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ASIA EDITION

World's first FDA approved liquid biopsy enters the Asian market as 'Guardant360Ã?Â® test'

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Guardant360 test provides fast, accurate, and comprehensive genomic profile of patients with any solid malignant neoplasm.



Guardant Health, a US-based leading precision oncology company has launched liquid biopsy-based Guardant360 and GuardantOMNI tests for advanced-stage cancer patients. On August 7, it announced that the US Food and Drug Administration has approved Guardant360 CDx for tumor mutation profiling, in patients with any solid malignant neoplasm (cancerous tumor). BioSpectrum Asia spoke with **Simranjit Singh, CEO, Guardant Health AMEA, Singapore** on the advantages of liquid biopsy and market opportunities.

- **Can you share more insights into the novel liquid biopsy for early cancer detection?**

While we are looking at the whole continuum of cancer from early detection to recurrence monitoring, our primary focus at Guardant Health AMEA is targeted at guiding treatment decisions for advanced-stage cancer patients with solid tumours. The liquid biopsy assay that we offer in Asia, Middle East and Africa (AMEA) is the Guardant360 test. Since its launch in 2014, the Guardant360 test has been ordered over 150,000 times by more than 7,000 oncologists worldwide.

With a simple blood draw from the cancer patient, the Guardant360 test provides fast, accurate and comprehensive genomic results. This is done in a quick turnaround time of seven days upon sample receipt in the laboratory. This liquid biopsy test is done using circulating tumour DNA (ctDNA), which is produced when tumours shed small pieces of their genetic material into

the bloodstream. Traces of this ctDNA can be detected in the blood using our digital sequencing technology.
The comprehensive genomic profiling information that is received from this liquid biopsy test allows oncologists to recommend treatment accurately without the complications and delays of invasive tissue biopsies. Tumour mutation profiling can detect specific genomic mutation for precision cancer therapy. Guardant360 test detects all four classes of genomic variations and microsatellite instability-high in 74 genes most relevant to solid tumours. Genomic profiling assists physician to make a therapy selection decision.

- **How advantageous is liquid biopsy to overcome the challenges at tissue biopsies?**

Compared to tissue biopsies, liquid biopsies have several advantages. Firstly, the Guardant360 test
has 90 per cent agreement with tissue for targetable alterations, making this a feasible alternative to pick up actionable tumour mutations that are missed during tissue biopsies. Secondly, tissue biopsies are invasive and this can be risky for some advanced cancer patients. Liquid biopsies, on the other hand, are safe and non-invasive. Thirdly, tissue biopsy procedures are time-consuming while liquid biopsies can be done in a matter of minutes either in a clinic or in the comfort of patients' homes, thanks to the mobile phlebotomy services that we offer in Guardant Health AMEA. Additionally, tissue biopsy test results can take up to 2-3 weeks whereas Guardant360 test results are received within seven days upon sample receipt in the laboratory. For advanced cancer patients, time to treatment is crucial and liquid biopsies make quick treatment decisions a reality. Lastly, the quantity of tissue from the biopsy may not be sufficient for genetic testing and the patient might need to go for a repeat tissue biopsy. In a liquid biopsy, repeat procedures like this can be avoided as all that is required is a single blood draw for the treating oncologist to see the comprehensive genomic profiling of the patient's cancer.

- **How do you foresee APAC liquid biopsy market?**

We anticipate that there would be a significant paradigm shift in using liquid biopsies for genomic profiling ahead of invasive tissue biopsies. Liquid biopsies are a significant game changer in precision oncology and allows selection of accurate treatment for advanced cancer patients. Guardant360 CDx has received the first Food and Drug Administration approval for comprehensive tumour mutation profiling across all solid cancer and we would be seeing more regulatory approvals across Asia.