

## **PRESS INFORMATION**

### **FDA issues Special Protocol Assessment (SPA) for pivotal Phase III trial with CA9-SCAN**

**Munich, 11 February 2008** – The Munich-based biopharmaceutical company WILEX AG (ISIN DE0006614720 / Frankfurt Stock Exchange / Prime Standard) has received a special protocol assessment (SPA) for the Phase III registration trial with its diagnostic product candidate CA9-SCAN from the US Food and Drug Administration (FDA). With this SPA the FDA confirms that the design and planned analysis of the clinical trial adequately address the requirements for a regulatory submission for CA9-SCAN. The FDA is considered to be bound by this protocol assessment as part of the approval process.

WILEX will start patient recruitment in the second quarter of 2008 and will conduct the study in accordance with the approved protocol. 166 patients suspected of having kidney cancer will be enrolled in more than 15 centres in the USA. Patients included are scheduled for complete or partial surgical removal of the affected kidney. They will be imaged with computer tomography (CT) and CA9-SCAN (positron emission tomography (PET) / CT) prior to surgery to examine whether they have clear cell renal cell carcinoma. The trial will evaluate whether imaging with CA9-SCAN can improve the diagnosis in comparison to the current standard (CT alone). CA9-SCAN could improve the planning of treatment and the post-operative monitoring of renal tumour patients.

Patient recruitment and follow-up is expected to be completed by the end of 2008 with the data and report available three to six months later.

Dr. Paul Bevan, Head of R&D and Member of the Executive Management Board at WILEX AG, commented: "We are delighted with the SPA because it demonstrates the positive communication we have had with the FDA. Assuming positive results, we will be able to file for approval soon after the end of the trial. We expect the SPA to significantly reduce the time for approval of CA9-SCAN".

#### **About SPA**

By applying for an SPA WILEX has followed the recommendation of the FDA resulting from the pre-IND meeting in which the draft clinical protocol was reviewed. Special protocol assessment (SPA) is an instrument of the FDA whereby, if granted, the FDA evaluates a clinical protocol submitted by a sponsor. The SPA documents that the FDA confirms that the design and planned analysis of the clinical trial adequately address the requirements for a regulatory submission for CA9-SCAN. The FDA is considered to be bound by this protocol assessment as part of the approval process. The SPA can significantly reduce development time since the design of the pivotal protocol has been approved in advance.

## About CA9-SCAN

CA9-SCAN is one of two product candidates from WILEX's late stage multi-product portfolio which is in a Phase III registration trial. CA9-SCAN is a radioactively labelled form of the antibody WX-G250. The labelled antibody WX-G250 targets clear cell renal cell carcinoma and accumulates in the tumour tissue. This accumulation can be visualised by means of Positron Emission Tomography (PET) / Computer Tomography (CT). An earlier feasibility study found that a positive result with CA9-SCAN was confirmed as clear cell renal cell carcinoma in 100% of cases (positive predictive value). CA9-SCAN could determine whether the patient had clear cell renal cell carcinoma before surgery and the subsequent pathology. Therefore, CA9-SCAN could improve treatment planning for patients suspected of having renal cancer.

## About WILEX

WILEX is a biopharmaceutical Company based in Munich founded in 1997 by a team of physicians and oncologists from the Technical University of Munich. WILEX's mission is to develop drugs and diagnostic agents with a low side effect profile and targeted treatment of different types of cancer as well as for early detection of tumours. WILEX's product candidates are based on antibodies and small molecules. WILEX possesses an attractive pipeline which includes both drug and diagnostic product candidates: The substances RENCAREX<sup>®</sup> and CA9-SCAN are currently undergoing a Phase III registration trial. The substance WX-671 is currently in a Phase II programme. Based on this pipeline, WILEX's aim is to achieve profitability within a few years through the commercialisation of its products and in the long term to finance its research and development programmes from its operating business. WILEX AG is listed at the Frankfurt Stock Exchange at the Regulated Market / Prime Standard. ISIN DE0006614720 / WKN 661472 / Symbole WL6

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