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ASIA EDITION

Clearbridge BioMedics' ClearCell FX1 system achieves FDA listing

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Singapore - Clearbridge BioMedics announced that it has successfully registered its target cell enrichment device, the ClearCell FX1 system, with the U.S. Food and Drug Administration (FDA) as a Class I Medical Device, for in vitro diagnostic use. This registration marks a significant milestone in providing a reliable liquid biopsy solution for clinical research in the United States. The ClearCell FX1 system has also previously attained CE marking to be used as an in-vitro diagnostic medical device in Europe and China Food and Drug Administration-approved Class I Medical Device status via the company's MGI partnership.

The ClearCell FX1 System is a leading, automated, label-free liquid biopsy device for the enrichment of target cells from blood. The system incorporates the innovative microfluidics CTChip to isolate and retrieve intact, viable target cells from a patient's blood sample.

Commercially launched in 2015, the ClearCell FX1 System has since been installed in laboratories worldwide and empowered numerous liquid biopsy studies. In 2017, it was chosen to be part of the prestigious CANCER-ID consortium, where leading cancer institutes and researchers use the technology to better understand the underlying biology of circulating tumor cells (CTCs). The objective of such efforts is to generate new insights into the disease, to develop innovative cancer therapies and improve patient management protocols. The technology enables seamless processing of both CTCs and circulating tumor DNA (ctDNA) from the same patient sample for subsequent analysis, allowing comprehensive cancer profiling.

"We believe, the ClearCell FX1 System will play a critical role in the development of new therapies by providing label-free, intact and viable cells for analysis. Successfully listing the unit with the U.S. FDA for in vitro diagnostic purposes will accelerate research and the adoption of diagnostics from the tumor cells obtained. We will continue to work with our partners and the authorities to further validate the system, for use in cancer diagnostics, personalized therapy management and patient monitoring," said Michael Paumen, CEO of Clearbridge BioMedics.

In the U.S. the ClearCell FX1 system is sold directly through Clearbridge BioMedics Inc. In EMEA and Asia, the platform is currently available in more than 22 countries through distribution partnerships. In China, it is available through a strategic partnership with MGI, an associate of BGI.