109})

PromarkerD Test Performance in CANVAS

Participants		Placebo	Placebo+Canagliflozin
Number with outcome/total (%)		274/982 (27.9%)	926/2,976 (31.1%)
ROC-AUC (95%CI)		0.79 (0.76, 0.82)	0.81 (0.80, 0.83)
At optimal cut-off*:		(7.1%)	(5.9%)
	Sensitivity (%)	69.3	73.2
	Specificity (%)	76.7	76.8
	PPV (%)	53.5	58.8
	NPV (%)	86.6	86.4
At moderate-risk cut-off:			
	Sensitivity (%)	59.1	60.6
	Specificity (%)	81.8	84.6
	PPV (%)	55.7	64.0
	NPV (%)	83.8	82.6
At high-risk cut-off:			
	Sensitivity (%)	35.8	37.7
	Specificity (%)	93.4	94.0
	PPV (%)	67.6	73.9
	NPV (%)	79.0	77.0

Performance measures are given for moderate (10%), and high (20%) risk cut-offs for incident CKD, as well as for the * optimal cut-off (shown in parentheses) defined by maximum Youden Index (YI). ROC-AUC = receiver operating curve - area under the curve; PPV = positive predictive value; NPV = negative predictive value.

- PromarkerD provided good discrimination for incident CKD in both placebo- and canagliflozin-treated participants
  - AUC = 0.81 (95% CI 0.80, 0.83)
  - Test sensitivity = 73.2%
  - Test specificity = 76.8%
- Demographic and clinical differences with FDS2 may explain the lower test performance (FDS2: AUC=0.88, Sn=86%, Sp=78%)
- Further work is needed to explore these differences

Conclusions

▶ Analysis of the PromarkerD test system in CANVAS shows the test predicted clinically significant incident CKD over 4 years in this multi-center clinical study of 2,976 individuals with type 2 diabetes

▶ These data provide further validation of the prognostic utility of PromarkerD and thus its potential to facilitate preventive management strategies by enabling earlier intervention of at-risk individuals

▶ PromarkerD shows potential for monitoring disease progression, improvement in patient outcomes and risk stratification in future clinical trials. Future studies are needed to investigate the role of PromarkerD in these areas