ANGLE

Parsortix FDA clearance marks a key transition point

26 May 2022

- The long-awaited FDA clearance of the Parsortix system as a Class II medical device for harvesting CTCs (circulating tumour cells) for subsequent analysis in metastatic breast cancer (mBC) is a transition point for ANGLE. It provides gold standard validation of the Parsortix platform, which could be important for potential partners, and allows commercial sales in the mBC setting. It should also facilitate more rapid clearances in other cancers with this initial precedent now set. Parsortix is the first CTC harvesting system approved for subsequent analysis, giving ANGLE first mover advantage in non-invasive repeat testing of intact cancer cells.
- FDA clearance is a key de-risking event which could accelerate revenues, nearer-term most likely in Pharma Services. This is one of multiple significant commercial opportunities that ANGLE has been progressing to broaden Parsortix availability across the healthcare industry. These include potential partnerships with Medtech to extend existing tissue-based tests, and with Pharma, currently for exploratory use in clinical trials allowing longitudinal analysis of patient blood samples before, during, and after investigational drug treatment, and in the longer-term potentially allowing development of a companion diagnostic.
- The Parsortix opportunity in breast cancer alone could transform ANGLE, with management estimating US commercial potential in this setting of more than $500m. This could be crystallised via direct sales to hospitals and clinics for mBC, although uptake in the clinical setting will likely take time. Nearer-term, we see greater revenue traction in the nascent Pharma Services business, which is already displaying positive momentum. FDA clearance provides additional credibility to ANGLE's offering that could encourage prospective new partners, in our view.
- Other opportunities include the grant of CLIA and UKAS accreditation, expected H222, which will permit validated clinical tests to be offered through ANGLE's own clinical laboratories. The first laboratory developed test (LDT) will likely be in ovarian cancer, pending positive top line results of the ovarian cancer assay clinical verification study expected mid-2022. Development of a second LDT, for prostate cancer, should begin once collaboration terms are finalised with a large US urology clinic network.

Price	156.00p
Market Cap	£366.8m
Primary exchange	AIM
Sector	Healthcare
Company Code	AGL
Corporate client	Yes

Company description:

ANGLE is a specialist diagnostics company. Its proprietary Parsortix technology can capture and harvest very rare cells, including CTCs (circulating tumour cells), from a blood sample. The FDA clearance for its clinical use to guide precision cancer care will open up further multiple commercial opportunities.

Trinity Delta view: FDA clearance of the Parsortix system in mBC has been a clear focus for many investors. Achievement of this gold standard validation could transform ANGLE, with a potential near-term acceleration in revenues from the Pharma Service business, in which we see significant value. Longer-term, this could also drive revenues in mBC. We continue to believe ANGLE is well positioned to capitalise on growing recognition of the utility of CTC analysis in investigating protein markers on cancer cells, without the limitations of ctDNA (circulating tumour DNA) liquid biopsy (inapplicable to proteins) or tissue biopsies (unsuitable for longitudinal monitoring). We value ANGLE at £506m ($658m), or 215p/share with significant upside once Parsortix's positioning becomes clearer.

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