PRESS RELEASE

Phase III ARISER data for the adjuvant treatment of clear cell renal cancer with RENCAREX® including retrospective subgroup analysis presented at ASCO

- **RENCAREX® improves disease free survival significantly by over 22 months (44%) in the subgroup of patients (ITT) with a high CAIX score ≥ 2.6 (HR=0.54; p=0.02)**
- **In patients under the age of 65 years RENCAREX® clinically and statistically improves disease free survival with a CAIX score ≥ 2.0 (HR=0.60; p=0.01)**

Munich, Germany, 03 June 2013 – WILEX AG (ISIN DE0006614720 / WL6 / FSE) published the results from the Phase III ARISER trial with RENCAREX® for the adjuvant treatment of patients with clear cell renal cell carcinoma at the Annual Meeting of the American Society of Clinical Oncology (ASCO). The data were presented by Professor Arie S. Belldegrun, Principal Investigator of the ARISER trial, Director of the UCLA Institute of Urologic Oncology and Chief of Urologic Oncology at the David Geffen School of Medicine at UCLA, Los Angeles.

In the ARISER trial 864 subjects were enrolled from 142 sites across Europe, North and South America. Baseline demographics were well balanced across treatment groups. Up to six months of treatment demonstrated an excellent safety profile and was well tolerated. As reported previously, the primary endpoint in the ARISER trial was not reached. After 54 months median duration of follow up, the median disease free survival (DFS) was 71.4 months in the RENCAREX® arm and was not reached in the placebo arm (HR=0.97; p=0.74).

Analysis of the data confirmed that CAIX expression is a characteristic of ccRCC. However, the antigen density, as determined by the CAIX score, varies from patient to patient. Subgroup analysis for all CAIX scores from 0.0 to 3.0 revealed that as the CAIX score increases, the more pronounced the RENCAREX® treatment effect becomes. A CAIX score of ≥ 2.6 resulted in a clinically and statistically significant treatment effect with median DFS increasing from 51.2 months in the placebo arm to 73.6 months in RENCAREX® patients (N=151; HR=0.54; p=0.02).

Patients who had received at least eight consecutive administrations of study medication (week 1 to 8) and had no major protocol deviation were defined as the per protocol population. In these patients with a CAIX score ≥ 2.6 both the hazard ratio and the significance level (N=139; HR=0.51; p=0.007) improved even further.

In patients under the age of 65 years RENCAREX® showed a clinically and statistically significant DFS with a CAIX score ≥ 2.0 (N=286; HR=0.60; p=0.01).

Treatment with RENCAREX® has an excellent safety profile and is well tolerated. The retrospective subgroup analysis indicates that RENCAREX® significantly improves DFS in patients with a high CAIX score i.e. a high antigen density. The treatment effect could be detected within 24 months of the start of treatment. Thus the CAIX score may be

helpful in identifying and stratifying patients who may benefit from RENCAREX® adjuvant therapy. RENCAREX® could deliver an effective therapy for patients with ccRCC and a high CAIX score.

Professor Arie Belldegrun commented: “The ARISER trial, which is one of the most important prospective trials in kidney cancer in the past decade, has demonstrated a surprisingly long Disease Free Survival. This might pose a challenge for adjuvant ccRCC drug development without appropriate patient stratification. The finding that a subgroup of patients had a 40% lower risk of recurrence if treated with RENCAREX® is important and should be confirmed in a future prospective trial now that we know that CAIX density can serve as a predictive companion diagnostic for RENCAREX®.”

WILEX plans to start discussions with regulatory authorities (FDA and European Authorities) in the second half of 2013 on a confirmatory prospective Phase III trial with RENCAREX® in the adjuvant therapy of ccRCC in the defined subgroup using the biomarker CAIX for stratification.

The definition of the subgroup might lead to a revised peak sales potential of RENCAREX® in the adjuvant setting of ccRCC of over 300 million USD. The stratification by the biomarker CAIX may also be applicable to other indications with CAIX expression such as colon, non-small cell lung, head and neck and oesophageal cancer.

Following the recommendation of the IDMC to terminate the ARISER study, WILEX and its partner Prometheus are currently in discussion on the formalities and timing regarding the termination of the existing licensing agreement for the US marketing rights of RENCAREX®. Once completed, WILEX will be able to offer a new partner world-wide rights (excluding southern Europe).

Invitation to the conference call to present the ARISER subgroup data

WILEX will hold a public conference call for media, analysts and investors on 4 June 2013 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 04 June 2013 at 2:30 p.m. CET.

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 (**A**djuvant **R**ENCAREX® **I**mmunotherapy trial to **S**tudy **E**fficacy in non-metastasised **R**enal 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.

RENCAREX® has Fast Track designation for ccRCC in the USA and Orphan Drug designation for RCC in the USA and EU.

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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