

PRESS INFORMATION**WILEX receives US FDA approval (IND) for clinical Phase II trial with its uPA inhibitor WX-671 in metastatic breast cancer**

Munich, 28 January 2008 The Munich-based biopharmaceutical company WILEX AG (ISIN DE0006614720 / Frankfurt Stock Exchange / Prime Standard) today announced that the U.S. Food and Drug Administration (FDA) approved an Investigational New Drug application (IND) for a clinical Phase II trial with its drug candidate WX-671. The study will evaluate the efficacy of WX-671 in combination with the chemotherapeutic agent capecitabine (Xeloda[®], Hoffmann La Roche AG, Basel, Suisse) in patients with HER2-receptor negative metastatic breast cancer. The trial is supported under the agreement number DAMD17-03-1-0634 by the US Department of Defense Breast Cancer Research Program.

The study will be conducted in 114 patients in approximately 40 centres in six countries. The Fox Chase Cancer Center (FCCC) in Philadelphia, a member of the Eastern Cooperative Oncology Group (ECOG), will be the lead centre in the US (the FCCC also participated in the Phase I trial with WX-UK1 reported recently). The study is a randomised, double blind Phase II trial in patients with metastatic breast cancer. It will evaluate the efficacy of combination therapy of WX-671 and capecitabine in comparison to capecitabine monotherapy. Patients will receive daily doses of WX-671 for three weeks in one of the two treatment groups, while the other treatment group will receive placebo. All patients will receive daily capecitabine concomitantly for the first 2 weeks of every cycle. The treatment cycles will be continued until progression or unacceptable toxicity.

Progression free survival is defined as a primary endpoint of the trial. The study will also evaluate the overall survival and the objective response rate. The start of patient recruitment is expected in Q2 2008.

WILEX recently published the results of a Phase I clinical trial with WX-UK1, the intravenously administered drug candidate, of which WX-671 is the orally administered pro-drug. In this difficult to treat patient population with advanced tumours and no standard efficacious treatment options, combination therapy with WX-UK1 showed encouraging effects in several patients including evidence of prolonged stable disease and in 3 patients, 2 of whom with metastatic breast cancer showed a partial response.

“The effects that we have seen in the Phase I trial have supported our decision to further develop the combination with our uPA inhibitor and capecitabine”, Paul Bevan, PhD, Head of R&D and Member of the Executive Management Board at WILEX AG remarked. “We will switch to the oral pro-drug WX-671, which is converted into WX-UK1 in the body, because it is more convenient for the patients getting oral therapy. This will facilitate the long-term treatment of patients.”



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About the uPA programme

WILEX's late stage multi-product portfolio includes two drug candidates, WX-UK1 and WX-671, which are being developed as part of the Company's urokinase-type Plasminogen Activator programme ("uPA programme"). In this programme WILEX is developing various compounds that inhibit the uPA system. The uPA system plays a key role in the growth, spread and metastasis of various malignant tumours. The Company expects that drug candidates which emerge from the uPA programme may be used for the treatment of patients with tumours such as breast, pancreatic, ovarian, gastric and colon cancer.

WILEX successfully completed Phase I studies with WX-UK1 and WX-671. The compounds were found to be safe and well tolerated. WX-671 can be administered orally and is converted into WX-UK1 in the body. This facilitates the long-term treatment of patients. Therefore, the Company decided to investigate the efficacy of WX-671 in two Phase II trials. In addition to the trial starting now the Company conducts a Phase II trial in which patients with pancreatic cancer are treated with WX-671 in combination with the chemotherapeutic agent Gemcitabine (Gemzar[®], Eli Lilly and Company, Indianapolis, USA). After a positive outcome from these Phase II trials, the Company intends to test WX-671 in different types of 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 is focused on the development of new cancer therapies based on antibodies and small molecules. The therapeutic approach of WILEX targets the prevention of growth, spread and the metastasis of malignant tumours and the destruction of malignant tumours in the body. The late stage multi-product portfolio includes both drug and medical product candidates ranging from research to late stage clinical development. Currently the following compounds are in clinical development: WX-G250 (development name: RENCAREX[®]), WX-671, WX-UK1 and CA9-SCAN. The company's strategy is to develop WILEX into a commercially successful biopharmaceutical company with a broad portfolio of new drugs and medical products for the treatment of cancer. WILEX AG is listed at the Frankfurt Stock Exchange on the Regulated Market (Regulierter Markt) / Prime Standard.

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