

REDECTANE[®]

Pre-BLA Meeting with FDA

17 June 2011



→ Presenters of the Conference Call

- Professor Olaf G. Wilhelm, CEO WILEX
- Dr Paul Bevan, Head R&D/Member of the Executive Management Board WILEX
- Renaud Dehareng, President IBA Pharma
- Jean-Marc Bothy, CFO IBA Group

→ Commercialisation agreement with IBA

- Signed in June 2008
- WILEX responsible for antibody manufacture and clinical development
- IBA responsible for manufacturing of finished radio-labelled antibody, distribution, sales & marketing
- Worldwide co-promotion rights for WILEX



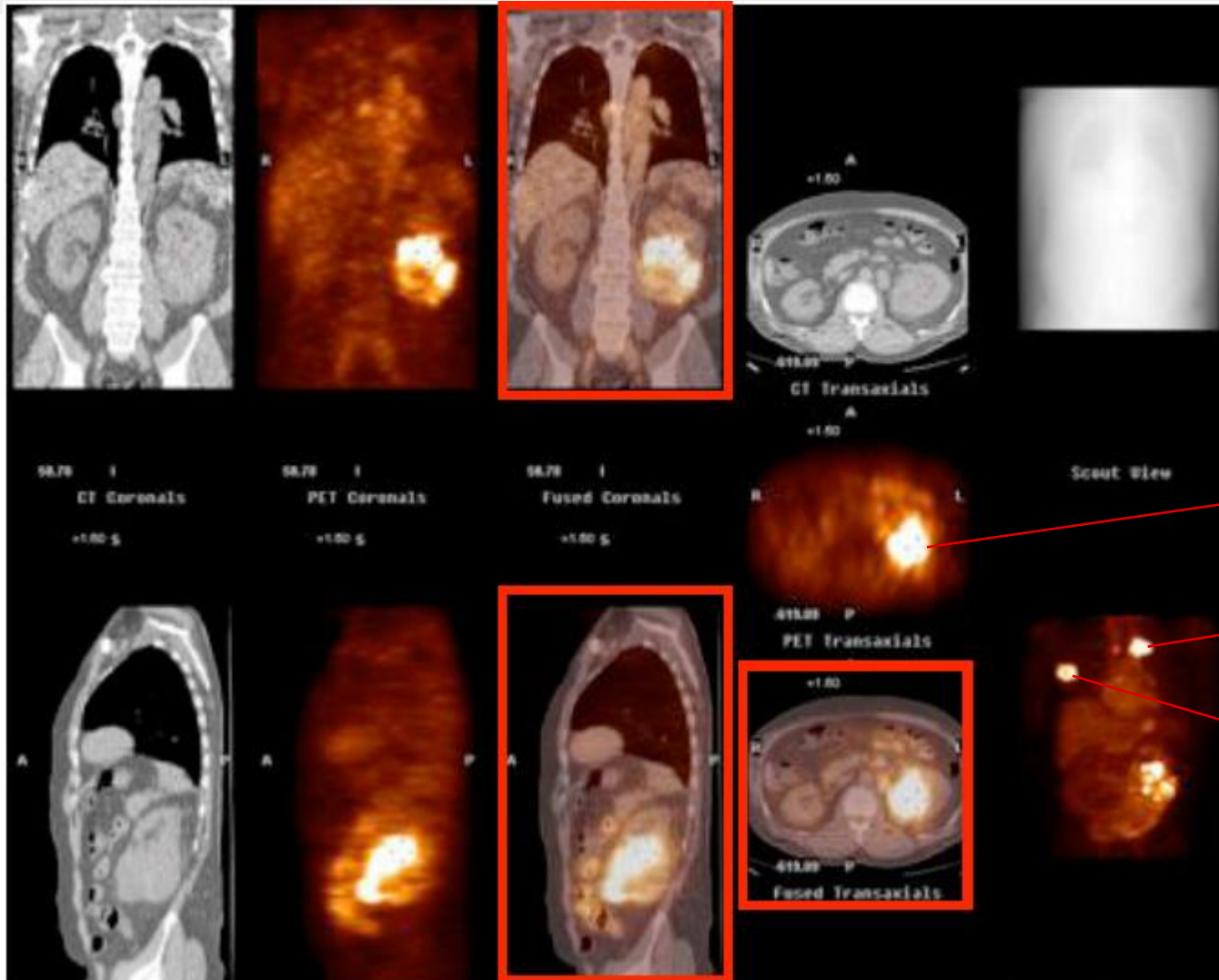
- **Current standard of care for a surgery/no surgery decision is typically based on lesion size and presumption of malignancy as may be ascertained by anatomical imaging***
- **Current standard of contrast-enhanced CT provides poor specificity**
- **Urologists utilise all available clinical information as part of patient management**
 - To manage patients non-surgically, particularly in elderly and those with known comorbidity
 - To assess benefit/risk in this cohort for a definitively positive study to allow greatest chances for cure

*AUA guideline



- **Girentuximab (cG250) specifically and selectively binds to CAIX**
 - CAIX is constitutively upregulated in >95% ccRCC
 - Rarely expressed by indolent RCC
 - Not expressed by benign tumours such as oncocytoma and angiomyolipoma
- **Early studies in Nijmegen with ¹³¹I-cG250 show excellent specific tumour targeting**
 - Primary renal tumour and metastases visualised with radioscintigraphy
- **Concept of using ¹²⁴I-labelled girentuximab (REDECTANE®) developed by MSKCC/LICR**
- **Positive proof-of-concept study**
 - Ability to detect ccRCC malignancies pre-operatively confirmed
- **Pivotal study protocol (REDECT) developed with FDA input**
 - SPA approved by FDA

REDECTANE® detects primary tumour and distant metastases



Primary tumour left kidney

Rib metastasis

Clavicle metastasis

Courtesy of Michael Yu, Fox Chase Cancer Center



- **Final data published in May 2010: REDECTANE® outperformed CT**
- **REDECTANE® in comparison to CT**
 - Specificity: confirmed with a highly statistical value $p < 0.001$
 - Sensitivity: also achieved statistical significance with $p \leq 0.016$
- **REDECTANE® in comparison to an arbitrary value of 75% for specificity and sensitivity**
 - Specificity of 87% (95% CI 75-95%) ($p = 0.057$)
 - Sensitivity of 86% (95% CI 79-91%) ($p \leq 0.002$)
- **To avoid unnecessary surgery, high specificity is required (ccRCC is not present)**

Pre-BLA: Two issues remain to be resolved by WILEX and IBA

- **Outcomes based study to investigate the clinical benefit before BLA filing**
 - Demands that a doctor determines patient management based on the diagnostic result with REDECTANE and PET/CT
 - In the Phase 3 study, doctors were not allowed to utilise the REDECTANE PET/CT results to influence the decision for or against surgery

- **Data concerning the manufacturing of REDECTANE**
 - From WILEX/ cooperation partner AVID: Process validation data from the third production run of the naked antibody Girentuximab
 - From IBA: data pertaining to the commercial production of REDECTANE, in particular product characterisation and process validation

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Such factors include, among others, the following: uncertainties related to results of our clinical trials, the uncertainty of regulatory approval and commercial uncertainty, reimbursement and drug price uncertainty, the absence of sales and marketing experience and limited manufacturing capabilities, attraction and retention of technologically skilled employees, dependence on licenses, patents and proprietary technology, dependence upon collaborators, future capital needs and the uncertainty of additional funding, risks of product liability and limitations of insurance, limitations of supplies, competition from other biopharmaceutical, chemical and pharmaceutical companies, environmental, health and safety matters, availability of licensing arrangements, currency fluctuations, adverse changes in governmental rules and fiscal policies, civil unrest, acts of God, acts of war, and other factors referenced in this communication.

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