**Ad-hoc release pursuant to § 15 Wertpapierhandelsgesetz (German Securities Trading Act)**

# MESUPRON® met its primary objective of demonstrating efficacy in the proof of concept phase II breast cancer trial

**Munich, Germany, 14 June 2012.** WILEX AG (ISIN DE0006614720 / WL6 / Frankfurt Stock Exchange) today published data from its Phase II trial with its oral drug candidate MESUPRON® in first line treatment of patients with HER2-receptor negative metastatic breast cancer.

The uPA inhibitor MESUPRON® (INN: Upamostat) was given in combination with the chemotherapeutic agent Capecitabine (Xeloda®, Hoffmann La Roche AG, Switzerland). The double blind randomised Phase II trial evaluated the efficacy and safety of MESUPRON® 200 mg oral once daily in combination with Capecitabine compared to Capecitabine alone (control group). 132 patients in 20 centres in five countries (Belgium, Brazil, Germany, Israel, US) were enrolled.

The primary objective of the study was to evaluate the efficacy of the combination of MESUPRON® and Capecitabine compared to Capecitabine alone by assessment of progression free survival (PFS). The study also evaluated the objective response rate, overall survival and safety as well as pharmacokinetics. Efficacy was evaluated by RECIST (Response Evaluation Criteria on Solid Tumours) by independent central read using computed tomography and bone scans.

In the total study population (intent to treat; ITT) MESUPRON® led to an increase of median progression free survival from 7.5 months in the control group to 8.3 months in the combination therapy. Capecitabine alone demonstrated an objective tumour response rate of 9%. Co-administration of 200 mg MESUPRON® almost doubled the response rate to 17%. Overall survival data have not matured yet as over 60% of patients were still alive at the time of analysis. The combination therapy of MESUPRON® and Capecitabine was safe and well tolerated. Pharmacokinetic analysis demonstrated no drug-drug interactions between MESUPRON® and Capecitabine.

Breast cancer is a heterogeneous disease. To test whether MESUPRON® also shows efficacy in a more homogeneous patient population two subgroups were evaluated which had sufficient numbers of patients to allow separate analysis: In the subgroup of patients who were Caucasian (n=109) median PFS improved from 7.5 months in the control group to 9.1 months in patients treated with MESUPRON®. In the subgroup of patients (n=95) who received adjuvant chemotherapy following the primary diagnosis of breast cancer, PFS improved from 4.3 months in the Capecitabine alone group to 8.3 months in the MESUPRON® combination group.

+++ End of the ad-hoc release +++ Further information in the press release.

**Invitation to the conference call**

WILEX will hold a conference call for media representatives, analysts and investors in English on Monday, 18 June 2012, at 10:00 a.m. CET. Please dial in ten minutes before the conference call using the following dial-in numbers:

1. Germany: +49 69 71044 5598
2. UK: +44 20 3003 2666
3. USA: +1 212 999 6659
4. USA Freephone: +1 866 966 5335

You will be welcomed by an operator taking your name and company. The presentation for the conference (in English) will be available for download 10 minutes before the presentation at the website www.wilex.com. A replay of the conference will be available after the presentation on the website http://www.wilex.de/IR/Presentations.php.

More information regarding WILEX' uPA programme are available in the press release or on our website.

**About WILEX AG**

WILEX AG is a biopharmaceutical company based in Munich, Germany. Focused on oncology, the Company has a broad portfolio of diagnostic and therapeutic products for the specific detection and targeted treatment of various types of cancer. WILEX's therapeutic product candidates are based on antibodies (RENCAREX® in Phase III) and small molecules (MESUPRON® in Phase II, WX-554 in Phase Ib/II and WX-037 in preclinical development). In the field of diagnostics, REDECTANE® is an antibody-based, imaging in vivo diagnostic agent that is currently in a Phase III programme. WILEX's US subsidiary WILEX Inc. in Cambridge, MA, markets a portfolio of research use only tests and in vitro diagnostic agents under the brand Oncogene Science, which are used as companion diagnostics for clinical trials and therapy monitoring. The wholly owned subsidiary Heidelberg Pharma GmbH offers an attractive and highly promising antibody drug conjugate technology platform and preclinical contract research services. The business model of WILEX comprises research, technology, product development and commercialisation. WILEX's customers and partners include leading international pharmaceutical companies.
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