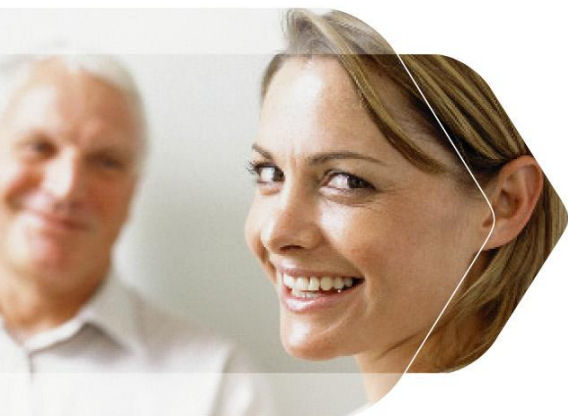


# WILEX

Focused Cancer Therapies



## Company update

German Equity Forum, Frankfurt  
November 2011

- Oncology-focused biopharmaceutical company
- Transition from R&D to commercially driven business
- Product candidates with strong competitive profiles
- Important clinical and commercial milestones in the next months
- Integrative approach through combination of therapeutics and diagnostics

## Development success

Phase I II III

REDECTANE®

RENCAREX®

MESUPRON®

WX-554

## Significant sales potential

- REDECTANE® ~ \$100m
- RENCAREX® ~ \$500m
- MESUPRON® ~ \$1bn

## Deals & Alliances










## Products & Technologies

OncogeneScience



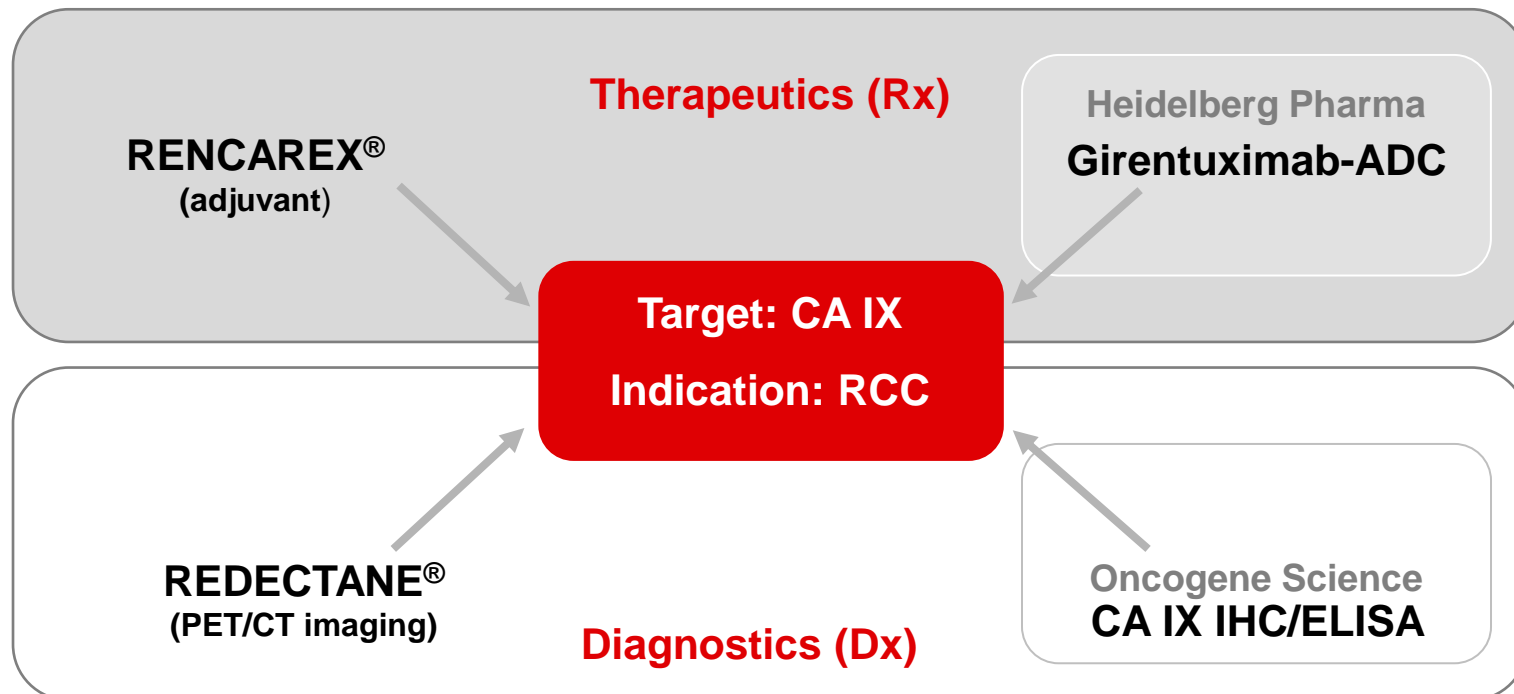
**Therapeutics (Rx) + Diagnostics (Dx) + Customer Specific Research (Cx)**

# Broad portfolio and strong partners

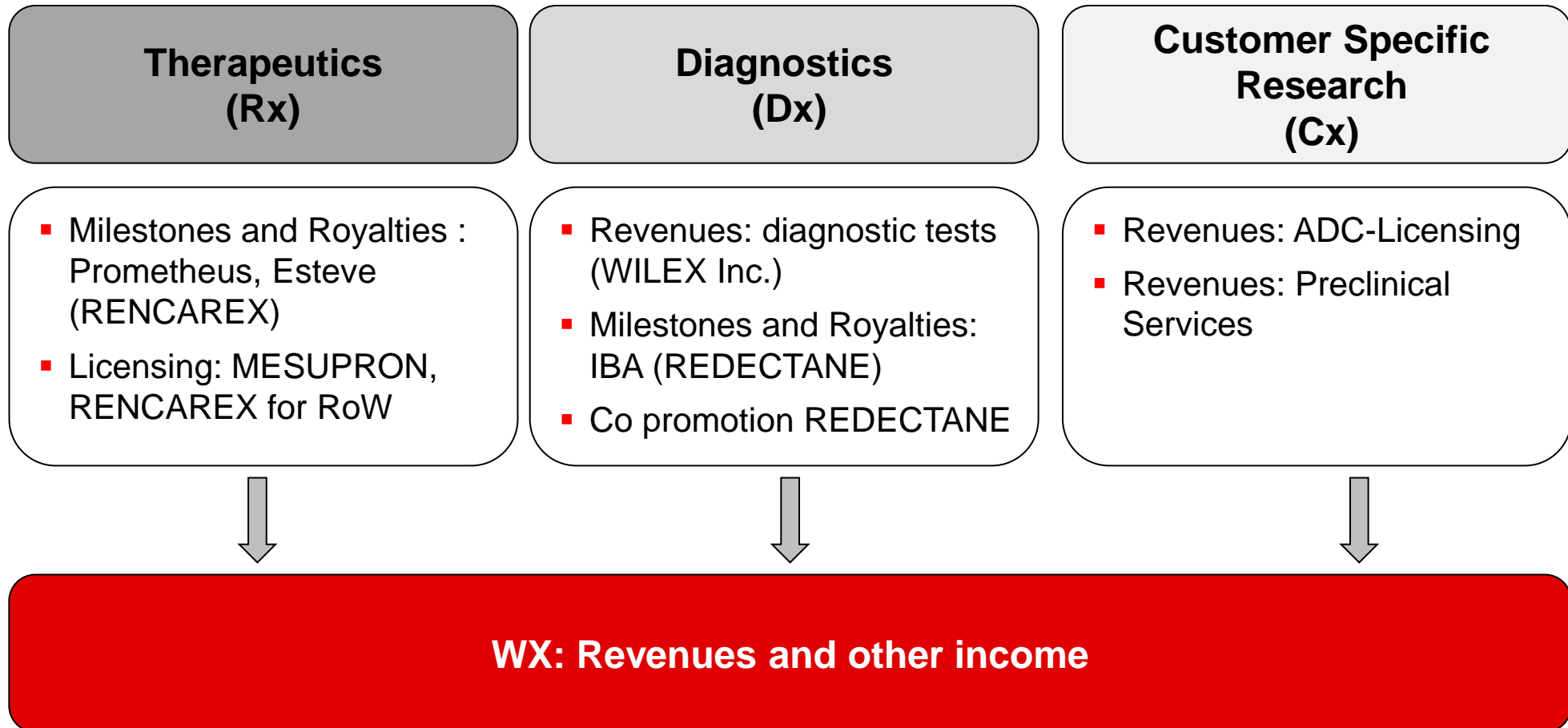
Product	Technology	Indication	Research	Pre-clinical	Clinical development			Market	Partner
					Phase I	Phase II	Phase III		
REDECTANE®	Antibody (diagnostic)	Renal mass	→						 (ww**)
RENCAREX®	Antibody (therapeutic)	non-metast. ccRCC*	→						 (Southern Europe)  PROMETHEUS® (USA) Therapeutics & Diagnostics
MESUPRON®	uPA inhibitor	Pancreatic cancer	→						
		Breast cancer	→						
WX-554	MEK inhibitor	Cancer	→						 (ww)
WX-037	MEK inhibitor	Cancer	→						 (ww)
2 Antibodies		Cancer	→						 (ww)
ADC Platform	Antibody drug conjugates	Cancer	→						WILEX Group
Diagnostic tests	ELISA/IHC	HER-2, CAIX, uPA, PAI-1, EGFr; VEGF etc.	→						 WILEX Group

\*clear cell Renal Cell Carcinoma, non-metastatic, \*\* worldwide

- Focussed on target and indication with various mode of actions for personalised cancer treatment
- CA IX as an example for an integrative approach through combination of therapeutics and diagnostics

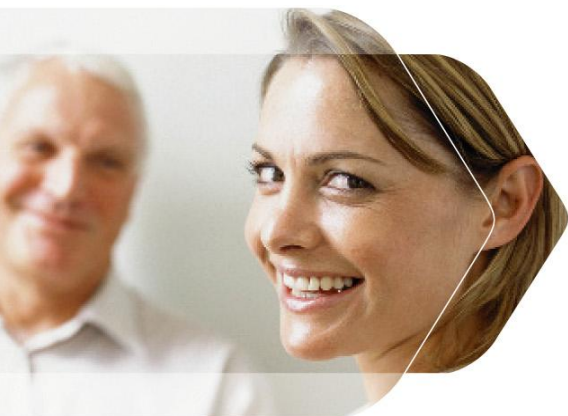


→ Realisation of the commercialisation strategy



# WILEX

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**REDECTANE<sup>®</sup>**

**(INN: 124I-girentuximab)**

**Radio-labelled antibody targeting CAIX for diagnostic use**

# REDECTANE®: First in class diagnostic imaging agent

→ **Antibody Girentuximab radio-labelled with <sup>124</sup>I for diagnostic use**

→ Targets CA IX\* antigen

→ Antigen abundantly expressed in clear cell Renal Cell Carcinoma (ccRCC), bladder, head & neck and colon cancers

→ **High medical benefit**

→ could avoid surgery

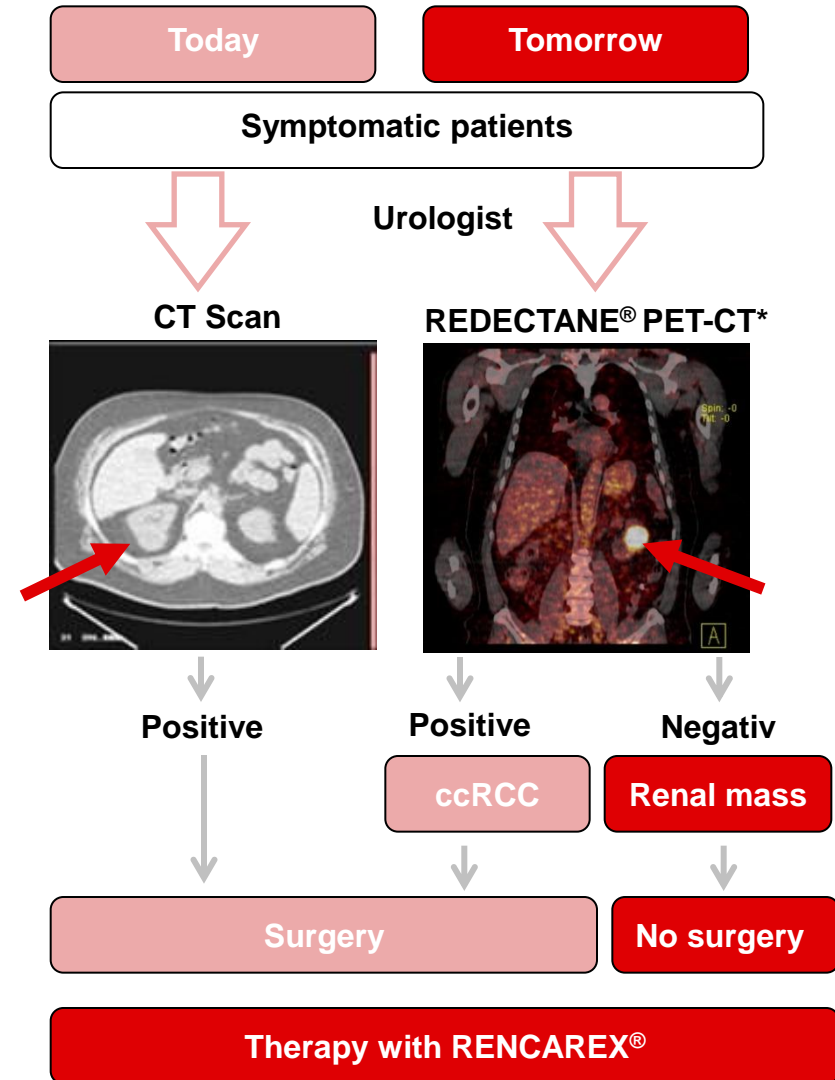
→ **Expected to be the first commercial product**

→ **Peak sales potential > \$100m in ccRCC only**

→ **Strong worldwide commercial partnership with Ion Beam Applications (IBA)**

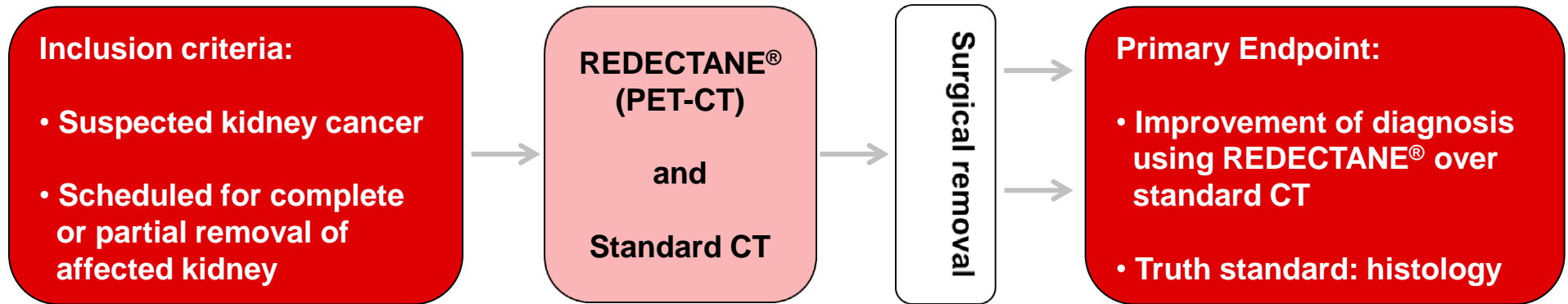
\* Carbonic Anhydrase IX

\*\* PET-CT: Positron-Emission Tomography – Computerised Tomography,



# REDECTANE®: Phase III\* trial PET/CT outperformed CT

→ Phase III trial of 226 patients with renal masses in 14 US sites

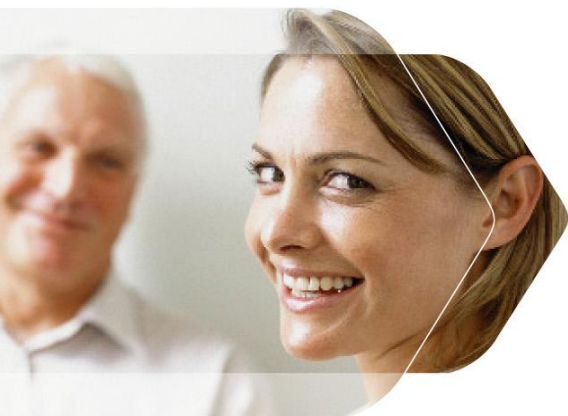


\*with SPA Special Protocol Assessment

Study endpoints	Specificity correct diagnosis that ccRCC is not present	Sensitivity correct diagnosis of ccRCC
REDECTANE® (PET-CT)	87%	86%
CT	47%	76%
REDECTANE® vs. CT	p<0.001	p≤0.016
REDECTANE® vs. arbitrary value of 75%	p=0.057	p≤0.002

# WILEX

Focused Cancer Therapies



**RENCAREX<sup>®</sup>**

(INN: girentuximab)

CA IX targeting monoclonal antibody for therapeutic use

# RENCAREX®: Therapy for adjuvant treatment of clear cell Renal Cell Carcinoma (ccRCC)

- **Monoclonal antibody for therapeutic use**
  - INN: Girentuximab
  - Specifically binds to the antigen CA IX on tumour cells
  - Validated mechanism of action (ADCC\*)
- **High medical benefit**
  - Targets micro-metastases to delay onset of metastatic disease
- **No drug approved by FDA / EMA in non-metastatic ccRCC**
  - Peak sales potential of ~ \$500m in ccRCC only
- **Commercialisation and co-development deals with Esteve for Southern Europe (2004) and Prometheus in the USA (2011)**



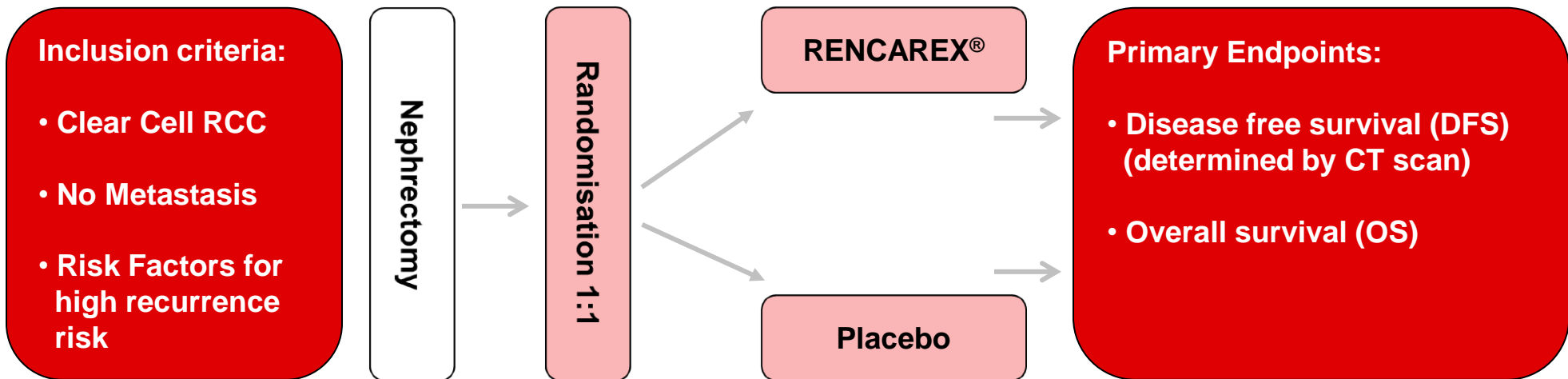
\* Antibody Dependant Cellular Cytotoxicity

## RENCAREX®

- **Exclusive US commercialisation deal with Prometheus Laboratories**
  - Signed in April 2011
- **WILEX receives from Prometheus**
  - \$39 million in cash:
    - \$19 million upon signing **AND**
    - either \$15 million after six months or \$20 million after twelve months or European commercial rights to an undisclosed product **AND**
  - Milestones and co-funding for the ongoing development of RENCAREX® **AND**
  - Royalties on US net sales of RENCAREX®
  - RCC and potential development in further indications
- **Deal valued at > \$145 million in cash for upfront, milestone payments and reimbursed costs plus royalties for US only**

## → International, pivotal Phase III trial: 864 renal cancer patients enrolled

- Non-metastatic RCC patients post nephrectomy
- Double-blind, placebo-controlled study in adjuvant setting
- 142 sites in North & South America and Europe

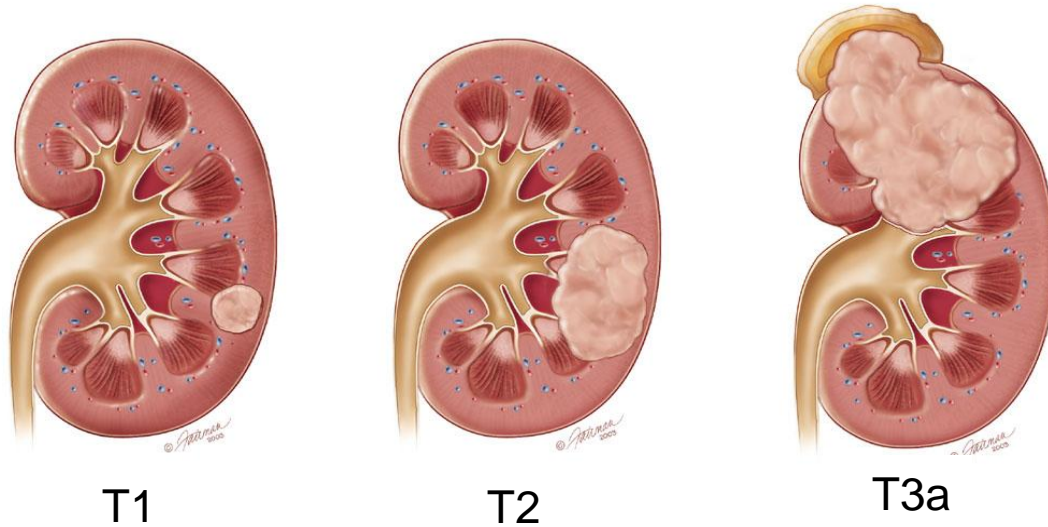


	Conducted at	Date	Outcome / Options
<i>Interim analysis for futility</i>	<i>100 events DFS</i>	<i>Dec 2007</i>	<i>IDMC recommended “continue trial”</i>
<i>All patients enrolled</i>	<i>864 patients</i>	<i>July 2008</i>	<i>6 months medication completed, Follow-up CT-scans</i>
Interim analysis for efficacy	343 events DFS	Start Jan 2011	IDMC: “Consider filing”, “Continue trial” or “Stop trial”
Final analysis	512 events DFS*	-	FDA filing: if $p < 0.01$

\*DFS: Disease free survival

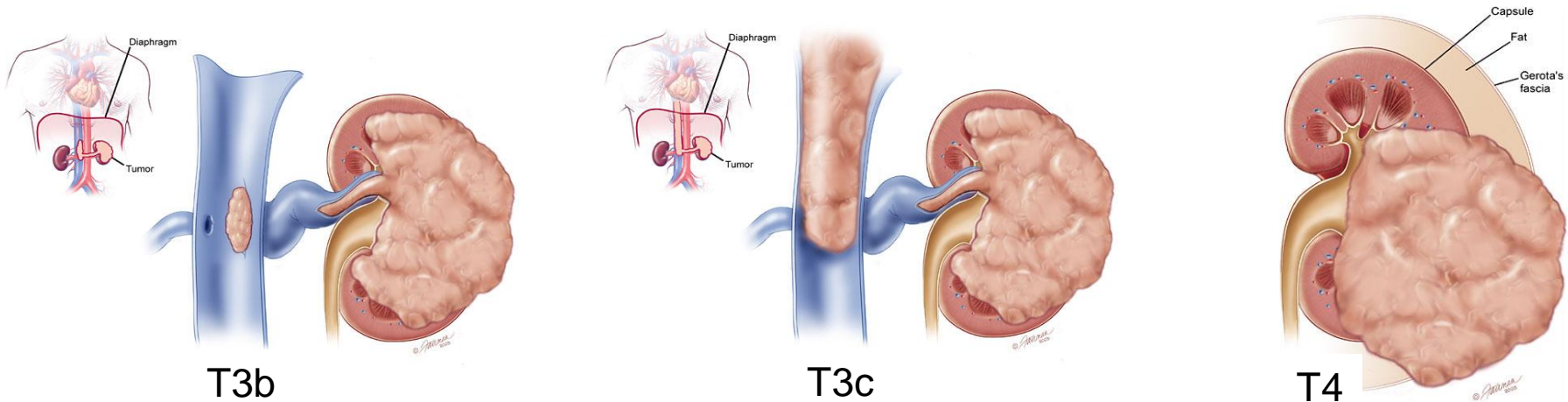
## → Current status:

- Process of interim analysis started in January 2011
- Fast track designation Q3 2011
- IDMC recommendation H2 2011



**Relapse within 2 years:** Risk Group

- T3aN0/XM0 or T3bN0/XM0 or T3cN0/XM0 or T4N0/XM0 I
- or
- any T stage and N+ disease and M0 II
- or
- T1bN0/XM0 or T2N0/XM0, each with grading G ≥ 3\* III



# Results of other completed adjuvant studies

Treatment	N	Reference	Year	Outcome
IFN-a vs observation	283	Messing et al	2003	Median RFS: 3 yr (observation)
Vitespen vs observation	728	Wood et al	2008	Median RFS: ~3 yr (observation)
IL-2 + IFN-a + FU vs observation	309	Aitchison et al	2011	3 yr DFS: 50% (observation)

- **IDMC meeting on 21 November 2011**
- **Trial matured, recurrence rate further declined**
- **Recommendation: Conduct final analysis now instead of after 512 events**
- **IDMC recommendation consistent with Medical Advisory Board and regulatory authorities**
- **Supported by our commercialisation partners Prometheus and Esteve**
- **Trial remains blinded until final analysis will take place**

# Next steps and timeline assumptions

- **Submit protocol amendment** Q1 2012
  
- **Subject to regulatory approvals:**
  - Final analysis results may be expected Q4 2012
  - Possible filing in EU and US H1 2013

# WILEX

Focused Cancer Therapies



**MESUPRON<sup>®</sup>**  
(INN: Upamostat )  
Oral uPA inhibitor

# MESUPRON®: First-in-class therapy targeting primary and metastatic tumour growth

- **MESUPRON® inhibits the Urokinase-type Plasminogen Activator (uPA) system**
  - Oral small molecule for novel non-cytotoxic, anti-metastatic approach in cancer therapy
  - To specifically block tumour metastasis in solid cancers
- **uPA level a predictor of survival**
  - Hypothesis that inhibiting uPA should therefore increase survival
- **World leader in uPA inhibitors:**
  - Strong IP position and high entry barrier
- **Extensive Ph I programme to determine safety, tolerance and Ph II dose rationale**
- **Peak sales potential of ~ \$ 1 bn for various indications**
- **Worldwide partnership planned**

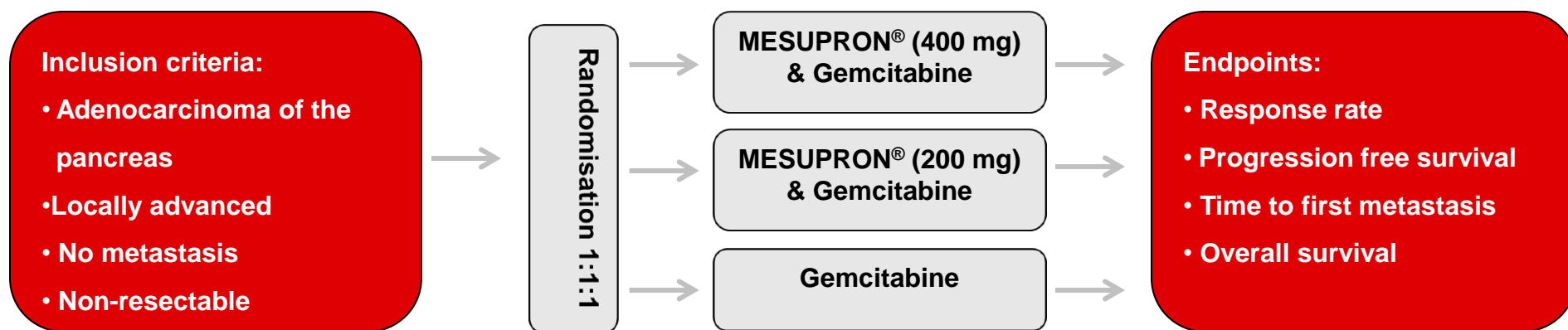


# MESUPRON®: Phase II pancreatic cancer trial

## Encouraging clinical proof of concept data

### → Phase II trial of 95 pancreatic cancer patients

→ 30 centres in 6 European countries, completed in June 2010



Final data	Gemcitabine alone	Gemcitabine & MESUPRON® (200 mg)	Gemcitabine & MESUPRON® (400 mg)	Improvement***
Tumour response*	15.4%	21.4%	35.5%	doubled
PFS rate at 12 months	16.2%	22.5%	26.9%	66%
Median OS (months)	9.9	9.7	12.5	26%
1 year survival	33.9%	40.7%	50.6%	49%

\* Partial response (All CTs were assessed by central independent radiology. Responses were assessed from Waterfall plots using RECIST cut-off criteria.)

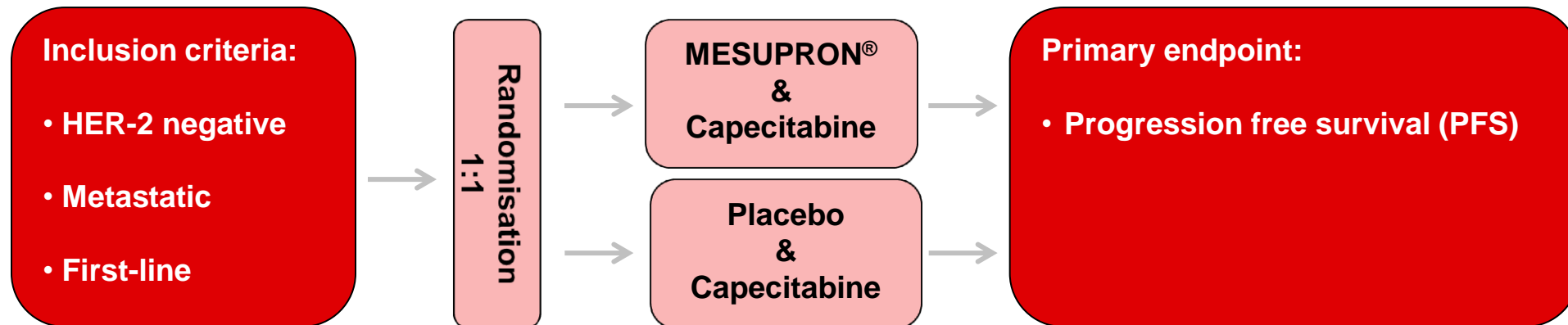
\*\* Poplin et al JCO Aug 2009: 9.2 months for Gemcitabine

\*\*\* Improvement between Gemcitabine alone and Gemcitabine & MESUPRON 400mg

PFS /progression free survival , OS / overall survival

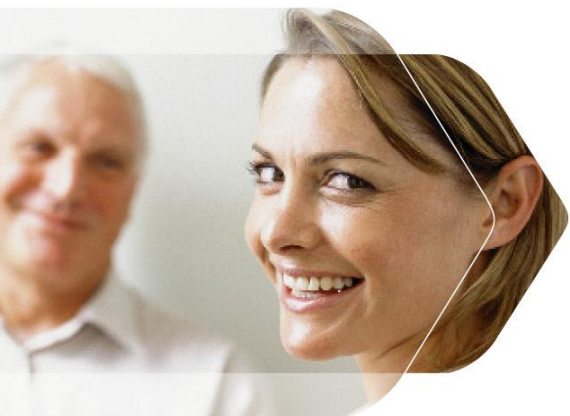
## → Phase II trial of 132 breast cancer patients ongoing

- First line therapy for HER-2 receptor negative, metastatic breast cancer
- Combination therapy with Capecitabine (Xeloda®), double-blind design
- 20 centres in Belgium, Brazil, Germany, Israel, USA
- Patient recruitment started in August 2008 and completed in May 2011



## → Next milestones

- Study data (PFS) expected during 2012



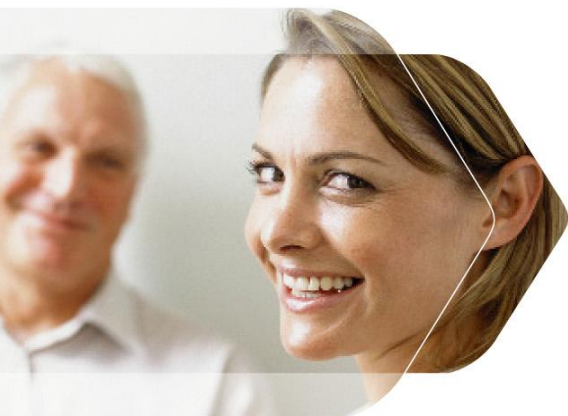
**WX-554 (MEK inhibitor)**

## → **WX-554 oral small molecule MEK inhibitor**

- Mitogen-activated protein kinase (MEK) plays a central role in signal transduction
- MEK signalling pathway is over expressed in more than 30% of cancers, resulting in increased tumour growth and proliferation
- Data of first Phase I, i.v. administered in healthy volunteers published in Q2 2010
- Oral Phase I in healthy volunteers started in Q2 2011
- Further oral Phase I in cancer patients planned for 2012

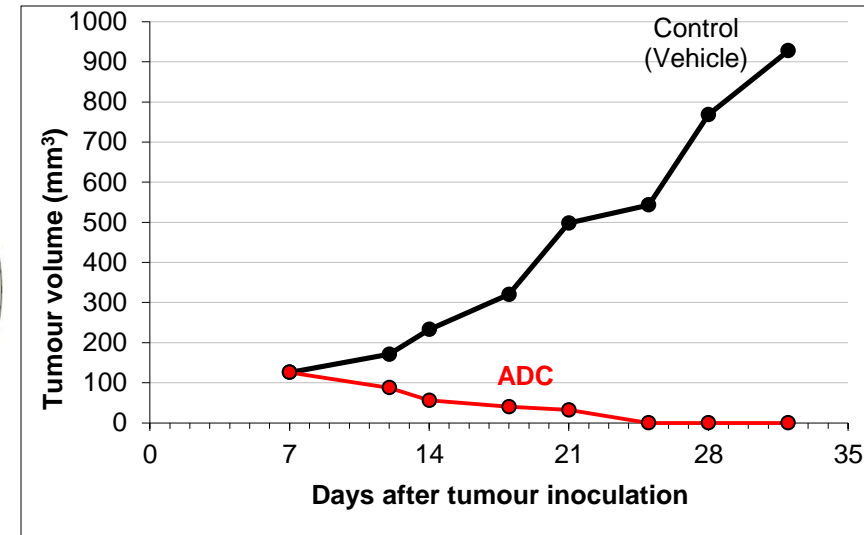
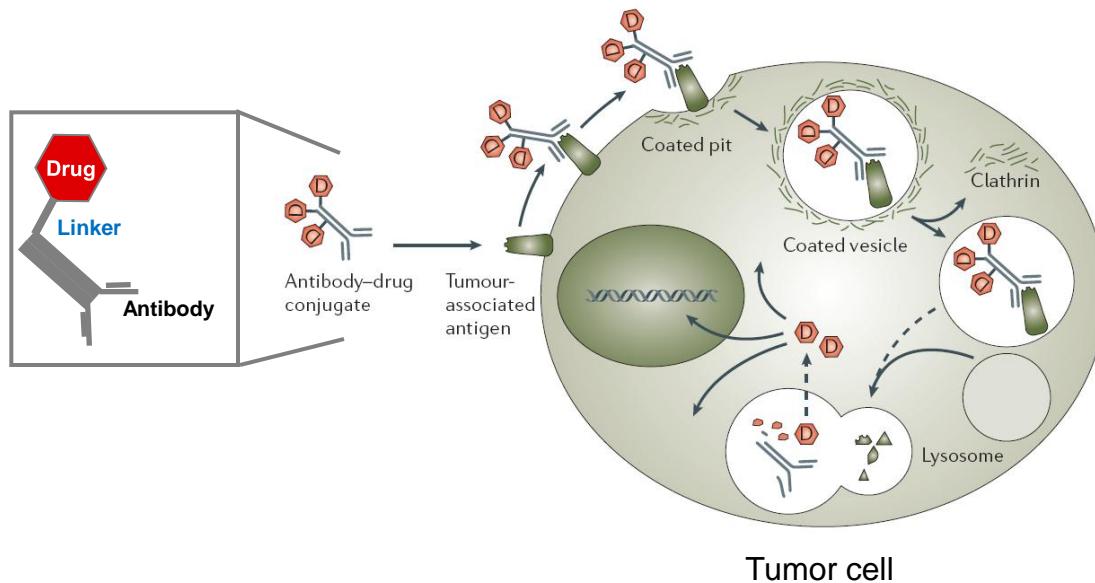
**WILEX**

Focused Cancer Therapies



**Products and technologies**

<b>Profile</b>	→ Focused on novel cancer therapies
<b>Business Model</b>	→ ADC technology platform business → Preclinical contract research business (CSR)
<b>Capabilities</b>	→ Proprietary antibody drug technology → Preclinical: Bioanalytics, Cell Biology, Pharmacology
<b>Organisation</b>	→ Located in Ladenburg, Germany → 41 Employees (32 FTE)
<b>Financials</b>	→ Revenues through preclinical client specific contract research business



- **Mode of action:** The antibody guides the toxin high selectively to the tumour cell, the linker provides cleavage and release of the toxin within the targeted tumour cell ONLY, the toxin kills the tumour cell
- Combining specificity & efficacy
- Proof of concept in vivo tumour model showed impressive results

<b>Profile</b>	<ul style="list-style-type: none"><li>→ Former Companion diagnostics business unit of Siemens Healthcare</li><li>→ Strategic IP and commercial products in Companion diagnostics</li></ul>
<b>Business Model</b>	<ul style="list-style-type: none"><li>→ Manufacturing and commercialisation of oncology biomarker assays</li><li>→ Biomarker diagnostics (ELISA and IHC): HER2, CA IX, uPA, PAI-1, EGFr, TIMP</li></ul>
<b>Capabilities</b>	<ul style="list-style-type: none"><li>→ GMP manufacturing facility</li><li>→ State of the art facilities and equipment</li></ul>
<b>Organisation</b>	<ul style="list-style-type: none"><li>→ Located in Cambridge, MA/USA</li><li>→ 11 Employees (10 FTE)</li></ul>
<b>Financials</b>	<ul style="list-style-type: none"><li>→ Cash flows from product sales</li><li>→ Exclusive co-marketing and distribution agreement with ALPCO Diagnostics for the commercialization of the Serum HER-2/neu ELISA test in North America</li></ul>

## Positioning

- IP and biomarker tests to provide tools for targeted therapies



## Advantages

- Measuring proteins in blood with ELISA tests
- Bioanalytical methods designed to select patients for therapy
- Assessment how patients will respond to a specific medical treatment
- Monitoring of patient's treatment and outcome

Rx

**RENCAREX®**

**MESUPRON®**

**WX-554**

- ✓ US commercialisation rights to Prometheus Laboratories Inc.
- ✓ Fast track designation from FDA
- ✓ IDMC recommendation
- ✓ Patient recruitment Phase II breast cancer trial completed
- ✓ Phase I with oral WX-554 in healthy volunteers started
- ✓ Pre-clinical development (GMP and toxicity studies) for WX-037

Dx

**REDECTANE®**

**In-vitro  
diagnostics**

- ✓ Pre-BLA Meeting with FDA

- ✓ WILEX Inc. ISO certification
- ✓ US marketing and distribution agreement with ALPCO

Cx

**ADC + CSR**

- ✓ Integration of Heidelberg Pharma into the Group completed
- ✓ Material Transfer Agreements with third companies for ADC

In € m	Results 2010	Guidance 2011
Sales revenue & other income	1.3	9.0 – 11.0
Operating expenses	24.4	26.0 – 30.0
Operating result	(23.1)	(16.0) – (20.0)
Total funding requirement	25.5	24.0 – 27.5
Funds required per month	2.06	2.0 – 2.3
Employees	80	119

→ **Improved guidance for 2011**

→ **Guidance comprises WILEX AG, WILEX Inc. and Heidelberg Pharma AG**

Rx	RENCAREX®	→ Decision: product or \$15m / \$20m cash from Prometheus agreement
	MESUPRON®	→ Full study results of final DFS analysis expected in Q4 2012
	WX-554	→ Data breast cancer Phase II trial expected 2012
Dx	REDECTANE®	→ Data Phase I in healthy volunteers (oral) expected Q1 2012
	In-vitro diagnostics	→ Start Phase I in cancer patients (oral) expected early 2012
Cx	ADC + CSR	→ Design of an outcome based study and meeting with FDA
		→ Increase marketing activities and revenue
		→ Third-party ADC collaborations
		→ Increase sales revenue

## Forward looking statements

This communication contains certain forward-looking statements, relating to the Company's business, which can be identified by the use of forward-looking terminology such as "estimates", "believes", "expects", "may", "will", "should", "future", "potential" or similar expressions or by general discussion of strategy, plans or intentions of the Company. Such forward-looking statements involve known and unknown risks, uncertainties and other factors, which may cause our actual results of operations, financial condition, performance, or achievements, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements.

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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## WILEX AG

Grillparzerstr. 10  
81675 Munich, Germany  
Tel.: +49 (0)89-41 31 38-0  
Fax: +49 (0)89-41 31 38-99  
Website: [www.wilex.com](http://www.wilex.com)

## Corporate Communications

Katja Arnold (CIRO)  
Email: [investors@wilex.com](mailto:investors@wilex.com)  
Tel.: +49 (0)89-41 31 38-126

ISIN: DE0006614720  
Symbol: WL6  
Reuters: WL6G.DE  
Bloomberg: WL6G.GR