



Proteomics International

LABORATORIES LTD

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Proteomics International contracts Biotem to manufacture PromarkerD test kits

- Immunoassay specialist Biotem contracted to produce the PromarkerD test kits for Proteomics International's predictive test for diabetic kidney disease
- Biotem is a global manufacturer of immunoassays and antibodies for diagnostic products and holds ISO 13485 certification for the manufacture of medical devices
- Agreement will support production of PromarkerD test kits at scale in the Northern Hemisphere
- Announcement follows engagement of Abcam to produce specialist reagents for the world-first predictive test for diabetic kidney disease

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) has contracted French immunoassay specialist Biotem to manufacture test kits for the PromarkerD predictive test for diabetic kidney disease.

The milestone agreement will see Biotem manufacture Proteomics International's immunoassay kit version of PromarkerD, which identifies a unique 'fingerprint' of protein biomarkers in the blood using specialist reagents (antibodies) developed by Proteomics International and produced by global life science company Abcam [ASX: 28 July].

Biotem is an ISO 13485-certified company, which has produced specialised immuno-technology products for more than 40 years. Biotem's core competency is in immunoassay production covering ELISA (enzyme-linked immunosorbent assay) and also LFIA (lateral flow immunoassay) technology. ELISAs are the most commonly used laboratory technique for detecting biomarkers in the blood.

Working with Abcam, Proteomics International also recently produced recombinant versions of the antibodies, which are more stable than those produced from classical hybridoma cells. This strengthens the supply chain and will result in a more consistent product over the long term [ASX: 22 July].

Proteomics International's managing director Dr Richard Lipscombe said engaging Biotem and Abcam were key elements in achieving the Company's goal of selling a test with full regulatory approvals at scale worldwide.

"Currently, the PromarkerD immunoassay (ELISA) kits are manufactured under licence in Australia," he said. "Now, by contracting these specialist manufacturers we are building our production capacity to meet our anticipated demand for the test in the Northern Hemisphere and worldwide."

The manufacturing contract builds upon Proteomics International itself achieving ISO 13485 certification – the most widely-used international standard for quality management systems in the manufacture of medical devices – in April [ASX: 23 April 2021], and securing CE Mark registration for the PromarkerD software hub [ASX: 14 January 2020] and CE Mark registration for the PromarkerD immunoassay (ELISA) as an IVD medical device (*in vitro* diagnostic) [ASX: 16 April 2020].

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The term of the manufacturing agreement is for three years and Proteomics International has the option to extend for additional periods of one year. Biotem will manufacture PromarkerD test kits on a fee-for-service basis. The agreement is non-exclusive and both parties have the right to terminate the agreement with immediate effect upon the breach of any material terms of the agreement. The agreement is also subject to the standard terms, conditions, and warranties typical of a contract of this type.

After engaging Abcam as the reagent producer, contracting Biotem, a respected global manufacturer, for the kit production was the last remaining foundation block required to complete the Northern Hemisphere manufacturing capability for PromarkerD. The manufacture of the PromarkerD kits to the ISO 13485 standard also enables Proteomics International to extend its regulatory approvals across additional jurisdictions. Prospective partners and licensees can now have confidence that PromarkerD can be manufactured in high volumes and to international regulatory standards.

Dr Lipscombe said Proteomics International was building a robust manufacturing framework that could be applied to the Company's other diagnostics under development, including tests being developed in relation to endometriosis and asthma. *"The engagement of global manufacturing partners will help accelerate the worldwide roll-out of PromarkerD, as well as the commercialisation of our pipeline of other diagnostics under development,"* he said.

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

ENDS

About Biotem (www.biotem-antibody.com)

Biotem is a French company specialising in immuno-technologies since 1980 and operating for clients all over the world. It is an ISO 13485:2016 certified company that offers high value-added solutions for the custom development and production of immunoassays [enzyme-linked immunosorbent assay (ELISA) and lateral flow immunoassay (LFIA)]. Biotem is organised and sized to address various demands, in particular within the framework of the European Regulation 2017/746 (IVDR) on *in vitro* diagnostic medical devices (IVDMD). Biotem is renowned for its ability to address from the inception a number of downstream constraints induced by the ultimate goals (pure research, diagnostic and/or therapeutic) of its clients.

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)). 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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