

## Guardant's liquid biopsy matches tissue testing in lung cancer



[Elizabeth Cairns](#)



### **Guardant gets a liquid biopsy trial win, but if it wants to drive sales it must get cancer societies on board.**

The liquid biopsy developed by Guardant Health is both more accurate and faster than tissue biopsy in patients with lung cancer, according to topline data from the head-to-head Nile study. This could position the Guardant360 assay as the best way to assign targeted drugs to patients; the company's stock is up 11% so far today.

But a meaningful increase in uptake of the test, which has been available since 2014 in the US, will require oncology societies to change their guidelines. A year ago [Asco concluded](#) that there was not enough evidence to know whether use of these tests is justified. Perhaps [the Nile data](#) can change its mind.

### **Sensitivity**

The Nile study enrolled 282 patients with untreated metastatic non-squamous non-small cell lung cancer, making it the largest trial in this setting assessing cell-free tumour DNA in patients' blood. The results [will be presented at the AACR meeting](#) on April 2.

The trial looked at the ability of Guardant360 to detect the seven guideline-recommended predictive genomic biomarkers for patients with newly diagnosed NSCLC - EGFR, Alk, Ros1, BRAF, Ret, Met and Her2 as well as the prognostic KRAS marker. All of the patients were tested with both Guardant360 and standard-of-care tissue biopsy.

One or more of the predictive biomarkers was identified by tissue biopsy in 60 patients (21.3%) and by cfDNA in 77 patients (27.3%), a significant difference. However, only 48 patients had their biomarker(s) picked up by both tests. 12 patients had markers detected by tissue biopsy but not liquid biopsy, and 29 by Guardant's blood test but not by tissue genotyping.

Nile data	
No of patients enrolled	282
Positives detected by Guardant360	77
Of which just by Guardant360	29
Positives detected by tissue biopsy	60
Of which just by tissue biopsy	12
Positives detected by both	48
Total positives	89
Total negatives	193
Source: <a href="#">AACR abstract #4460</a> .	

Of the 193 patients with no predictive biomarker detected by tissue or Guardant's test, 24 (12.4%) had an activating KRAS alteration detected by tissue biopsy versus 92 by Guardant360; 21 cases were picked up by both tests.

### Nine days' wonder

Positive predictive value for Guardant360 versus tissue genotyping was 100% for the four genetic targets for which NSCLC drugs are approved – EGFR, Alk, Ros1, and BRAF. In other words, a hit on tissue biopsy was always a hit with Guardant's test.

The question now is how many of the Guardant360 results are correct readings and how many false positives. The AACR abstract notably does not give the test's negative predictive value for the four drugged targets. Doubtless the test's specificity will be an area of discussion at AACR.

It could be argued that when it comes to metastatic NSCLC it is better to get patients on treatment as soon as possible, even at the risk of giving unnecessary drugs to people without the disease. Guardant wants to position the test not as a replacement for tissue biopsy but as an initial test for when an oncologist prefers to initiate treatment sooner rather than later.

One Nile finding is clearly in favour of the test: it is faster than tissue biopsy. Median turnaround time was nine days versus 15, a significant difference with a p value of less than 0.0001. It is also, of course, easier, cheaper and less traumatic.

It is possible that the full dataset, when presented at AACR, will prompt greater uptake of Guardant360, which is sold in the US as a lab-developed test, and therefore is not regulated by the FDA. The only liquid biopsy for NSCLC approved by the FDA is Roche's Cobas EGFR Mutation Test v2, which tests for just one genetic variant and is used as a companion diagnostic for AstraZeneca's Iressa.

Guardant has a market cap of \$5.3bn, but its sales guidance for 2018 is just \$82-84m. A sharp increase in Guardant360 sales would go a long way towards keeping its shareholders happy.

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