PRESS RELEASE

WILEX AG and the FDA agree on the further development of REDECTANE®

- FDA follows positive ODAC recommendation regarding the clinical usefulness of a clear cell renal cell carcinoma (ccRCC) imaging test
- Confirmatory diagnostic performance trial accepted by the FDA instead of an outcomes-based study

Munich, Germany, 5 October 2012. WILEX AG (ISIN DE0006614720 / WL6 / FSE) today announced that the Company has received the FDA's (Food and Drug Administration) minutes of the Type C meeting held in September 2012. The FDA accepted the positive vote of the Oncologic Drugs Advisory Committee (ODAC) regarding the clinical usefulness of an imaging test which identifies ccRCC within the kidney of patients with an indeterminate renal mass. In its meeting in July 2012, ODAC voted by 16 to 0 (1 abstention) in support of the imaging information being clinically useful.

Furthermore the Company and the Agency agreed to conduct a second diagnostic performance trial instead of an outcomes-based study (i.e. a trial that studies patient outcomes such as survival) that the FDA had previously required. The FDA does however require a second trial to confirm the diagnostic performance and safety of REDECTANE®. WILEX assumes that approval can be expected after successful conclusion of this second trial.

The concept and the design of the new trial were discussed with the FDA. WILEX is currently developing the protocol for this Phase III trial (REDECT 2) for submission to the FDA under a Special Protocol Assessment (SPA). Details on the study design will be announced after approval of the study protocol.

Dr Paul Bevan, Head of Research and Development and member of the Executive Management Board of WILEX AG, said: "Supported by the ODAC recommendation, we have now agreed with the FDA on the further development of REDECTANE®. Eliminating the need for an outcomes-based study – which in our opinion was not a feasible option – will enable us to move forward with our strategy as the regulatory pathway for marketing approval of this innovative imaging agent is now clear. We are delighted with the result."

About REDECTANE® and the REDECT trial

The drug candidate REDECTANE® (INN: Iodine (^{124}I) Girentuximab) is the radioactively labelled form of the antibody Girentuximab and is being developed for the diagnosis of clear cell Renal Cell Cancer (ccRCC). The labelled antibody targets ccRCC and accumulates in the tumour tissue. This accumulation can be visualised by means of positron emission tomography (PET). REDECTANE® may be used during diagnostic work up to detect ccRCC in patients with renal masses. At present, only histopathology results after surgery can determine whether the tumour is benign or malignant. As ccRCCs are associated with an aggressive phenotype their identification may help guide appropriate therapeutic management.

In May 2010 WILEX published final data of the Phase III REDECT trial with REDECTANE®. REDECTANE® fulfilled expectations in distinguishing clear cell from non-clear cell renal cell

carcinoma. The results of the study demonstrate that PET/CT with REDECTANE® leads to a significantly improved diagnosis in comparison to CT alone. The endpoint sensitivity, the correct diagnosis that clear cell renal cell cancer is present, was reached with statistical significance (p value, p≤0.016) compared to CT. The study endpoint specificity, the correct diagnosis that clear cell renal cell cancer is not present, was confirmed with a highly statistical significance (p<0.001). To rule out that the superiority of REDECTANE® resulted from the poor performance of CT, the endpoints of REDECTANE® were also compared to an arbitrary value of 75% for specificity and sensitivity as defined in the study protocol. REDECTANE® achieved sensitivity of 86% (p≤0.002) and specificity of 87% (p=0.057).

The FDA suggested in the second quarter of 2011 that WILEX AG and the marketing partner IBA Pharma SPRL, Louvain-la-Neuve, Belgium, (IBA) consider conducting an outcomes-based study to obtain additional evidence of the product's clinical usefulness. However, WILEX, IBA and external medical advisors were of the opinion that such a trial could only be conducted as a Phase IV trial after market approval. Thus, in the fourth quarter of 2011, a Type C meeting took place at the FDA, in which the further development of REDECTANE® was outlined, including the scheduling of a second trial and the options to conduct an "outcomes-based study" or a "confirmatory" study similar to the REDECT trial to confirm the candidate's diagnostic performance. The FDA suggested resolving the question of clinical usefulness and the resulting regulatory pathway with an FDA Advisory Committee.

The following question was discussed in the Oncologic Drugs Advisory Committee meeting on 25 July 2012: "Would an imaging test provide useful clinical information if it identified only clear cell renal cell carcinoma (ccRCC) within the kidney of patients with an indeterminate renal mass?" The Advisory Committee voted by 16 to 0 (1 abstention) in support of the imaging information being clinically useful. As the ODAC provides the FDA with independent expert advice and recommendations, the final decision is made by FDA.

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® two Phase IIa trials completed, WX-554 in Phase Ib/II and WX-037 in preclinical development). In the field of diagnostics, REDECTANE® is an antibody-based, imaging diagnostic 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. The 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.

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