

PRESS RELEASE

Further analysis of the ARISER study identifies a subgroup which shows significant improvement of disease-free survival with RENCAREX[®]

- **Patients expressing high CAIX tumour levels in clear cell renal cell carcinoma (ccRCC) show a statistically and clinically significant improvement in median disease-free survival with RENCAREX[®]**

Munich, Germany, 26 February 2013 – WILEX AG (ISIN DE0006614720 / WL6 / FSE) today announced that the subgroup and biomarker analysis of the Phase III ARISER trial conducted over the last few months has been completed. The subgroup analysis shows that with increasing density of CAIX expression in tumour tissue, as quantified by a CAIX score, the more significant the treatment effect becomes. Disease-free survival showed a clinically and statistically significant improvement in the patient population with a high CAIX level treated with RENCAREX[®] compared to both placebo and patients with a low CAIX score.

The CAIX score can be determined by a FDA registered in vitro diagnostic (IVD) marketed by WILEX Inc. and may be helpful in identifying and stratifying patients who may benefit from RENCAREX[®]. Therefore, an immunotherapy for ccRCC in the adjuvant setting would appear to be still an option. RENCAREX[®] has Fast Track designation for ccRCC in the USA and Orphan Drug designation for RCC in the USA and EU.

The detailed results will be presented at a major conference in the second quarter this year.

Dr Paul Bevan, Head of R&D at WILEX AG, said: “This finding that therapeutic success is dependent on the CAIX level is new and the result of many detailed analyses. WILEX will now evaluate the business case and discuss the implications for development with our partners and regulatory authorities”.

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) was an international, multicentre, randomised Phase III trial that examined 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 analysis – executed in October 2012 - showed no improvement in median DFS (approximately 72 months) following RENCAREX[®] treatment compared with placebo. The trial did not meet its primary endpoint. RENCAREX[®] was safe and well tolerated. The Independent Data Monitoring Committee (IDMC) recommended terminating the Phase III ARISER trial.

Invitation to the annual press conference:

On 27 February 2013, 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 27 February 2013 at 2:30 p.m. CET.

About WILEX

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. In the field of therapeutics, WILEX develops small molecules (MESUPRON[®] two Phase IIa trials completed, 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. The Company also has a portfolio of research use only tests and in vitro diagnostic agents that are marketed via its US subsidiary WILEX Inc. in Cambridge, MA, under the brand Oncogene Science. WILEX's subsidiary Heidelberg Pharma GmbH offers preclinical contract research services and a highly promising antibody drug conjugate (ADC) technology platform. The business model of WILEX comprises research and product development as well as the commercialisation of its activities. 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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