



## PRESS RELEASE

### **WILEX and IBA report on the Pre-BLA Meeting with the FDA and the next steps in the REDECTANE® approval process**

**Munich, Germany, and Louvain-la-Neuve, Belgium, 17 June 2011.** WILEX AG (ISIN DE0006614720 / WL6 / Frankfurt Stock Exchange) and IBA (Ion Beam Applications SA: Reuters IBAB.BR and Bloomberg IBAB.BB) today announced that the Pre-BLA Meeting with the American Food and Drug Administration planned for the second quarter has taken place. The aim of this type of meeting is to discuss the application for approval and the approval process for a product in advance of filing. Two issues remain to be resolved by WILEX and its partner IBA.

The FDA had granted WILEX a special protocol assessment (SPA) for the design of the pivotal Phase III trial with REDECTANE® prior to the start of the trial. With this SPA the FDA confirms that the design and planned analysis of the clinical trial adequately address the requirements for a regulatory submission for REDECTANE®. The aim of the Phase III REDECT trial was to determine whether the combination of REDECTANE® with positron emission tomography (PET) and computer tomography (CT) versus the use of CT alone could improve the diagnosis of renal masses. Sensitivity and specificity were the defined endpoints of the study.

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% ( $p = 0.057$ ).

During the pre-BLA discussions the FDA confirmed that the trial provides reasonable evidence for the diagnostic efficacy and safety of REDECTANE® and stated that three hypotheses were confirmed. In order to strengthen the position for approval, the FDA suggested that WILEX and IBA might consider an outcomes based study to provide additional evidence of clinical benefit before BLA filing. Such an outcomes based study demands that a doctor determines patient management based on the diagnostic result with REDECTANE® and PET/CT. During the Phase III REDECT trial, and in accordance with the trial design agreed in the SPA, doctors did not utilise the REDECTANE® PET/CT results to influence the decision for or against surgery. For the completed Phase III trial, the diagnostic results of CT or PET/CT had to be confirmed by an histological analysis post-surgery under the terms of the trial design. WILEX and IBA agree with the FDA that a trial with a clinical benefit outcome could represent the next logical step in REDECTANE's development. WILEX, IBA and external medical advisors however are of the opinion that such a trial should be conducted as a Phase IV trial after market approval. WILEX and IBA will first discuss the trial design and strategy with the Medical Advisory Board and subsequently with the FDA. Following agreement a further announcement will be made.



The second issue discussed with the FDA concerns the manufacturing of REDECTANE<sup>®</sup>. WILEX has successfully completed two consecutive consistency lots for process validation of the naked antibody Girentuximab at the manufacturer Avid Bioservices, Inc., Tustin, CA, USA. The third production run was started before the pre-BLA meeting and will be completed shortly. Process validation data from this third run were to be submitted to the FDA by WILEX during the approval process. The FDA has made clear that all necessary process validation data from all three consistency lots must be delivered as part of BLA filing.

Furthermore, the FDA has requested from IBA (responsible for radioactive labelling of the antibody) data pertaining to the commercial production of REDECTANE<sup>®</sup>, in particular product characterisation and process validation. By building a new manufacturing facility with central manufacturing and quality assurance, IBA has created an infrastructure in which REDECTANE<sup>®</sup> can be produced not only as study medication but also as a marketable product. WILEX and IBA will provide the FDA with the necessary data in the next few months.

George Mills, MD, Regulatory Consultant for WILEX AG and the past Division Director of the CDER/FDA Medical Imaging Division commented: "The pre-BLA meeting with the FDA was highly constructive, as in the past. The topics which were discussed are comprehensive and will be evaluated and implemented by WILEX and IBA in the coming months. We plan further discussions with FDA on how to best demonstrate additional clinical benefit for REDECTANE<sup>®</sup> in an additional outcomes trial and its timing with respect to submission."

**Invitation to the conference call:**

On 17 June, WILEX will hold a public conference call for media, analysts and investors in English at 3:00 p.m. CET. Please dial in ten minutes before the conference call using the following dial-in numbers:

1. Germany: +49 69 6677 75756
2. UK: +44 20 3003 2666
3. USA: +1 212 999 6659
4. Belgium: +32 (0) 2 789 8603

You will be welcomed by an operator taking your name and company. The presentation for the conference will be available for download at the website <http://www.wilex.de/IR/Presentations.php> at 2:00 p.m. CET. A replay will be available after the conference on the website.

**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 oncological diagnostic tests under the brand Oncogene Science. These diagnostic tests can be used as companion diagnostics in clinical trials and for therapy monitoring. Furthermore, the acquisition of Heidelberg Pharma AG is set to give 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.

Website: <http://www.WILEX.com>, 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](http://www.iba-worldwide.com)

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