Evaluate Vantage

June 22, 2021

Guardant steps into a new arena

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A test that tracks response to therapy is useful, but approval and reimbursement will be key.

One of the groups locked in battle for dominance of the pan-cancer blood test market has just pulled ahead in a new setting. Today Guardant Health launched in the US what it claims is the first liquid biopsy that can track a patient's response to immunotherapy or targeted drugs, and do so more quickly than current methods used by oncologists.

Questions remain, notably around pricing and reimbursement. Given that the Guardant360 Response test will have to be administered repeatedly, costs could mount up fast. But the existing approved tumour-agnostic liquid biopsies are seeing increased acceptance, so Guardant360 Response could find a market – though formal FDA approval would probably be a necessary step to get payers on board.

Guardant360 Response, launched in the US as a lab-developed test, can pinpoint the levels of circulating tumour DNA (ctDNA) in a patient's blood; by tracking how these fluctuate it can determine whether the patient is responding to their prescribed drug regimen. This is a different setting from the group's only FDA-approved test, Guardant360 CDx, which is used to profile a patient's tumour biomarkers.

Guardant360 Response is believed to test for 74 genetic mutations, whereas Guardant360 CDx is more comprehensive.

Guardant Health's liquid biopsies		
Test	**Setting**	**Status**
Guardant360	Pan-cancer; helps assign targeted therapy	Launched as LDT May 30, 2014
Guardant360 CDx	Pan-cancer; helps assign targeted therapy	Approved Aug 7, 2020
Guardant360 Response	Pan-cancer; tracks response to targeted or immunotherapy	Launched as LDT Jun 22, 2021
Guardant360 TissueNext*	Pan-cancer tissue test; helps assign targeted therapy – to be ordered at same time as Guardant360 CDx	Launched as LDT Jun 22, 2021
GuardantOMNI	Pan-cancer; sold to biopharma companies to aid drug development.	Launched in 2017 for research use only
Guardant Reveal (formerly Lunar-1)	Colorectal cancer; postsurgical, detects disease recurrence	Launched as LDT Feb 16, 2021
Lunar-2	Screening for colon cancer	Clinical trials
**Tissue test rather than liquid biopsy. Source: company website.*		

It is not clear how frequently patients will have to undergo blood draws to assess changes in their ctDNA levels, though in a study looking at metastatic NSCLC patients treated with Keytruda – the first-line checkpoint inhibitor used in almost all NSCLC patients – the test was administered at baseline and again nine weeks later.

In 51 evaluable patients the test's conclusions correlated with a more traditional approach to evaluating response, in this case Recist 1.1, which includes assessment of tissue biopsy and radiological procedures such as CT scans.

Patients who had complete or partial response or stable disease that lasted more than six months were significantly more likely to be flagged as responders by Guardant's test than those who did not, and responders as designated by the test had significantly longer progression-free survival and overall survival compared with non-responders.

Guardant says this has been mirrored in other cancers too, with more than 40 studies demonstrating that patients with decreasing ctDNA levels showed significantly longer progression-free and overall survival rates than non-responders. This held true across targeted drugs, immunotherapy and chemotherapy, and tumour types, including colorectal, breast and bladder as well as non-small cell lung cancers.

Two months earlier

And, because Guardant360 Response can be conducted more swiftly than Recist methods, the gold standard for assessing cancer patients' response to treatment, Guardant says its results are tantamount to predicting response. The company claims that it can provide oncologists with insights into treatment response up to two months earlier than the Recist methodology.

If this holds up in clinical practice some oncologists will doubtless jump at the test. But changes to guidelines and reimbursement will be crucial for expanding the market, just as they were with the initial tumour profiling liquid biopsies (*Liquid biopsies: the future of cancer diagnosis?, June 12, 2019*).

Guardant's chief executive, Helmy Eltoukhy, told *Evaluate Vantage* via email that the market for Guardant360 Response is similar to that for Guardant360 CDx, which is to say the roughly 700,000 advanced cancer patients in the US. Mr Eltoukhy added that the US opportunity for Guardant360 CDx is $6bn, and that adding Guardant360 Response would boost this, "but we are not providing a forecast at this time".

He said that the price of Guardant360 Response would be similar to that of the approved test, which is reimbursed under Medicare at $5,000.

Guardant declined to elaborate on its plans for seeking FDA approval for Guardant360 Response. This is generally considered a necessary step for persuading cancer societies to recommend use of the test in their guidelines, and for securing widespread reimbursement. Unless or until this occurs, the test will remain a minor revenue stream.

This article has been updated with comments from Guardant.

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