Evaluate Vantage

September 25, 2020

Exact gatecrashes the liquid biopsy party

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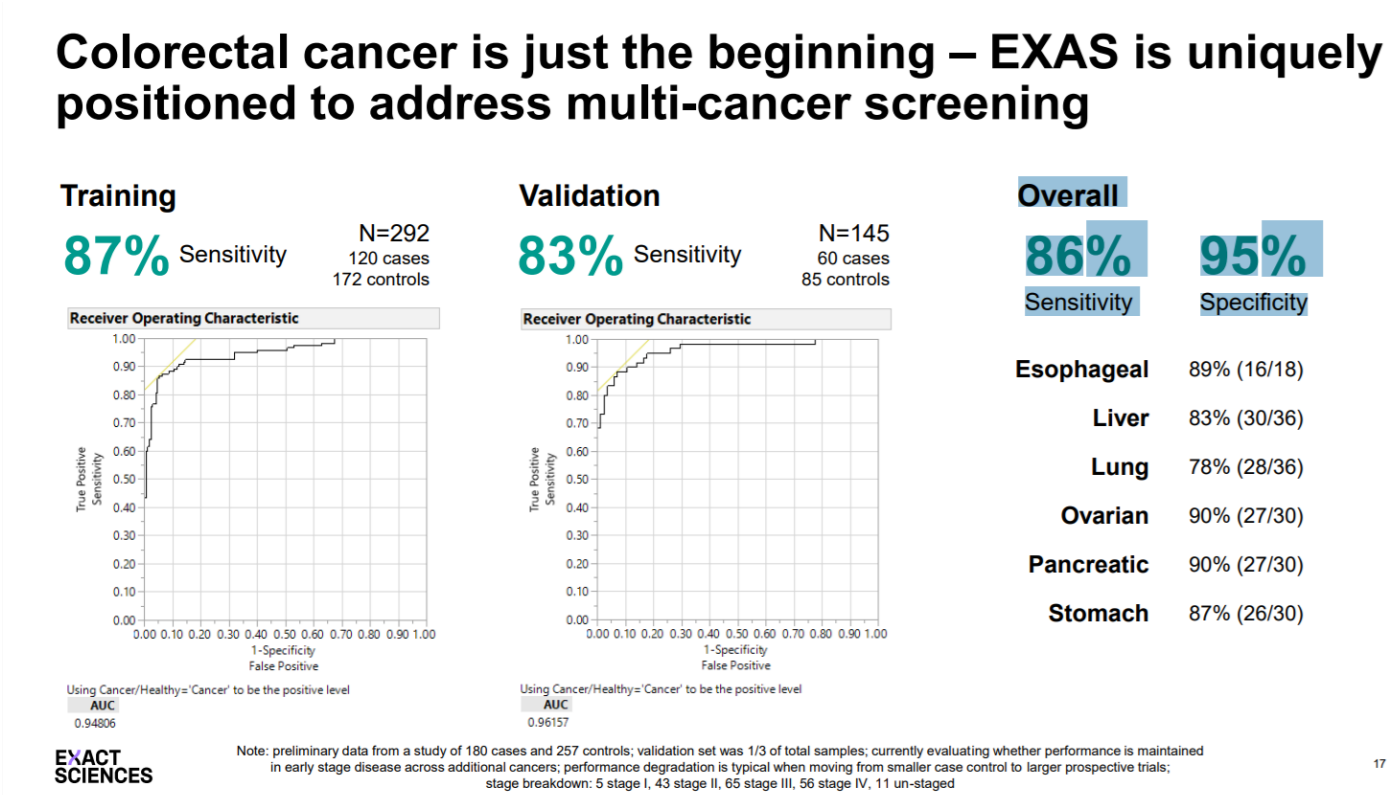
Preliminary data on its pan-cancer blood test appear surprisingly competitive.

It is fair to say that liquid biopsies are having a moment. The past month has seen two pan-cancer blood tests approved in the US and the developer of a third acquired in a multibillion-dollar deal. Now Exact Sciences has posted unexpectedly encouraging data on its own multi-cancer blood test, and has enjoyed a 27% share price jump as a result.

Though the data look good they are from a small study, and even if Exact prioritises this programme above its other work its test will still be some way behind the leading assays, from Guardant Health and Roche. Still, Exact's proven success in selling its colorectal cancer screen, Cologuard, bodes well for the pan-cancer assay being a commercial hit if it does reach market.

Results with the unnamed test were presented at a conference organised by the investment bank Cowen, and show overall sensitivity of 86% and specificity of 95% across six cancer types. The dataset included 180 patients with cancer and 257 controls, and is presumed to be an early cut from the only study in multiple cancers Exact has initiated.



Source: Exact Sciences presentation.

This trial is planned to evaluate samples from 7,500 participants with 12 tumour types. So far Exact has obtained more than 3,500 samples from cases across all cancer stages, of which more than 1,400 were from early cancers, at stages 0 to 2.

This is the first time data on the multi-tumour assay have emerged. Before these data were released much of the attention had been on Exact's single-tumour liquid biopsy – a blood test for hepatocellular carcinoma, which is expected to launch this year (*Exact eyes 2020 launch for liver cancer liquid biopsy, November 8, 2019*). Several of these single-tumour tests are in development or on sale – Oncimmune and Thermo Fisher Scientific are looking at blood tests for lung cancer, for example.

Exact has not given any timeline for launch or approval of its multi-cancer assay. The clinical trial is expected to conclude its primary analysis in July next year, but whether the data from the study might be registrational is not known. For comparison, the pan-cancer tests that are on sale have clinical trial patient counts in the tens of thousands, and Grail – soon to be Illumina – is recruiting just shy of 100,000 women for its Strive study.

Data on a version of Grail's Galleri test presented at last year's Esmo cancer conference indicated a 54.7% sensitivity across 20 different tumour types at a fixed specificity of 99.4%.

Comparing this with Exact's data is not strictly fair: the different tumour profiles and enrolment criteria see to that. But Exact's showing is an undeniably good start. Further clinical results will be awaited, and scrutinised, keenly.

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