ANGLE achieves world first with FDA clearance for its Parsortix PC1 clinical system

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ANGLE (AGL:AIM) is a world-leading liquid biopsy company that has developed the Parsortix system for harvesting intact circulating tumour cells (CTCs) from a patient's blood sample for subsequent analysis.

In May 2022, ANGLE received US Food and Drug Administration (FDA) clearance for its Parsortix PC1 system. This is the first ever FDA product clearance for a device to harvest CTCs from metastatic breast cancer patient blood samples for subsequent, user-validated analysis.

FDA product clearance, the global gold standard for medical devices, gives ANGLE first mover advantage for intact cancer cell analysis in the global liquid biopsy market, which is estimated will grow to over US$100 billion per annum in the US alone.

LIQUID BIOPSY - HELPING HEALTHCARE SYSTEMS MANAGE THE REPERCUSSIONS OF COVID-19

Across the globe Covid-19 continues to disrupt cancer services, slowing diagnoses and delaying treatment, creating a backlog that could take more than a decade to clear. Cancer remains a leading cause of death in most developed nations with an estimated 90% of deaths due to metastasis. As such, early diagnosis and care optimisation remain a priority.

Given the dynamic nature of cancer, selecting the appropriate treatment requires access to the most up-to-date status of a patient's disease and will be an urgent priority moving forward.

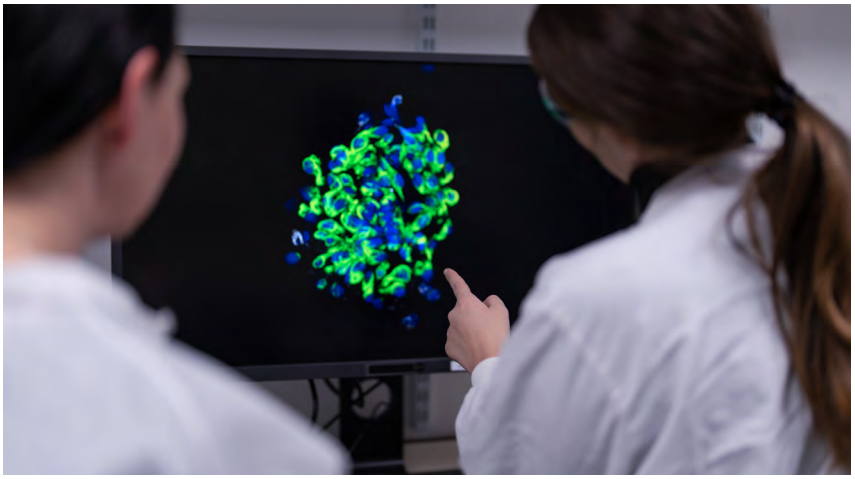
ANGLE believes its Parsortix liquid biopsy system can help to meet that need. CTCs as a liquid biopsy, have significant potential as a prognostic and diagnostic tool for clinicians. By enabling minimally-invasive, repeat liquid biopsies from a simple blood test to assess cancer status, the Parsortix system has the potential to deliver profound improvements in clinical and health economic outcomes in the diagnosis and treatment of cancer.

A CLEAR PATH TO SUCCESS

ANGLE has a clear, four-pronged strategy for achieving widespread adoption of the Parsortix system:

- **Regulatory approval**

The FDA De Novo Class II classification means that an entirely new medical device



classification has been granted by the FDA for the Parsortix PC1 system. The credibility associated with medical device FDA product clearance cannot be over-estimated and we anticipate that this will turbocharge all aspects of commercialisation of the Parsortix system.

- **Pharma services**

In March 2021, ANGLE opened new clinical service laboratories ahead of schedule in the UK and US (under its new 'Onc-ADaPT Labs' brand) with the first four biopharma customers now onboarded.

In April 2021, ANGLE secured its first large-scale sample processing services contract with an oncology focused pharmaceutical company, valued at up to $1.2 million.

In June 2022, ANGLE secured an additional contract, again worth $1.2 million, with the same pharma services customer demonstrating market confidence in both ANGLE and the solutions it offers. The customer, a pharma company with revenues exceeding $1 billion per annum, has selected the Parsortix system to undertake longitudinal monitoring of patients in its clinical trials, including a large, multi-centre, late stage trial in prostate cancer.

- **Clinical Studies**

ANGLE has signed a master clinical study agreement with Solaris Health Holdings LLC and its affiliate MidLantic Urology LLC, to collaborate and conduct clinical studies in prostate cancer and as a potential route to market in the US. Together with MidLantic Urology, ANGLE will initiate clinical studies aimed at investigating the use of the Parsortix system for the detection of prostate cancer and prediction of its severity in patients.

Assuming results are positive, the prostate cancer test, and other tests developed by ANGLE, will be offered from its clinical laboratories, which are currently undergoing CLIA and UKAS accreditation to enable use of Parsortix based tests for patient management.

- **Published evidence**

Leading independent cancer centres continue to publish positive results on their use of the Parsortix system with 66 peer-reviewed publications as of July 2022, across 24 different cancer types.

The Parsortix system has enabled breakthrough research into cancer metastasis and its treatment. It was recently used in a remarkable study published in Nature, demonstrating that in breast cancer patients CTCs are shed at a higher rate during sleep and that these CTCs have greater metastatic potential.

FDA CLEARANCE PROVIDES ANGLE WITH A MAJOR OPPORTUNITY IN AN EMERGING AND GROWING GLOBAL MARKET

The recent FDA clearance of ANGLE's Parsortix PC1 system, renewal of a substantial contract with a significant pharma services customer, involvement with large, critical clinical studies, the increasing rate of publications utilising the Parsortix system combined with a recent successful fundraise (£20 million in July 2022), demonstrates that ANGLE is gaining momentum in an expanding, large scale market.

ANGLE has the potential to positively impact cancer diagnosis, treatment, and monitoring for the millions of people whose lives are impacted by this disease every day. In the words of ANGLE's chief executive officer, Andrew Newland, 'the effective execution of ANGLE's strategy has the potential to deliver significant financial returns for ANGLE's shareholders, profoundly improve the outcome for cancer patients, and reduce healthcare costs'.