



## PRESS RELEASE

# WILEX Inc. signs distribution agreement with Immundiagnostik AG for D-A-CH region

**Munich / Bensheim, Germany, 12 December 2012.** WILEX AG (ISIN DE0006614720 / WL6 / Frankfurt Stock Exchange) today announced that its US subsidiary WILEX Inc., Cambridge, MA, USA, has entered into an exclusive distributor agreement with Immundiagnostik AG, Bensheim, Germany for the commercialisation of the serum HER-2/neu and CA IX ELISA tests in Germany, Austria and Switzerland (D-A-CH region). Immundiagnostik AG is specialised in the development and production of innovative immunoassays and other analytical detection methods. Financial terms of the agreement were not disclosed.

WILEX Inc. specialises in serum based oncoprotein diagnostics and offers various biomarker tests under the brand name Oncogene Science. The serum HER-2/neu test is the only FDA-cleared IVD ELISA that 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. WILEX's serum HER-2/neu ELISA test is used to monitor breast cancer patients on a variety of therapies, including HER-2/neu-targeted therapies. 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.

The CA IX ELISA test is used for the quantitative detection of the circulating form of the CA IX (Carbonic Anhydrase IX) in serum and plasma. The protein CA IX is overexpressed in many types of cancer and its expression is strongly induced by hypoxia. In a variety of human cancers, tumour hypoxia is associated with an increased incidence of metastases.

Professor Olaf G. Wilhelm, CEO of WILEX Inc. and WILEX AG, comments: "With Immundiagnostik AG we have found a competent and experienced partner with a broad product and service portfolio in the field of in vitro diagnostics. Their extensive network and cooperation with universities and international research institutions as well as with laboratory medicine units offers the right framework for the distribution of our serum HER-2/neu and CA IX ELISA tests in the important German speaking market."

"We look forward to working with WILEX. Both serum based oncoprotein ELISA tests ideally complement our portfolio and provide the opportunity to further expand into the field of companion diagnostics. The serum HER-2/neu test is the most frequently used ELISA based assay in clinical trials worldwide, which offers laboratories an efficient and reliable possibility for the measurement of HER-2/neu in serum with no need for further equipment", Dr Franz Paul Armbruster, CEO of Immundiagnostik AG, said.



### **About Immundiagnostik AG**

Immundiagnostik AG, founded in 1986, is a globally operating diagnostics company represented in over 60 countries. The company focuses on the development and production of innovative assays for medical routine and research. Immundiagnostik's core competence lies in antigen/antibody-based analytical detection methods such as immunoassays (ELISA, EIA) and immunologically-based HPLC and LC-MS/MS. Immundiagnostik's mission is to provide effective tools for prevention, differential diagnosis and therapy monitoring in the areas of gastroenterology, cardiovascular diseases, disorders of the skeletal system and oxidative stress. The product portfolio is completed by a broad range of antibodies and antigens developed in-house. Multiple collaborations with the pharmaceutical industry and a tight network with scientific organisations are the basis for a successful product development with new parameters. The comprehensive range of products is continuously refuelled by a rich pipeline of proprietary developments. With a headcount of more than 60 employees, Immundiagnostik's headquarter is located in Bensheim, south-western Germany. For more information, please visit the website [www.immundiagnostik.com](http://www.immundiagnostik.com).

### **About WILEX Inc.**

WILEX Inc. is a wholly owned US subsidiary of WILEX AG, Munich, Germany and manufactures, markets and sells diagnostic tests in oncology 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 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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