

For immediate release

19 April 2023

ANGLE plc ("the Company")

HER2 ASSAY DEVELOPMENT PARTNERSHIP WITH BIOVIEW

Agreement with BioView to develop a CTC-based HER2 assay

First phase expected to generate c. £1.2 million revenue

ANGLE plc (AIM: AGL; OTCQX: ANPCY), a world-leading liquid biopsy company, is delighted to announce it has signed an agreement with BioView Ltd. ("BioView") (BIOV.TA) to develop a liquid biopsy circulating tumor cell (CTC) HER2 assay for breast cancer utilising ANGLE's FDA cleared Parsortix[®] PC1 Clinical System to harvest CTCs and BioView's automated microscopy systems and software to detect and assess the HER2 expression and/or gene amplification in CTCs.

BioView develops, manufactures and markets innovative automated cell imaging and analysis solutions and has received FDA product clearance for its fluorescent in situ hybridisation (FISH) application for HER2 analysis of FFPE breast tissue sections, hybridised with Abbott's PathVysion HER2 DNA probe kit (see <https://bioview.com/applications/pathology/breast/>). ANGLE has already successfully integrated BioView's technology in its R&D and clinical laboratories for assay development and pharma services.

ANGLE and BioView will now begin the programme of developing a HER2 assay for the detection of HER2 protein via immunofluorescence (IF) and *HER2/neu* gene amplification by FISH, utilising Abbott's PathVysion HER2 DNA probe kit, in CTCs from breast cancer patients' blood samples harvested using ANGLE's FDA cleared Parsortix PC1 Clinical System and analysed using BioView's automated imaging and analysis technology.

It is recognised that breast cancer can be highly heterogeneous and that HER2 status can change over time. In addition, results from a recent high impact study have revealed that patients categorised with HER2-low breast cancer (and defined as immunohistochemistry (IHC) score 1+ and 2+ and HER2-negative by FISH), can in fact, benefit from new HER2 targeted antibody-drug conjugates, where typical HER2 targeted drugs have previously been reserved for HER2-positive (HER2 IHC 3+ and/or HER2 FISH positive) breast cancer patients. This new understanding is driving the adoption of HER2-low targeted drugs such as ENHERTU[®] marketed by Daiichi-Sankyo and AstraZeneca.

This changing market dynamic has provided ANGLE and BioView with a major commercial opportunity to develop a quantitative CTC-based HER2 assay, to assess HER2 protein expression and/or gene amplification levels by analysing fluorescence intensities. This would be the only product-based solution on the market for this purpose leveraging both companies' previous FDA product clearances. Unlike current standard of care tests developed for use on FFPE tissue, a CTC HER2 assay could be used for longitudinal monitoring of HER2 status throughout disease progression, thereby ensuring the patient is targeted for the most appropriate treatment at every stage. The development phase is estimated to take around a year to complete with the assay development work generating c. £1.2 million of revenues for ANGLE.

HER2-low breast cancer accounts for 55% of all breast cancer cases whereas HER2-positive cancer accounts for 25% of cases. The new use of trastuzumab deruxtecan (ENHERTU[®]) to include HER2-low patients has resulted in analysts predicting up to a US\$3 billion annual increase in sales value. Because of market expansion into HER2-low patients, and the need for novel biomarkers enabling ongoing patient monitoring of HER2 status, ANGLE and BioView believe there will be demand from

medtech and pharma companies for quantitative CTC-based HER2 detection assays to enable regular and accurate stratification of patient populations.

Given the significant third-party interest in a new assay for quantitative HER2 analysis based on CTCs, ANGLE and BioView have agreed to allow for the inclusion of third parties in this project and its funding as we move into the commercialisation stage after the initial development work is complete. The parties are continuing to discuss strategic routes to market with potential corporate partners.

BioView President and CEO, Dr. Alan Schwebel, commented:

"We are excited for this development partnership opportunity with ANGLE, where we plan to leverage the strengths of both our technologies to develop an impactful liquid biopsy HER2 CTC test. CTCs present a unique opportunity to access protein and/or genomic alterations of HER2 throughout the patient's cancer treatment to help ensure eligibility for the right therapy to improve patient outcomes."

ANGLE Founder and Chief Executive, Andrew Newland, added:

"We are delighted to have entered into this partnership with BioView utilising our established bespoke assay development capability. The changing breast cancer treatment landscape has created a major commercial opportunity for a CTC-based HER2 assay allowing repeat testing and longitudinal monitoring of patients to personalise cancer care. We believe this new 'content' will drive wide adoption of the Parsortix system in the treatment of breast cancer."

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Notes for editors

About BioView www.bioview.com

BioView develops, manufactures and markets innovative automated microscopy imaging and analysis solutions that applies machine learning algorithms to automatically detect and classify target cells. Operating since 2000, BioView is headquartered in Israel and has a fully owned subsidiary in the United States, which is responsible for sales and support in America. Products are also internationally distributed by Abbott Molecular.

Founded and managed by physicists and software experts, BioView leverages its knowledge and extensive expertise in the areas of medical devices combined with clinical and research applications, in creating its breakthrough imaging and analysis solutions. The suite of instruments and software have been adopted for use in cytology, cytogenetic, pathology clinical and research laboratories across the world. BioView has remained focused on oncology molecular diagnostic testing solutions and has received US FDA 510K clearance for five FISH tests and regulatory approvals in China, Korea, Australia and European Union CE mark as the imaging and analysis solution. Over the years BioView has applied their expertise in detection and classification of cells that are low in abundance to detection of the CTCs to enable their use in a liquid biopsy.

Lead by senior executives with vast accumulated experience in both the development and successful marketing of

solutions such as diagnostic equipment with vision applications, BioView remains one step ahead of the game with assay-specific applications ready for use even before the tests reach the market.

About ANGLE plc www.angleplc.com

ANGLE is a world leading liquid biopsy company with sample-to-answer solutions. ANGLE's proven patent protected circulating tumor cell (CTC) harvesting technology is known as the Parsortix[®] system.

ANGLE's Parsortix[®] system is FDA cleared for its intended use in metastatic breast cancer and is currently the first and only FDA cleared medical device to harvest intact circulating cancer cells from blood.

Intended use

The Parsortix[®] PC1 system is an in vitro diagnostic device intended to enrich circulating tumor cells (CTCs) from peripheral blood collected in K₂EDTA tubes from patients diagnosed with metastatic breast cancer. The system employs a microfluidic chamber (a Parsortix cell separation cassette) to capture cells of a certain size and deformability from the population of cells present in blood. The cells retained in the cassette are harvested by the Parsortix PC1 system for use in subsequent downstream assays. The end user is responsible for the validation of any downstream assay. The standalone device, as indicated, does not identify, enumerate or characterize CTCs and cannot be used to make any diagnostic/prognostic claims for CTCs, including monitoring indications or as an aid in any disease management and/or treatment decisions.

The Parsortix system enables a liquid biopsy (a simple blood test) to be used to provide the circulating metastatic breast cancer cells to the user in a format suitable for multiple types of downstream analyses. The system is based on a microfluidic device that captures cells based on a combination of their size and compressibility. The system is epitope independent and can capture all phenotypes of CTCs (epithelial, mesenchymal and EMTing CTCs) as well as CTC clusters in a viable form (alive). CTCs harvested from the system enable a complete picture of a cancer to be seen; as being an intact cell they allow DNA, RNA and protein analysis as well as cytological and morphological examination and may provide comparable analysis to a tissue biopsy in metastatic breast cancer. Because CTC analysis is a non-invasive process, unlike tissue biopsy, it can be repeated as often as needed. This is important because cancer develops and changes over time and there is a clear medical need for up-to-date information on the status of a patient's tumor. In addition, the live CTCs harvested by the Parsortix system can be cultured, which offers the potential for testing tumor response to drugs outside the patient.

The Parsortix technology is the subject of 26 granted patents in Europe, the United States, China, Australia, Canada, India, Japan and Mexico with three extensive families of patents are being progressed worldwide.

In the United States, the Parsortix[®] PC1 system has received a Class II Classification from FDA for use with metastatic breast cancer patients. FDA clearance is seen as the global gold standard. ANGLE's Parsortix system is the first ever FDA cleared system for harvesting CTCs for subsequent analysis. ANGLE has applied the IVD CE Mark to the same system for the same intended use in Europe.

ANGLE has also completed three separate 200 subject clinical studies under a programme designed to develop an ovarian cancer pelvic mass triage test, with the results showing best in class accuracy (AUC-ROC) of 95.4% with sensitivity of 90% and specificity of 93%. This excellent clinical result demonstrates the utility of cells harvested by the Parsortix system, which the Company believes is the "best sample" for liquid biopsy analysis as it recovers intact, living cancer cells that are involved in the progression of the disease providing prospective information.

ANGLE has established formal collaborations with world-class cancer centres and major corporates such as Abbott, Philips and QIAGEN, and works closely with leading CTC translational research customers. These Key Opinion Leaders (KOLs) are working to identify applications with medical utility (clear benefit to patients), and to secure clinical data that demonstrates that utility in patient studies. The body of evidence as to the benefits of the Parsortix system is growing rapidly from our own clinical studies in metastatic breast cancer and ovarian cancer and also from KOLs with 77 peer-reviewed publications and numerous publicly available posters from 35 independent cancer centres, available on our website.

ANGLE has established clinical services laboratories in the UK and the United States to accelerate commercialisation of the Parsortix system and act as demonstrators to support product development. The laboratories offer services globally to pharmaceutical and biotech customers for use of Parsortix in cancer drug trials and, once the laboratories are accredited and tests validated, will provide Laboratory Developed Tests (LDTs) for patient management.

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