

PRESS INFORMATION

Phase I study with uPA inhibitor WX-UK1 successfully completed

Munich, 25 January 2008. The Munich-based biopharmaceutical company WILEX AG (ISIN DE0006614720 / Frankfurt Stock Exchange / Prime Standard) has successfully completed a Phase I dose escalation study with its drug candidate WX-UK1 in combination with the chemotherapeutic agent Capecitabine (Xeloda[®], Hoffmann La Roche AG, Basle, Suisse) in patients with advanced solid tumours. The study was conducted as a single centre trial at Fox Chase Cancer Center, Philadelphia, PA (USA), and funded under the agreement number DAMD17-03-1-0634 by the US Department of Defense Breast Cancer Research Program.

25 patients were treated with the combination of both substances. Patients received once weekly infusions of WX-UK1 for three weeks at various fixed doses and daily capecitabine concomitantly for 2 weeks. This three-week cycle was repeated until progression or toxicity. The maximum number of treatment cycles was 15 (eleven months). Twenty-three patients completed at least one treatment course with an average of 4.5 treatment courses.

The combination therapy was safe and well tolerated. The typical capecitabine-related adverse events were observed and no apparent changes in the frequencies or intensities of these side effects were reported. There was no increased rate of adverse events, nor of increased intensity associated with co-administration of WX-UK1. No serious adverse events related to WX-UK1 were reported. Pharmacokinetic analysis showed no significant reciprocal drug-drug interactions. WX-UK1 showed dose-linear pharmacokinetic profile over the dose range tested.

In this difficult to treat patient population with advanced metastatic 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 had metastatic breast cancer, partial responses.

“These effects are particularly noteworthy as all three patients showed disease progression at the time of study entry”, comments Dr. Paul Bevan, Head of Research & Development and Member of the Executive Management Board of WILEX AG. “The results of the trial confirm our therapeutic approach of long term treatment of various types of cancer with anti-metastatic uPA inhibitors. Treatment of eleven months with 46 infusions confirms that the combination of our drug candidate with Capecitabine was safe and well tolerated. With this trial our Phase I-programme with uPA inhibitors is completed. A Phase II study with WX-671, an oral pro-drug of WX-UK1, is currently underway.”

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. 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 medicinal product candidates as well as research candidates. 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 has been listed in the Regulated Market / Prime Standard of the Frankfurt Stock Exchange
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