Hikma gets FDA approval for liquid biopsy panel product

Hikma Pharmaceuticals PLC, the multinational pharmaceutical group, welcomes the recent U.S. Food and Drug Administration (FDA) approval of Guardant360® Liquid CDx, the largest FDA-approved liquid biopsy panel, developed by Guardant Health, Inc. This development was highlighted at the sidelines of the 5th Annual International Oncology Forum IOF 2026 in the UAE, where Hikma and Guardant Health were platinum sponsors.

Guardant360 Liquid CDx is the largest FDA-approved liquid biopsy panel (a type of test that detects cancer-related genomic material from a simple blood draw), offering a less invasive alternative to traditional tissue-based biomarker testing. Powered by Guardant's proprietary Smart Platform, the test integrates both genomic and epigenomic profiling from a single blood draw. It analyses a tumour's DNA mutations, allowing clinicians to make better-informed clinical decisions for patients with advanced cancer originating from solid organs. The test delivers a 100x wider genomic footprint and a several-fold increase in sensitivity for circulating tumour DNA (ctDNA) detection compared to the previous Guardant360 CDx. With this approval, the seven previously FDA-approved companion diagnostic indications for Guardant360 CDx transfer to Guardant360 Liquid CDx.

Hikma signed an exclusive agreement with Guardant Health, Inc. in 2024 for the commercialisation and marketing of its liquid and tissue biopsy tests for cancer screening, recurrence monitoring and tumour mutation profiling across all solid cancers in the Middle East and North Africa (MENA). Guardant is the only precision oncology company to offer a complete portfolio of cancer solutions in the region.

Commenting on this milestone, Mazen Darwazeh, Hikma's Executive Vice Chairman and Deputy CEO – MENA, said: "Our collaboration with Guardant Health is very important for introducing next-generation diagnostics in the MENA region, that can redefine cancer care. The recent FDA approval of Guardant360® Liquid CDx brings a highly advanced solution to clinicians, enabling a deeper understanding of tumour biology to guide precise treatment decisions. As a trusted and experienced partner in the region with a strong oncology portfolio, Hikma remains committed to enhancing access to precision medicine and delivering better outcomes for patients battling cancer."

"Guardant Health is the only precision oncology company to have three solutions receive FDA approval, reinforcing our leadership in comprehensive molecular profiling across the cancer continuum. With our proprietary Smart Platform, clinicians have access to advanced molecular insights to inform their treatment selection decisions, marking a new era in advanced cancer care," said Simranjit Singh, Chief Executive Officer, Guardant Health AMEA.

Results from Guardant360 Liquid CDx are available in as little as seven days once the sample is received in the laboratory, supporting more informed treatment decisions for patients regardless of tissue availability or line of therapy. Approved as a companion diagnostic across non-small cell lung cancer, colorectal cancer, and advanced breast cancer, it delivers a comprehensive view of tumour biology from a single blood draw.

News Source:

https://www.pharmabiz.com/NewsDetails.aspx?aid=186707&sid=2