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Wilex, GeneDiagnostics enter ELISA deal in China

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Wilex, GeneDiagnostics collaborate to commercialize ELISA test in China



Singapore:Ã?Â Wilex Ã?Â has entered into an exclusive distribution agreement with GeneDiagnostics for the commercialization of the serum HER-2/neu ELISA test in China.

This biomarker test is FDA cleared in the US, carries the CE mark for the European market, and is currently for supplied for research-use-only in the Chinese market.

GeneDiagnostics plans to conduct clinical studies in leading hospitals in China for the IVD clearance through the State Food and Drug Administration (SFDA) in China as part of the terms. GeneDiagnostics is a clinical research and service provider based in Hangzhou, China, and has well-established business relationships with major hospitals. Financial terms of the agreement are yet to be disclosed.

Professor Olaf G Wilhelm, CEO, Wilex, commented that, "The Chinese market is expected to be one-of-the-fastest growing pharma markets in the world. Therefore, we are pleased to have in GeneDiagnostics a competent partner to pursue an IVD approval for our serum HER-2/neu test as well as to distribute the test in this key market."

"According to the latest statistics from the Chinese Ministry of Health, 126,000 new cases of breast cancer were reported each year. This corresponds to roughly one-tenth of the world's total and is expected to increase by at least four percent annually. We look forward to introducing this HER-2/neu ELISA test into the Chinese market as we believe that it can help physicians administer targeted treatments to carefully diagnosed patients with metastatic breast cancer," said Dr Mark Han, president and chief scientist, GeneDiagnostics.