PRESS RELEASE

WILEX and IBA report on follow up meeting with the FDA on further steps in the development of REDECTANE®

- FDA recommends an Advisory Committee meeting to review the regulatory pathway as well as the timing and design of a second clinical trial
- Constitution and availability of the Advisory Committee to be confirmed by the FDA

Munich, Germany and Louvain-la-Neuve, Belgium - 14 December 2011. WILEX AG (ISIN DE0006614720 / WL6 / Frankfurt Stock Exchange) and IBA (Ion Beam Applications S.A: Reuters IBAB.BR and Bloomberg IBAB.BB) today announced that the follow up meeting with the American Food and Drug Administration (FDA) has taken place. The aim of the Type C Meeting was to discuss next steps in the development process of REDECTANE®.

The FDA and WILEX discussed the further development of REDECTANE® including the timing of a second trial and the options of an outcomes based study or a confirmatory diagnostic performance study similar to the REDECT trial. As this product is first in class the FDA offered and WILEX accepted the option of discussing the regulatory pathway, timing and design of a second study with an FDA Advisory Committee. The FDA is expected to confirm the Advisory Committee discussion after internal verification of the logistics for the meeting.

Dr Paul Bevan, Head of R&D and member of the Executive Management Board of WILEX AG, commented: "We are pleased with the outcome of this meeting. The Advisory Committees provide independent, expert advice on significant scientific, technical, and on specific regulatory decisions, such as product approvals, and general policy matters. We believe this recent FDA meeting represents progress towards a common understanding of REDECTANE's further development. "

WILEX and IBA also report today on the progress made on the CMC issues discussed in the Pre-BLA Meeting in the second quarter 2011. WILEX's manufacturing partner Avid Bioservices, Inc., Tustin, CA, USA, has successfully completed the production run of the third consecutive consistency lot for process validation of the naked antibody Girentuximab. IBA, responsible for radioactive labelling of the antibody, is assembling the data on the commercial production of REDECTANE®, in particular product characterisation and process validation. The new facility for central manufacturing of REDECTANE® and the subsequent quality assurance is completed and documentation is in preparation by IBA.

About REDECTANE and the REDECT trial

The drug candidate REDECTANE® (INN: 124I-Girentuximab) is the radioactively labelled form of the antibody Girentuximab and is being developed for the pre-surgical diagnosis of clear cell Renal Cell Cancer (ccRCC). The labelled antibody 124I-Girentuximab targets ccRCC and accumulates in the tumour tissue. This accumulation can be visualised by means of positron emission tomography (PET). REDECTANE® may be used before surgery to detect ccRCC in patients with renal masses. At present, only histopathology results after surgery can determine the type of tumour histopathology characterisation, means whether the tumour is benign or malignant. As ccRCCs are associated with an aggressive phenotype their a priori determination may help guide appropriate surgical/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® lead 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, $p \leq 0.016$) 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% ($p \leq 0.002$) and specificity of 87% ($p = 0.057$).

About WILEX AG

WILEX AG is a biopharmaceutical company based in Munich, Germany. Focused on oncology, the company has a broad portfolio of near-to-market therapeutic and diagnostic products for the targeted treatment and specific detection of various types of cancer. The company's therapeutic product candidates are based on antibodies and small molecules. Through its US subsidiary WILEX Inc. in Cambridge, MA, WILEX markets a portfolio of research use only and in vitro diagnostic tests under the brand Oncogene Science. These diagnostic tests could be developed as companion diagnostics in clinical trials and for therapy monitoring. The wholly owned subsidiary Heidelberg Pharma AG gives WILEX access to an attractive and highly promising antibody drug conjugate technology platform and a pre-clinical service business. The business model of WILEX covers the entire value chain in the oncology market and comprises research, technology, development collaboration as well as sales and marketing. WILEX's customers and partners include leading international pharmaceutical companies. ISIN DE0006614720 / WKN 661472 / Symbol WL6

About IBA

IBA develops and markets leading edge technologies, pharmaceuticals and tailor-made solutions for healthcare with a focus on cancer diagnosis and therapy. Leveraging on its scientific expertise, IBA is also active in the field of industrial sterilization and ionization. Listed on the pan-European stock exchange EURONEXT, IBA is included in the BelMid Index. (IBA: Reuters IBAB.BR and Bloomberg IBAB.BB). Website: www.iba-worldwide.com

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