Evaluate Vantage

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Asco 2019 – Guardant and Grail square up

Elizabeth Cairns

Two closely-watched liquid biopsy developers are to present data on their respective solid tumour blood tests.

Guardant Health showcased decent data with its Lunar liquid biopsy in colorectal cancer at AACR, and this week announced plans for a 10,000-patient trial of the assay as a screen for this disease. Data to be presented at Asco will be the subject of much scrutiny.

Abstract 3602, concerning the use of Lunar to monitor recurrence of colorectal cancer, suggests that the test's positive predictive value of 93% and negative predictive value of 80% allows "accurate and quantitative" tumour detection in early stages of the disease.

In surgically-treated patients PPV was 88% and NPV 79%, but it was much more accurate in patients treated with adjuvant therapy: PPV was 100% and NPV 81%. Leerink analysts write that these data could be highly relevant to driving adoption of Lunar as a recurrence monitoring test.

Abstract 3057 focuses on Lunar's utility as a screen for colorectal cancer, and indicates 99% specificity and 100% sensitivity – though this is simply an analytical validation on samples rather than a "real" trial screening people at risk of cancer. Even so, it is a positive sign ahead of the vast study the company intends to kick off in this setting (*Exact falls on Guardant's liquid biopsy plans, May 13, 2019*).

Wider clinical studies of Lunar could start in the second half of this year. The market for Lunar in this setting could reach $15bn, Guardant claims, with the screening market slightly larger. This may indeed be possible, but an awful lot more data will be required for widespread adoption of this test by healthcare systems.

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Potential rival Grail also has data out at the meeting, including sub-studies from its huge CCGA trial. Abstract 3049 suggests that Grail's methylation test can detect the tumour tissue of origin with high accuracy – a feature that will be critical for the multi-cancer early detection test the Illumina spin-out is attempting to develop.

Blood samples from 166 cancer patients in the CCGA trial were tested using Grail's methylation technology. The assay correctly identified the tumour's tissue of origin in 144 of 166 samples tested (87%), including 96% of breast cancers, 88% of lung cancers; 90% of liver cancers and 100% of pancreatic cancers. Further testing in a larger cohort of CCGA participants is ongoing.

Another analysis of CCGA patients detailed in abstract 1545 suggests that Grail's methylation test could

identify patients with more aggressive disease. The 1,289-patient analysis showed that people whose cancer was detected by the methylation technology were three times more likely to die from their cancer compared with those whose cancer was not detected by the technology – independent of the disease's clinical stage (HR=3.0, $p<0.001$).

Geoffrey Oxnard of Dana-Farber Cancer Institute and Harvard Medical School claimed that the test might be able to detect the types of cancers more in need of immediate treatment, and its use could mitigate overdiagnosis.

These data are interesting, not least because they give an insight into the different tacks being taken – Grail is going all-out on a pan-cancer test, for which it recently scored breakthrough designation, while Guardant is focusing on individual indications. But it will be a good while before either of these tests are ready for prime time, and before it will become clear which of these strategies was the more successful.