

PRESS RELEASE

WILEX regains US rights for RENCAREX[®] from Prometheus

Munich, Germany, 07 November 2013. WILEX AG (ISIN DE0006614720/ WL6 / FSE) and Prometheus Laboratories Inc. (Prometheus), San Diego, CA, USA, agreed as of 31 October 2013 on the terms of the termination of the 2011 license agreement on RENCAREX[®] (Girentuximab). As announced on 3 June 2013, Prometheus and WILEX decided to finalise the cooperation and to discuss the formalities and timing regarding the termination.

According to the settlement agreement, WILEX regains the US commercialisation rights for RENCAREX[®] and will receive a final payment of USD 1.75 million covering Prometheus' obligations under the collaboration agreement for the RENCAREX[®] development costs. Prometheus will no longer participate in the RENCAREX[®] development. The parties have no further mutual obligations.

WILEX has received upfront and milestone payments of USD 39 million plus 40% of development costs since the beginning of the collaboration.

RENCAREX[®] is a Phase III product candidate for adjuvant therapy of non-metastatic clear cell Renal Cell Carcinomas (ccRCC). In October 2012, the Phase III ARISER trial failed to meet its primary endpoint. The final analysis showed no improvement in median disease-free survival following treatment with RENCAREX[®] compared to placebo. However, WILEX carried out an extensive subgroup and biomarker analysis and presented positive subgroup data at the ASCO Annual Meeting in June 2013. The results of this retrospective analysis showed that RENCAREX[®] has a therapeutic effect in the subgroup of patients with a high score of the antigen CAIX. Disease-free survival in this group showed a clinically and statistically significant improvement compared to both placebo and patients with a low CAIX score.

Professor Olaf G. Wilhelm, CEO of WILEX AG, commented: "We look back on a very valuable collaboration with Prometheus. Due to the top line data of RENCAREX[®] and the delay of a marketable product, Prometheus' request to terminate was not a surprise to us. We are delighted that we came to an agreement that works for both parties. The return of the US rights for RENCAREX[®] offers us new and broader options for its commercialisation."

WILEX has already started discussions with regulatory authorities (FDA and European agencies) on a confirmatory prospective clinical Phase III trial with RENCAREX[®] in the subgroup of patients with high CAIX scores. WILEX has received initial positive feedback from the authorities. In addition, talks are being held with several parties for the out-licensing of the global rights (except Southern Europe). WILEX's goal is to find a partner that will participate in financing, development and commercialisation. Should RENCAREX[®] receive regulatory approval, the definition of the subgroup could open up a market with adjusted peak sales potential of over USD 300 million for RENCAREX[®] as an adjuvant therapy of ccRCC.

About RENCAREX[®]

RENCAREX[®] (Girentuximab) is a highly specific chimeric monoclonal antibody that binds to a cell surface antigen, the CAIX-antigen, which is found on 95% of clear cell Renal Cell Carcinomas (ccRCC) and on various other solid tumours but not on healthy tissue. Renal cell cancer, or RCC, is the most common type of kidney cancer and accounts for more than 90% of malignant kidney tumours. Two-thirds of RCC patients with no evidence of metastases at the time of first diagnosis have a high risk of relapse within a few years after surgery. WILEX developed the product candidate RENCAREX[®] with the aim of preventing metastases (adjuvant therapy). There is no adjuvant treatment approved by the FDA or EMA for patients after surgery. RENCAREX[®] was tested in the double-blind, placebo-controlled Phase III trial for adjuvant therapy (Adjuvant RENCAREX[®] Immunotherapy trial to Study Efficacy in non-metastatic Renal cell carcinoma, "ARISER trial") but failed to meet the primary endpoint. However, a retrospective subgroup analysis showed that RENCAREX[®] has a clear therapeutic effect in the subgroup of patients with a high CAIX score. Disease-free survival in this group showed a clinically and statistically significant improvement compared to both placebo and patients with a low CAIX score.

With the support of the cooperation partner Nuclea Biotechnologies Inc., a CAIX in-vitro diagnostic test will be developed as a companion diagnostic, which will be helpful in identifying and stratifying patients who might benefit from RENCAREX[®] therapy.

About WILEX

WILEX AG is a biopharmaceutical company based in Munich, Germany. Focused on oncology, the Company develops diagnostic and therapeutic product candidates for the specific detection and targeted treatment of various types of cancer based on antibodies and small molecules. The subsidiary Heidelberg Pharma GmbH offers preclinical contract research services and an antibody drug conjugate (ADC) technology platform. The business model comprises research and product development as well as the commercialisation of its activities. Our customers and partners include leading international pharmaceutical companies. WILEX AG is listed at the Frankfurt Stock Exchange. ISIN DE0006614720 / WKN 661472 / Symbol WL6. More information is available at www.wilex.com.

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