

PRESS INFORMATION

WILEX starts patient recruitment in Phase II breast cancer trial with its uPA inhibitor MESUPRON[®] (WX-671)

Munich, 11 August 2008 The Munich-based biopharmaceutical company WILEX AG (ISIN DE0006614720 / Frankfurt Stock Exchange / Prime Standard) has randomised the first patient in its second clinical Phase II trial with the oral drug candidate MESUPRON[®] (WX-671). The drug will be given in combination with the chemotherapeutic agent Capecitabine (Xeloda[®], Hoffmann La Roche AG, Suisse) to patients with HER2-receptor negative¹⁾ metastatic breast cancer for first line treatment.

The double blind two arm randomised Phase II trial will evaluate the efficacy of the combination therapy in comparison to capecitabine monotherapy. The study will treat 114 patients in approximately 40 centres in six countries. 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. More details regarding the study design, information about the participating centres and the inclusion criteria are available for review on the company's website www.wilex.com or www.clinicaltrials.gov.

Dr. Paul Bevan, Head of R&D and Member of the Executive Management at WILEX AG remarked: "By starting the patient recruitment in this study our uPA programme with the drug candidate MESUPRON[®] progressed as scheduled."

The trials with WX-UK1 and MESUPRON[®] have been supported since 2003 by the US Department of Defense (DOD; Award DAMD17-03-1-0634) in their Breast Cancer Research Program (BCRP). The DOD hosted the "5th Era of Hope" meeting in June this year where more than 1,600 researchers, oncologists and breast cancer patients met to discuss the progress in research in this field. "MESUPRON[®], together with three other projects out of 1,200 presented, was selected for a separate press release by the DOD. From the Company's perspective this is a special distinction underlining our uPA inhibitor programme", Dr. Paul Bevan added.

More information regarding WILEX' uPA programme

WILEX has a late stage multi-product portfolio. In this portfolio MESUPRON[®] is being developed as part of the Company's urokinase-type Plasminogen Activator programme (uPA programme).

¹⁾ Breast tumours that are HER2 receptor negative have a reduced risk of relapse and respond more positively to chemotherapy and anti-hormone therapy than HER2 receptor positive tumours.



Focused Cancer Therapies

The aim of MESUPRON[®] is to inhibit the uPA system, which plays a key role in the growth, spread and metastasis of various malignant tumours. In 2007, determining the uPA content in a patient's primary tumour was incorporated into the treatment guidelines of the American Society of Clinical Oncology (ASCO). The guideline recommends that the uPA test is used in making the prognosis for patients who are newly diagnosed with breast cancer that has not affected lymph nodes in order to determine the appropriate treatment. The uPA content enables doctors to predict the statistical likelihood of a patient's survival. This was established on the basis of a meta analysis of 18 different European studies on the length of survival in relation to the uPA content in the tumour involving a total of 8,377 patients. The tumour-associated proteolytic factor²⁾ uPA and its inhibitor PAI-1 are the only tumour biological factors which have provided the highest level of evidence (LOE1) in terms of their prognostic and predictive significance.

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 MESUPRON[®]. The compound is found to be safe and well tolerated. MESUPRON[®] can be administered orally. This facilitates the long-term treatment of patients. Therefore, the Company decided to investigate the efficacy of MESUPRON[®] 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 MESUPRON[®] in combination with the chemotherapeutic agent Gemcitabine (Gemzar[®], Eli Lilly and Company, USA). After a positive outcome from these Phase II trials, the Company intends to test MESUPRON[®] in different types of cancer.

About WILEX

WILEX is a biopharmaceutical company based in Munich and is listed at the Frankfurt Stock Exchange at the Regulated Market / Prime Standard. 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. The Company's product candidates are based on antibodies and small molecules. WILEX has an attractive product pipeline which includes both drug and diagnostic candidates: The substances RENCAREX[®] and REDECTANE[®] are currently undergoing a Phase III registration trial. The substance MESUPRON[®] is currently in a Phase II programme. Based on this pipeline, WILEX's aim is to achieve profitability within a few years through the consistent commercialisation of its products and in the long term to finance its research and development programmes from its operating business.

Website: <http://www.wilex.com>

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Contact

WILEX AG
Grillparzerstr. 10
D-81675 Munich
Germany
Website: <http://www.wilex.com>

Public Relations

Juliane Giese

² Proteolytic factor: A factor which helps to degrade the surrounding tissue



Focused Cancer Therapies

Manager Public Relations
Tel.: +49 (0)89-41 31 38-29
Fax: +49 (0)89-41 31 38-99
E-mail: press@wilex.com

Investor Relations

Katja Arnold (CIRO)
Manager Investor Relations
Tel.: +49 (0)89-41 31 38-126
Fax: +49 (0)89-41 31 38-99
E-mail: investors@wilex.com

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