Evaluate Vantage

April 01, 2019

AACR 2019 – Guardant looks to its other liquid biopsy

Elizabeth Cairns

With one cancer blood test established on the market Guardant is starting down the road to validating another – this time as a screening assay.

Guardant launched a new liquid biopsy, Lunar, in January, but only for researchers and biopharma companies developing new drugs. The group is now setting out a case for its use in patients, and data presented on Sunday at the AACR meeting in Atlanta give an early indication of the assay's potential value as a colorectal cancer screen.

In contrast to Guardant's marketed liquid biopsy, Guardant360, which is used to track patients' response to drugs and allow the most effective choice of future therapies, Lunar is intended – when it reaches the clinical market – as a way to monitor cancer recurrence in patients in remission, with an initial focus on lung, breast, colorectal and ovarian cancers.

Longer term, Guardant hopes to position Lunar as something approaching a true diagnostic – a screening test to identify solid tumours in the healthy population. These two aims are covered respectively by its Lunar-1 and Lunar-2 development programmes.

Lunar landing

Data presented on Sunday concerned Lunar's use as a screen for early-stage colorectal cancer. The assay was used to test plasma samples taken from 105 patients with colorectal cancer and 124 age-matched cancer-free controls. This was updated data from the 72 patients and 35 controls mentioned in the abstract.

Lunar delivered 79% sensitivity at a prespecified target specificity of 98% – this is a similar trial design to the Nile study of Guardant360 that was toplined earlier this year (*Guardant's liquid biopsy matches tissue testing in lung cancer, February 28, 2019*). When the specificity target in the Lunar screening trial was dropped to 94%, sensitivity was 88%. At 89% specificity, sensitivity was 90%.

It is the test's utility as a screen for early-stage disease that matters most. There were only 25 stage 1 cancer patients in this study, among whom sensitivities were 64% at target 98% specificity, 76% at 94% specificity, and 84% at 89% specificity.

This is a tiny, early trial, of course, meaning that comparisons to Exact Sciences' market-leading noninvasive screening test, Cologuard, are arguably unfair. For the record, Exact claims sensitivity and specificity of 92%

and 87% respectively for its test.

But Guardant's acquisition of Bellwether Bio last week, for an undisclosed sum, could aid its efforts to develop a screen. Bellwether is focused on the epigenomic content of tumour DNA, and Guardant says this will further advance its research into cancer detection at earlier stages of the disease.

Wider clinical studies of Lunar could start in the second half of this year. Guardant believes that Lunar's market opportunity as a cancer screen comes to $18bn, and sees a $15bn market opportunity in recurrence monitoring.

The other significant AACR data for Guardant will be further results from the Nile study assessing Guardant360 in non-small cell lung cancer. These are scheduled for Tuesday, and much of the discussion will doubtless concern the test's specificity in this setting.

Guardant360 is already sold as a lab-developed test, and Guardant plans to seek FDA approval and full Medicare reimbursement for it. On the last point the test has just received a positive sign.

A local Medicare contractor, Palmetto GBA, has proposed local coverage for the assay to guide treatment decisions several solid tumours; if confirmed, this would make Guardant360 the first liquid biopsy to receive broad local coverage across multiple tumours. Palmetto and other Medicare contractors already cover Guardant360 for patients with advanced NSCLC.

According to Leerink analysts, Guardant is on track for FDA approval for a pan-cancer indication in the second half of this year, with US-wide Medicare coverage in 2020.

Selected Guardant AACR liquid biopsy abstracts

Date	Presentation title	No.
Mar 31	Combined genomic and epigenomic assessment of cell-free circulating tumour DNA improves assay sensitivity in early-stage colorectal cancer	916
Apr 2	Colomate: colorectal cancer and liquid biopsy screening protocol for molecularly assigned therapy	LB-235/14
Apr 2	Nile: Clinical utility of comprehensive cell-free DNA analysis to identify genomic biomarkers in newly diagnosed metastatic non-small cell lung cancer	4460