

## PRESS RELEASE

### **WILEX Inc. and GeneDiagnostics Inc. enter into partnership for the IVD approval and distribution of the serum HER-2/neu test in China**

**Munich, Germany / Hangzhou, China, 23 January 2013.** WILEX AG (ISIN DE0006614720 / WL6 / Frankfurt Stock Exchange) today announced that its US subsidiary WILEX Inc., Cambridge, MA, has entered into an exclusive distribution agreement with GeneDiagnostics Inc. for the commercialization of the serum HER-2/neu ELISA test in China. This biomarker test is FDA cleared in the USA, carries the CE mark for the European market, and is currently 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 in China (SFDA) 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 were not disclosed.

Professor Olaf G. Wilhelm, CEO of WILEX Inc. and WILEX AG, comments: “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 4 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 of GeneDiagnostics Inc.

#### **About HER-2/neu ELISA**

The serum HER-2/neu test measures the serum HER-2/neu level for the management and monitoring of patients with metastatic breast cancer (MBC). HER-2 (Human Epidermal Growth Factor Receptor 2) is a protein found on some types of cancer cells, especially breast cancer cells. MBC patients who overexpress the HER-2/neu protein tend to have a worse prognosis and a more aggressive disease. The test measures changes in the HER-2 status with increasing serum levels of HER-2/neu being reflective of cancer progression while decreasing serum levels being reflective of therapy response. As the HER-2 tumour status may change between primary and metastatic breast cancer tumours, the serum HER-2/neu ELISA test can help monitor these changes in HER-2/neu levels and aid doctors in managing new treatment options. This test offers laboratories an efficient, reliable and cost-transparent possibility for the measurement of HER-2/neu in serum with no need of further equipment.

#### **About GeneDiagnostics Inc.**

GeneDiagnostics Inc., China, is engaged in the collaboration of R&D, distribution and provision of diagnostic products and services used for cancer screening, monitoring and diagnosis together with partners in China as well as worldwide. The company has been working with leading universities and hospitals extensively in China in introducing and promoting new and innovative diagnostic tools and services to benefit the patients.

### **About WILEX Inc.**

WILEX Inc. is a wholly owned US subsidiary of WILEX AG, Munich, Germany and manufactures, markets and sells serum based oncoprotein diagnostics and various biomarker tests under the brand name Oncogene Science. The product portfolio includes Enzyme-linked ImmunoSorbent Assays (ELISA) and immunohistochemical (IHC) assays. With the aim of supporting treatment regimens for cancer patients worldwide WILEX Inc. offers biomarker tests for measuring oncogenes, growth factor receptors (HER-2/neu, EGFr), proteases and protease inhibitors (uPA, PAI-1, TIMP-1), as well as markers of hypoxia (CA IX). In addition to the new CA IX IHC which is a class 1 IVD test, WILEX Inc. provides the only FDA-cleared IVD ELISA that measures the serum HER-2/neu level for the management and monitoring of patient care for women with metastatic breast cancer. WILEX Inc. is based in Cambridge, MA, USA and also provides GMP and ISO certified manufacturing services. More information is available on [www.oncogene.com](http://www.oncogene.com).

WILEX AG is a biopharmaceutical company based in Munich, Germany. Focused on oncology, the Company develops diagnostic and therapeutic product candidates for the specific detection and targeted treatment of various types of cancer based on antibodies and small molecules. Beside the manufacturing and marketing of the biomarker tests from WILEX Inc. the subsidiary Heidelberg Pharma GmbH offers preclinical contract research services and an antibody drug conjugate (ADC) technology platform. The business model comprises research and product development as well as the commercialisation of its activities. Our customers and partners include leading international pharmaceutical companies. WILEX AG is listed at the Frankfurt Stock Exchange. ISIN DE0006614720 / WKN 661472 / Symbol WL6. More information is available on [www.wilex.com](http://www.wilex.com).

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