BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Precision oncology is redefining cancer care at all stages of the disease

04 May 2023 | Opinion | By Hithaishi C Bhaskar

A leading precision oncology company, Guardant Health, is optimising clinical decisions across the cancer care continuum by guiding treatment decisions at all stages of the disease. Guardant Health is currently the only precision oncology company with cutting-edge diagnostics for advanced cancer, recurrence monitoring, and early detection of cancer. These precision oncology technologies can help to bend cancer mortality curves and cost curves through informed treatment decisions. Simranjit Singh, CEO of Guardant Health AMEA explains more about precision oncology and how it is redefining cancer care in Asia.

- **How is comprehensive genomic profiling (CGP) enhancing the quality of cancer management?**

Comprehensive genomic profiling tests such as the Guardant360® liquid biopsy are enhancing the quality of cancer management by helping the physician understand which alterations exist in a patient's cancer without the complications and delays of a tissue biopsy. Over 70 clinically relevant genes are examined in the Guardant360® test to identify genomic alterations within a patient's cancer DNA. In a short turnaround time of approximately seven days upon sample receipt in the laboratory, physicians can detect the most current genomic profile of a patient's tumour and recommend the appropriate treatment. Faster time-to-treatment is crucial for patients with advanced-stage cancer and certainly enhances the quality of cancer management.

In addition to this, Guardant Health's tissue-based biopsy, the Guardant360 TissueNext™ test, is also enhancing the quality of cancer management by helping oncologists identify patients with advanced cancer who may benefit from biomarker-informed treatment. Guardant360 TissueNext is an analytically validated comprehensive next-generation sequencing panel that includes clinically actionable biomarkers to enable informed treatment decisions for patients with advanced solid tumours. This tissue-based test report includes tumour mutational burden (TMB), microsatellite instability (MSI) status, homologous recombination repair (HRR) genes and selected fusions. A complementary testing approach of both tissue and blood-based comprehensive genomic profiling tests is recommended by the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. In most cases, the results from a liquid biopsy are obtained faster and the physician can quickly make a treatment selection for the patient.

- **How does the CGP approach provide a competitive advantage in the liquid biopsy test arena?**

The CGP approach provides a huge competitive advantage in the liquid biopsy test arena. The Guardant360® test detects all four classes of genomic variations in over 70 genes most relevant to solid tumours as well as microsatellite instability-high. This liquid biopsy test also has 90 per cent agreement with tissue testing for targetable alterations, making this a feasible alternative to pick up actionable tumour mutations missed during tissue biopsies.

Guardant Health, as a unique precision oncology company with cutting-edge diagnostics for all stages of cancer, has deployed its technologies to guide treatment decisions. Guardant's tests also detect residual and recurrent disease in patients with early-stage cancer and can screen to find cancer at its earliest and most treatable.

Guardant Health AMEA portfolio includes Guardant360®, Guardant360 TissueNext™ and Guardant360 Response™ for patients with advanced-stage cancer and Guardant Reveal™ for patients with early-stage cancer. In Asia, the Middle East and Africa, there will soon be Guardant Health's screening portfolio, which includes the Shield™ test, (currently offered in the U.S.) and this test aims to address the needs of individuals eligible for cancer screening.

- **How are the Japanese and China markets responding to the entry of Singapore's precision oncology CGP test kit? Can you share the regulatory approval journey?**

In July 2022, China's Adicon Holdings Limited, partnered with Guardant Health to offer Guardant's comprehensive genomic profiling (CGP) tests to biopharmaceutical companies conducting clinical trials in China.

Guardant Health Japan, which is a wholly owned subsidiary of Guardant Health AMEA, offers the Guardant360® CDx liquid biopsy test for tumour mutation profiling across all advanced solid cancers in Japan, enabling physicians to match patients to appropriate treatment quickly.

In March 2022, Japan's Ministry of Health, Labour and Welfare (MHLW) granted regulatory approval for Guardant360® CDx, a liquid biopsy test for tumour mutation profiling in patients with advanced solid cancers. The test was also granted approval as a companion diagnostic to identify patients with microsatellite instability-high (MSI-High) solid tumours who may benefit from Keytruda® (pembrolizumab) and patients with MSI-High advanced colorectal cancer (CRC) who may benefit from Opdivo® (nivolumab). This regulatory approval took on an added significance as CRC is the most commonly diagnosed cancer in Japan.

Both these milestones, which have created inroads into the Japanese and Chinese markets, are crucial to Guardant Health's mission of conquering cancer with data and offering comprehensive genomic profiling to patients with cancer across the globe.

- **How is Guardant Health managing investments and alliances to achieve in the precision oncology sphere? What are the competitive advantages of investing in Asian markets?**

Guardant Health AMEA has established various channel partnerships to provide access to the Guardant Health portfolio of tests in 41 markets in Asia, the Middle East & Africa. We are also actively looking at complementary technologies and solutions that help to advance cancer management in the region. In July 2021, Guardant Health made a strategic investment into Lunit, a South Korean company that develops AI solutions for precision diagnostics and therapeutics. Through the partnership, Guardant Health and Lunit have co-developed Guardant Galaxy™, an AI-powered scoring algorithm for PD-L1 testing. This algorithm improved the detection of the cancer biomarker by more than 20 per cent in non-small cell lung cancer (NSCLC) compared to manual pathologist interpretations.

Guardant Health has also undertaken several research collaborations with the National Cancer Center East hospital in Japan for LC-SCRUM and GOZILA basket clinical studies that are part of SCRUM Japan which is a nationwide cancer genome screening project for lung cancer, colorectal cancer and advanced gastrointestinal cancers. This has enabled several thousands of patients with advanced-stage cancer in Japan to get access to Guardant360® for comprehensive genomic profiling. Many of these patients have also been recruited in clinical trials for new therapeutics being developed by biopharmaceutical companies. This has also created a pathway for expedited regulatory approvals of effective new oncology

drugs in Japan.

- **How do you foresee the precision oncology market in Asia-Pacific? What is your outlook on the projections ahead?**

Advances in precision oncology will drive changes in the healthcare system from one that is predominantly reactive and centred towards treating the sick to one that is also predictive and preserves the health of individuals. The diagnostic accuracy of precision oncology can vastly improve patient care. The use of comprehensive genomic profiling helps eliminate the unnecessary or repeated testing of patients and reduces the use of expensive treatments that may be ineffective in different types of cancer for patients. The wide use of comprehensive genomic profiling for the stratification of patients based on the genomic alterations driving their cancer will further accelerate drug development and provide more effective treatment options for patients in the future.

Many countries in Asia still lack a regulatory approval pathway for next-generation sequencing (NGS) based tests for comprehensive genomic profiling which for the US FDA is covered by the NGS-based In Vitro Diagnostic (IVD) regulatory pathway. This regulatory pathway is important to ensure quality standards for the tests to enhance patient safety and physician confidence in the use of comprehensive genomic profiling for treatment selection. In Asia, Japan leads the way with the Pharmaceuticals and Medical Devices Agency (PMDA) regulatory pathway for medical device software for comprehensive genomic profiling to mandate quality and safety standards. It would be inevitable for countries in Asia to adopt these possible regulatory pathways to provide access to these tests that can have a massive impact on the quality of life for patients with cancer in the region.

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