Evaluate Vantage

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Asco 2021 – Guardant shoots for the moon

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And an expanded market awaits its colorectal cancer blood test, though Exact will benefit first.

Yesterday brought a compound win for Guardant Health. Data presented at Asco reaffirmed the performance of its Lunar-2 liquid biopsy, which it is developing as a screen for colorectal cancer, and at the same time screening guidelines changed, potentially increasing the market for this very test.

It will be some time before Guardant can take advantage of this guideline change, though, since Lunar-2 is still at least a year away from US approval. The same development will more immediately aid Exact Sciences, since its colorectal cancer screen, Cologuard, is already on sale – and on top of that, the guidelines recommend more frequent testing with this type of diagnostic.

Guardant's Asco data concern 434 patients with a colorectal cancer diagnosis, the largest early-stage patient cohort that has yet been assessed with Lunar-2. They reveal overall sensitivity of 91%, including 88% sensitivity in early stages I and II. Specificity was 94%.

Among the 139 asymptomatic patients, representing the crucial population for a screen, sensitivity was 88%. It was 91% among the 233 symptomatic patients.

Lunar-2 Asco data		
		Sensitivity
CRC stage	I / II	88%
	III	93%
Presentation at CRC diagnosis	Asymptomatic	88%
	Symptomatic	91%
	Unknown	94%
Location of primary tumour	Right-sided	93%
	Left-sided	90%
	Transverse	82%
Note: Specificity across the whole study was 94%. Source: Asco 2021 abstract #3536.		

Analysts from Stifel write that this solid performance should bolster confidence in Eclipse, a 10,000-patient prospective trial due to report early next year, and will back a US approval application for Lunar-2. The crucial bar for Eclipse to hit is specificity of 90% and sensitivity of 74%, since this is the threshold set by the Centers for Medicare and Medicaid to allow reimbursement of colorectal cancer screening tests.

Wide screen

It is other recommendations that could provide a different fillip for Guardant. The US Preventive Services Task Force has finalised a change it had drafted late last year, lowering the minimum age from which the US population ought to be screened for colorectal disease from 50 to 45. The alteration means that insurance companies have to cover screening of this age group under the Affordable Care Act.

These guidelines make no mention of liquid biopsy testing for colorectal cancer, because no such test is yet on the market. Should Lunar-2 gain approval it will likely be used for the 45-plus age group, however.

Unfortunately for Guardant, another group will already be occupying this niche. Exact Sciences' Cologuard can immediately expand into this lower age group.

And it gets even better for Exact. The USPSTF now recommends that people be screened with stool DNA-faecal immunochemical testing every one to three years, rather than every three. Cologuard is the only such test on the US market.

The USPSTF recommends other forms of screening too, and the gold standard for diagnosing colorectal cancer remains colonoscopy. But the non-invasive nature of Cologuard lies behind its high sales – the test made Exact $815m last year and sales are forecast to reach a jaw-dropping $3.5bn by 2026, according to *Evaluate Medtech*'s sellside consensus.

Liquid biopsy is non-invasive too. The availability of Lunar-2, should this come to pass, could cut into Exact's sales.