WILEX
Focused Cancer Therapies

iba

Press release |

REDECTANE® meets both endpoints specificity and sensitivity with superiority over CT in its pivotal Phase III trial

Munich, Germany, and Louvain-la-Neuve, Belgium, 18 May 2010. WILEX AG (ISIN DE0006614720 / WL6 / Frankfurt Stock Exchange) and IBA (Ion Beam Applications SA: Reuters IBAB.BR and Bloomberg IBAB.BB), announced today that the final results of the pivotal phase III registration trial REDECT have been received. The results of the study demonstrate that PET/CT with REDECTANE® lead to a significantly improved diagnosis in comparison to CT alone.

The aim of the Phase III-REDECT study was to determine whether the combination of REDECTANE® with positron emission tomography (PET) and computer tomography (CT) versus the standard use of CT alone could improve the diagnosis of renal masses. Sensitivity and specificity were the defined endpoints of the study.

In contrast to the preliminary data published in November 2009, the endpoint sensitivity, the correct diagnosis that clear cell renal cell cancer is present, was reached with statistical significance (p value, p) ($p \leq 0.016$) 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% ($p = 0.057$). Based on these results, WILEX plans to submit REDECTANE® for approval by the US Food and Drug Administration (FDA) at the end of 2010.

Prof Olaf G. Wilhelm, Chief Executive Officer of WILEX, commented: “We are very delighted about the strong and robust final data demonstrating that PET/CT with REDECTANE® is highly superior to CT alone in the diagnosis of clear cell renal cell cancer. This is a decisive milestone for WILEX; we plan to submit REDECTANE® for approval and, together with our partner IBA, to bring our first product to market“.

“We are convinced that REDECTANE® will be a leader in our PET product portfolio. This is an additional step towards our strategy to make available a range of innovative radiopharmaceuticals to the medical community”, said Pierre Mottet, Chief Executive Officer of IBA.

The trial results will be presented at the annual meeting of the American Urology Association (AUA), on the 1st June, 2010 in San Francisco, USA.

Invitation to the conference call
WILEX will hold a conference call for media representatives, analysts and investors in English on 18 May 2010, at 4:00 p.m. CET. Please dial in ten minutes before the conference call using the following dial-in numbers:

1. Germany: +49 (0) 69 6677 75756
2. UK: +44 (0) 2030032666
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 (in English) will be available for download at 3:30 p.m. CET at the website. A replay of the conference will be available after the presentation on the website http://www.wilex.de/IR/Presentations.php.

About the REDECT trial
The Phase III registration trial REDECT started in 2008. In total 226 patients suspected of having kidney cancer were enrolled in more than 14 centres in the USA. Patients included were scheduled for complete or partial surgical removal of the affected kidney. They were imaged with computer tomography (CT) and REDECTANE® (PET/CT) prior to surgery to examine whether they have clear cell renal cell carcinoma. The trial has evaluated that imaging with REDECTANE® can improve the diagnosis in comparison to the current standard (CT alone). In order to avoid unnecessary surgery of renal masses in future a diagnostic agent should predict that clear cell renal cell cancer is not present (specificity).

WILEX has received a special protocol assessment (SPA) from the US Food and Drug Administration (FDA) for this Phase III registration 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 FDA is considered to be bound by this protocol assessment as part of the approval process.

About WILEX AG
WILEX AG is a biopharmaceutical company based in Munich and is listed at the Frankfurt Stock Exchange at the Regulated Market / Prime Standard. WILEX's mission is to develop drugs with a low side effect profile and targeted treatment of different types of cancer as well as diagnostic agents for specific detection of tumours. The Company's product candidates are based on antibodies and small molecules. WILEX has an attractive product pipeline which includes both drug and diagnostic candidates: The candidates REDECTANE® and RENCAREX® are undergoing Phase III registration trials. MESUPRON® is in Phase II trials in two indications. The MEK inhibitor WX-554 is in a Phase I trial, and the other four oncology projects (PI3K inhibitor WX-037 and three antibody programmes) are in preclinical development. WILEX aims within a few years to be able to finance its research and development programmes from its operating cash flow. 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

Contact WILEX
Katja Arnold (CIRO)
Corporate Communications
Grillparzerstr. 10
81675 Munich, Germany
Tel.: +49 (0)89-41 31 38-126
Fax: +49 (0)89-41 31 38-99
Email: investors@wilex.com

Contact IBA
Thomas Ralet
VP Corporate Communication
Tel.: +32 10 47 58 90
Email: InvestorRelations@iba-group.com

Additional media contacts for Europe
MC Services AG
Raimund Gabriel
Tel.: +49 (0)89 210 228 0
Email: raimund.gabriel@mc-services.eu

Redectane® is a temporary development name