PRESS RELEASE

Wilex successfully completes first clinical Phase I study with new anti-cancer drug WX-671

Munich (Germany), 27 July 2005. Wilex AG, Munich, a privately held biopharmaceutical company dedicated to the development of novel cancer therapies, today announced that it has successfully completed its “first into man” clinical Phase I trial with its new oral non-cytotoxic anti-cancer compound WX-671.

The open-label, single dose study investigated the oral bio-availability, pharmacokinetics, and safety of WX-671 at four dose levels in 16 healthy male volunteers. WX-671 was safe and well tolerated at all dose levels tested and did not lead to any serious adverse events or other clinically relevant side effects. In addition, the compound showed good oral bio-availability.

WX-671 will now progress to a multiple-dose Phase I study in healthy volunteers to further investigate safety, tolerability and pharmacokinetics of WX-671.

WX-671 is Wilex’s third compound in clinical development. WX-671 is a second generation serine protease inhibitor targeting the uPA (urokinase Plasminogen Activator) system which has been shown to play a key role in metastasis and primary tumor growth of breast cancer and other solid tumors. WX-671 is an oral pro-drug of Wilex’s investigational drug WX-UK1, which, in intravenous form, is currently being studied in several clinical trials in cancer patients. In pre-clinical models, WX-671 effectively blocked metastasis formation and primary tumor growth.

Dr. Paul Bevan, Head of Research and Development and Member of the Executive Board of Wilex AG, said: “The successful completion of this study further strengthens our therapeutic approach of anti-metastatic non-cytotoxic small molecule inhibitors of the uPA system. With the uPA program, Wilex has another strong oncology platform with broad applications in breast cancer and a variety of other cancers in addition to our lead compound, the antibody Rencarex® which is currently in a pivotal Phase III study.”

Background on Wilex’s uPA inhibitor program

Wilex’s uPA inhibitor program is one of the most promising new non-cytotoxic approaches in cancer therapy to specifically block tumor metastasis. The uPA inhibitors developed by Wilex are the first uPA inhibitors in clinical testing in tumor patients. The uPA (urokinase-type Plasminogen Activator) system has been shown to play a key role in tumor cell invasion and metastasis and in primary tumor growth of various solid tumors including breast, ovarian, and gastric cancer. The uPA system is an extra-cellular enzyme system over-expressed on certain aggressive metastasizing solid tumors. The uPA system enables tumor cells to
degrade their surrounding tissue (i.e. the extracellular matrix), to invade into healthy tissue and blood vessels and thus to migrate and form new tumors at distant sites. Wilex is developing several compounds to inhibit the uPA system. In addition to its compounds in clinical development, WX-UK1 and WX-671, Wilex is conducting several research programs targeting components of the uPA system.

Background on Wilex AG (www.wilex.com)

Wilex AG, based in Munich (Germany), is a biopharmaceutical company developing novel cancer therapies for the treatment of various tumors including renal and breast cancer. Therapies are based upon biologic targets directly connected to cancer progression and pathogenesis in order to provide effective and well tolerated treatment and enhance patients’ quality of life. Wilex has a well-balanced product portfolio with three compounds in clinical trials and further programs in pre-clinic and research. The Company has two therapeutic platforms: antibodies and small molecules. The lead compound Rencarex® (WX-G250), a targeted antibody therapy for the treatment of solid tumors, is currently in a pivotal clinical Phase III trial in Renal Cell Cancer. The company’s non-cytotoxic small molecule uPA inhibitors WX-UK1 and WX-671 for the treatment of breast cancer and other solid tumors are currently studied in several Phase I/II clinical trials. Wilex was founded in 1997 by clinical oncologists from the Technical University of Munich.

Further Information:

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