**PRESS RELEASE**

# WILEX AG announces results of Phase III ARISER study with RENCAREX® in clear cell renal cell carcinoma

- **Trial did not meet its primary endpoint of median disease-free survival (DFS)**

**Munich, Germany, 16 October 2012** – WILEX AG (ISIN DE0006614720 / WL6 / FSE) today announced results of the Phase III ARISER trial with RENCAREX® (INN: Girentuximab) to treat clear cell renal cell carcinoma (ccRCC). The trial did not meet its primary endpoint. The analysis showed no improvement in median DFS (approximately 72 months) following RENCAREX® treatment compared with placebo. RENCAREX® was safe and well tolerated. The Independent Data Monitoring Committee (IDMC) has recommended terminating the Phase III ARISER trial.

Professor Seppo Pyrhoenen, Chairman of the ARISER IDMC, said: "I have over 30 years' experience in treating patients with kidney cancer and applaud this study for being well balanced, controlled and very well conducted. This is probably the most comprehensive study in the adjuvant setting conducted in the past 20 years".

"The information gained from this study is of utmost importance, specifically in the light of the surprising median DFS spanning to six years. This obviously represents a challenge to any company seeking to develop treatment for kidney cancer in the adjuvant setting" commented Professor Arie Belldegruen, Chairman of the RENCAREX Medical Advisory Board and Professor of Urology and Chief of the Division of Urologic Oncology at the David Geffen School of Medicine at UCLA, Los Angeles.

Professor Olaf G. Wilhelm, CEO and chairman of the Executive Management Board at WILEX, said: "Of course, we are very disappointed but we thank the patients, doctors, and investigators for their participation and engagement in the clinical evaluation of RENCAREX®. In light of today's news, we will focus resources to drive the development of REDECTANE® our Phase III diagnostic antibody for clear cell Renal Cell Cancer and other clinical programs".

**About RENCAREX® and the ARISER study**

The drug candidate RENCAREX® is based on the antibody Girentuximab, which binds to the tumour-specific antigen CAIX – an antigen that is overexpressed in clear cell renal cell carcinomas (ccRCC).

ARISER (Adjuvant **RENCAREX® Immunotherapy** trial to **Study Efficacy** in non-metastasised **Renal** cell carcinoma) is an international, multicentre, randomised Phase III trial that examines the efficacy of the antibody RENCAREX® in comparison to placebo in the treatment of clear cell renal cell cancer patients following complete or partial surgical removal of the affected kidney in patients with no detectable metastases but at high risk of recurrence. The study enrolled 864 patients that had had prior nephrectomy

of primary RCC no later than 12 weeks before study entry with documented clear cell histology, an ECOG score of 0 or 1 and no evidence of macroscopic or microscopic residual disease. Under the treatment schedule patients received a once-weekly infusion of RENCAREX® or placebo (50:50) for 24 weeks. Patients receiving RENCAREX® were dosed at 50 mg in the first week followed by weekly doses of 20 mg during weeks 2-24.

The last patient completed treatment in February 2009. Following the occurrence of the 100th relapse, an interim analysis for futility was carried out in late 2007. In November, 2011 the IDMC recommended to cancel an intended interim analysis and progress directly to the final Phase III trial analysis.

RENCAREX® has Fast Track designation for ccRCC in the USA and Orphan Drug designation for RCC in the USA and EU. WILEX has partnered RENCAREX® with Prometheus Laboratories Inc, which has exclusive rights to commercialise the treatment in the USA, and Laboratories Esteve S.A. in certain European countries.

**Invitation to the conference call:**

On 17 October 2012, WILEX will hold a public conference call for media, analysts and investors at 3:00 p.m. CET in English. 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 slides for the conference will be available for download at www.wilex.de on 17 October 2012 at 2:00 p.m. CET.

**About WILEX AG**

WILEX AG is a biopharmaceutical company based in Munich, Germany. Focused on oncology, the company has a broad portfolio of near-to-market therapeutic and diagnostic products for the targeted treatment and specific detection of various types of cancer. The company's therapeutic product candidates are based on antibodies and small molecules. 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. The 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.

Website: http://www.WILEX.com, ISIN DE0006614720 / WKN 661472 / Symbol WL6.

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