

CellSearch 'liquid biopsy' approved in China

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Singapore: China State Food & Drug Administration (SFDA) has approved CellSearch, circulating tumor cell (CTC) test as an in vitro diagnostic for women with metastatic breast cancer, developed by Veridex, a Johnson & Johnson company. This makes CellSearch the first and only approved CTC test for cancer patients in China, which is the seventh country outside of the US and the European Union to clear CellSearch for use as an aid in the monitoring of patients.

The SFDA approval is based on the results of a multi-center, prospective study of 294 women with metastatic breast cancer. The objective of the study was to evaluate whether CTC count, using the CellSearch test, is predictive of progression-free survival (PFS) and overall survival (OS) in Chinese metastatic breast cancer patients.

An estimated 189,500 women in China are expected to be diagnosed with breast cancer by 2013. Nearly two-thirds of Chinese women with breast cancer are diagnosed in the later stages of the disease. Further, the incidence of breast cancer is rising sharply at a rate of four percent per year.

"CellSearch is a useful new tool to help improve the care provided to China's growing number of women affected by metastatic breast cancer," said Dr Minetta C Liu, clinical molecular diagnostics laboratory, Georgetown University's Lombardi Comprehensive Cancer Center and a key investigator in the CTC study. "The use of CellSearch in conjunction with other diagnostic tests, such as imaging and routine blood work, provides oncologists with a more accurate and comprehensive understanding of their patients' prognoses."

"We are thrilled to make CellSearch available for women in China with metastatic breast cancer," said Mr Robert McCormack, head, technology innovation, Veridex. "Oncologists tell us that knowing a patient's CTC count provides them with a second measurement, complementary to traditional imaging, to help them assess the prognosis of a patient."