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Xylonix, Biogemex to co-develop predictive cancer immunotherapy

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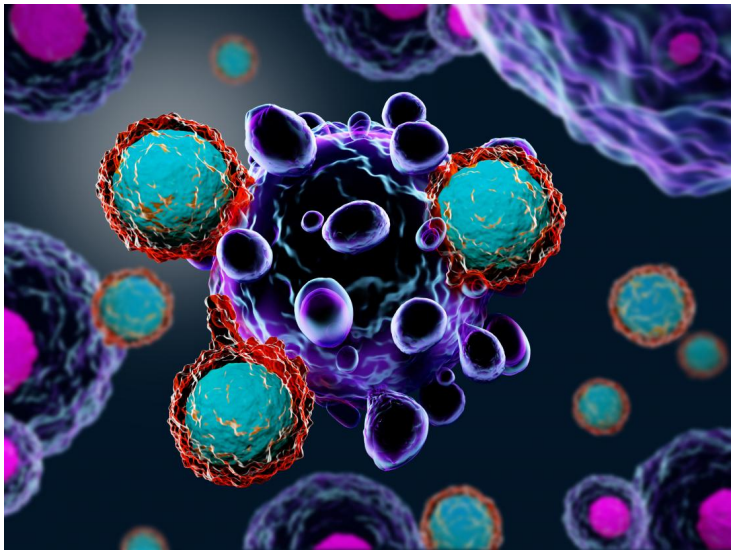
XDX-01, a novel, point-of-care pre-treatment diagnostic, has completed early validation studies, predicting patient responses (PFS, ORR) to cancer immunotherapies



Xylonix, Singapore based immuno-oncology biotech company has announced that it has signed a Memorandum of Understanding (MOU) with BioGemex, a leading Korean medical diagnostic company, to jointly develop a new pre-treatment point-of-care diagnostic, XDX-01, to better predict a patient's response to T-cell mediated cancer immunotherapies in solid tumours.

T-cell mediated cancer immunotherapies such as PD-1/L1 inhibitors are increasingly becoming first-line treatments in the treatment of solid cancer. While these breakthrough cancer treatments offer curative benefits in some patients, major challenges remain due to the high costs of treatment and low and unpredictable patient responses, leading to difficult issues surrounding insurance coverage and drug pricing policies for reimbursements by many governments.

Developed by Xylonix during its own immuno-oncology drug trial design optimization, the XDX-01 serum biomarker has demonstrated applicability in predicting the patient response and survival post PD-1 inhibitor treatments, with the prediction accountability of 88% and 79% for Objective Response Rate (ORR) and Progression-Free Survival (PFS), respectively, in a site-agnostic manner. The current standard predictive biomarker, TMB, was shown to perform at 70% and 46%, respectively. XDX-01 will be developed as a cartridge-based modular system on an FDA-approved point-of-care reader device.

Preliminary validation using PD-1 inhibitor clinical patient response and survival data showed superior prediction power compared to the current standard, tumour mutation burden (TMB). Low and unpredictable solid cancer patient response to cancer immunotherapies is a major challenge impacting clinical trial design, insurance coverage, and government reimbursement schemes

Dr Jinhyuk Chung, Founder and Chief Scientific Officer of Xylonix, commented: *"We are delighted to sign the MOU with BioGemex, their diagnostic manufacturing capabilities and expertise will be valuable to Xylonix as we accelerate the development of XDX-01 following our successful preliminary studies. We believe that XDX-01, our tumour microenvironment biomarker, has the potential to transform the cancer treatment decision pathway for patients with solid tumours. The rising costs of cancer treatment remains a pressing global issue but physicians, pharmaceutical companies and payors are yet to find a reliable tool to ensure that the right patients get the right treatments. We believe that XDX-01 has the potential to be the right decision support tool."*

Xylonix and BioGemex will work together to jointly scale the manufacturing of XDX-01 and conduct broader clinical validation studies in anticipation of a commercial launch in H2 2020.

Today in the US, the average cost of cancer immunotherapies is approximately $150,000 per year per patient to use, and it has been reported to fail in 85% of the prescribed patients in delivering any benefits.