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MedGenome Launches Liquid Biopsy Test for Indian, Southeast Asian Market

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Premium

NEW YORK (GenomeWeb) – Genomic testing firm MedGenome launched a new blood-based cancer test last month in India, where the firm is based.

Unlike many of the tests that have gained prominence in the US over the past year, which cover anywhere from tens to close to 100 genes, MedGenome's OncoTrack assay is narrowly focused on hotspots in just four genes, which the company believes are the most actionable for guiding currently available targeted therapies.

V.L. Ramprasad, the company's COO, said in an interview this week that this choice reflects the realities of the South Asian diagnostics market, which is largely patient-paid — favoring tests that have the highest likelihood of impacting care at the lowest cost.

MedGenome said that OncoTrack is the only liquid biopsy test to be validated in India using samples from cancer patients across the country. The assay covers mutations in just four genes — EGFR, KRAS, NRAS, and BRAF — which limits its use to patients with colorectal cancer, lung cancer, or melanoma, the main diseases for which targeted drugs are available in India and surrounding countries.

"We were an early adopter of [noninvasive prenatal testing] though our partnership with Natera, so the idea of blood-based detection was something we were thinking about for some time, but unlike the US, most countries here, including India, which has about a 1.2 billion population, do not have insurance coverage, so it’s a patient-pay market," Ramprasad said.

"Also, GDPs are generally low, so you can't come out with a test that costs $1,000 dollars ... Oncologists and patients look for high value for what they pay. It can't be exploratory like 300-gene tests where the majority of the genes have no immediate action you can take," he added.

The firm has been working for about a year on the initial validation of the new test, and has been conducting an ongoing concordance analysis with tissue samples, Ramprasad said, collecting about 500 so far.

A study reporting on the first 200 of these is awaiting publication, he added. Amongst those, the company found that its blood-based analysis was able to achieve 98 percent concordance with tissue testing results from a leading hospital in the country, where patient samples were tested in a standard clinical workflow using real-time PCR.

Interestingly, Ramprasad said, MedGenome found that among samples that were negative for mutations in the hospitals' PCR analysis, about 10 percent were positive for a mutation using the company's new sequencing-based liquid biopsy assay.

According to Ramprasad, this highlights not only the power of the company's new blood-based test, but also the added value of sequencing over PCR methods that are still commonly used as a first line test not only in India, but also across the Western world, especially for lung cancer patients.

As liquid biopsy tests have moved forward, there has been some conflicting data on the sensitivity of noninvasive methods to accurately detect all the potentially relevant mutations that might be in a patient's tumor.

Some data has shown worryingly low concordance, while other results reflect sensitivities closer to what MedGenome said that it has found. Researchers are increasingly identifying the strong influence of timing on these metrics. If samples from tissue and blood are taken at very different time points, this appears to affect concordance, potentially significantly, because of the evolution of tumors or changes in circulating DNA due to treatment with different drugs.

In MedGenome's study, tissue samples were taken at the same time as blood samples, and from largely new, treatment-naive patients, Ramprasad said.

Since completing its validation and launching the test last month, MedGenome has been working on physician adoption. One effort was a pilot to offer a free one-month liquid biopsy trial to 65 oncologists across India who treat most of the country's lung cancer patients.

By the end of the month, each physician had sent in three samples on average, Ramprasad said. "We expect good practical adoption based on this, in situations where it is really warranted," he added.

Keener attention to practicality is a key differentiator for markets like India versus the US in terms of all genomic testing, not just newer methods like liquid biopsy, Ramprasad said. "No one here does a 150-gene panel or a 300-gene panel."

But this doesn't mean there is a lack of enthusiasm for genomic medicine. "Routine tissue EGFR typing is done for about 70 to 80 percent of patients with access to either secondary or tertiary care," he explained.

"Doctors need to focus on genes with clear actionability for drugs that are actually available in the country."

Aside from Natera's NIPT test, the rest of MedGenome's menu is assays the firm developed in house Ramprasad said. Over the last year, the company has grown its menu of NGS panels, mainly in non-oncology areas such as inherited genetic disorders, to about 300 tests, he said.

In 2016 MedGenome acquired Foster City, California-based Lifecode Health, giving it access to the cancer molecular diagnostic firm's CLIA-certified and CAP-accredited laboratory in the Bay Area.

However, Ramprasad declined to comment on the firm's strategy for clinical NGS testing for US patients.

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