

PRESS RELEASE

MESUPRON[®] met its primary objective of demonstrating efficacy in the proof of concept phase II breast cancer trial

- MESUPRON[®] improves median progression free survival and objective response rate
- Therapy was safe and well tolerated

Munich, Germany, 14 June 2012. WILEX AG (ISIN DE0006614720 / WL6 / Frankfurt Stock Exchange) today published data from its Phase II trial with its oral drug candidate MESUPRON[®] in first line treatment of patients with HER2-receptor negative metastatic breast cancer.

The uPA inhibitor MESUPRON[®] (INN: Upamostat) was given in combination with the chemotherapeutic agent Capecitabine (Xeloda[®], Hoffmann La Roche AG, Switzerland). The double blind randomised Phase II trial evaluated the efficacy and safety of MESUPRON[®] 200 mg oral once daily in combination with Capecitabine compared to Capecitabine alone (control group). 132 patients in 20 centres in five countries (Belgium, Brazil, Germany, Israel, US) were enrolled.

The primary objective of the study was to evaluate the efficacy of the combination of MESUPRON[®] and Capecitabine compared to Capecitabine alone by assessment of progression free survival (PFS). The study also evaluated the objective response rate, overall survival and safety as well as pharmacokinetics. Efficacy was evaluated by RECIST (Response Evaluation Criteria on Solid Tumours) by independent central read using computed tomography and bone scans.

In the total study population (intent to treat; ITT) MESUPRON[®] led to an increase of median progression free survival from 7.5 months in the control group to 8.3 months in the combination therapy. Capecitabine alone demonstrated an objective tumour response rate of 9%. Co-administration of 200 mg MESUPRON[®] almost doubled the response rate to 17%. Overall survival data have not matured yet as over 60% of patients were still alive at the time of analysis. The combination therapy of MESUPRON[®] and Capecitabine was safe and well tolerated. Pharmacokinetic analysis demonstrated no drug-drug interactions between MESUPRON[®] and Capecitabine.

Breast cancer is a heterogeneous disease. To test whether MESUPRON[®] also shows efficacy in a more homogeneous patient population two subgroups were evaluated which had sufficient numbers of patients to allow separate analysis:

In the subgroup of patients who were Caucasian (n=109) median PFS improved from 7.5 months in the control group to 9.1 months in patients treated with MESUPRON[®].

In the subgroup of patients (n=95) who received adjuvant chemotherapy following the primary diagnosis of breast cancer, PFS improved from 4.3 months in the Capecitabine alone group to 8.3 months in the MESUPRON[®] combination group.

Dr. Paul Bevan, Head of R&D and Member of the Executive Management Board of WILEX commented: "We are pleased with the phase II MESUPRON[®] data. We achieved our goal and the data confirm the results of the pancreatic cancer trial reported in 2010. This proof-of concept study shows that MESUPRON[®] may be of benefit in breast cancer as well as pancreatic cancer. Because the uPA system has been implicated in a range of solid tumours, MESUPRON[®] could well find application in a variety of indications."

Invitation to the conference call

WILEX will hold a conference call for media representatives, analysts and investors in English on Monday, 18 June 2012, at 10:00 a.m. CET. 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 for the conference (in English) will be available for download 10 minutes before the presentation at the website www.wilex.com. A replay of the conference will be available after the presentation on the website <http://www.wilex.de/IR/Presentations.php>.

More information regarding WILEX' uPA programme

With MESUPRON[®] (INN: Upamostat), WILEX has developed a drug candidate to inhibit the Urokinase Plasminogen Activator (uPA) system. The uPA system has been shown to play a key role in tumour cell invasion and metastasis, as well as in primary tumour growth, of various solid tumours including breast, ovarian, gastric, colon and pancreatic cancer. The uPA programme of WILEX can be considered as a promising new non-cytotoxic approach in cancer therapy to specifically block tumour metastasis in solid cancers.

In 2007, determining the uPA level 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 level 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 level in the tumour involving a total of 8,377 patients. The tumour-associated proteolytic factor¹⁾ 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.

WILEX has developed the orally available drug candidate MESUPRON[®], as a pro-drug of WX-UK1. WX-UK1 and MESUPRON[®] are the first inhibitors of uPA in clinical oncology trials worldwide. Eight different clinical Phase I, Phase Ia and Ib trials with WX-UK1 and MESUPRON[®] in several indications with more than 150 patients were successfully conducted. Furthermore, MESUPRON[®] was tested very effective in a Phase II efficacy trial with 95 pancreatic cancer patients. MESUPRON[®] was found to be safe and well tolerated and can be administered orally. This facilitates the long-term treatment of patients.

About WILEX AG

WILEX AG is a biopharmaceutical company based in Munich, Germany. Focused on oncology, the Company has a broad portfolio of diagnostic and therapeutic products for the specific detection and targeted treatment of various types of cancer. WILEX's therapeutic product candidates are based on antibodies (RENCAREX[®] in Phase III) and small molecules (MESUPRON[®] in Phase II, 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

¹⁾ Proteolytic factor: A factor which helps to degrade the surrounding tissue

agent that is currently in a Phase III programme. WILEX's US subsidiary WILEX Inc. in Cambridge, MA, markets a portfolio of research use only tests and in vitro diagnostic agents under the brand Oncogene Science, which are used as companion diagnostics for clinical trials and therapy monitoring. The wholly owned subsidiary Heidelberg Pharma GmbH offers an attractive and highly promising antibody drug conjugate technology platform and preclinical contract research services. The business model of WILEX comprises research, technology, product development and commercialisation. 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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