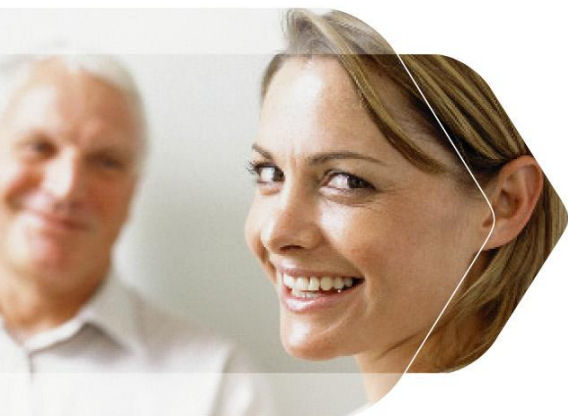


WILEX

Focused Cancer Therapies



RENCAREX[®]

ARISER Phase III Update

22 November 2011

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

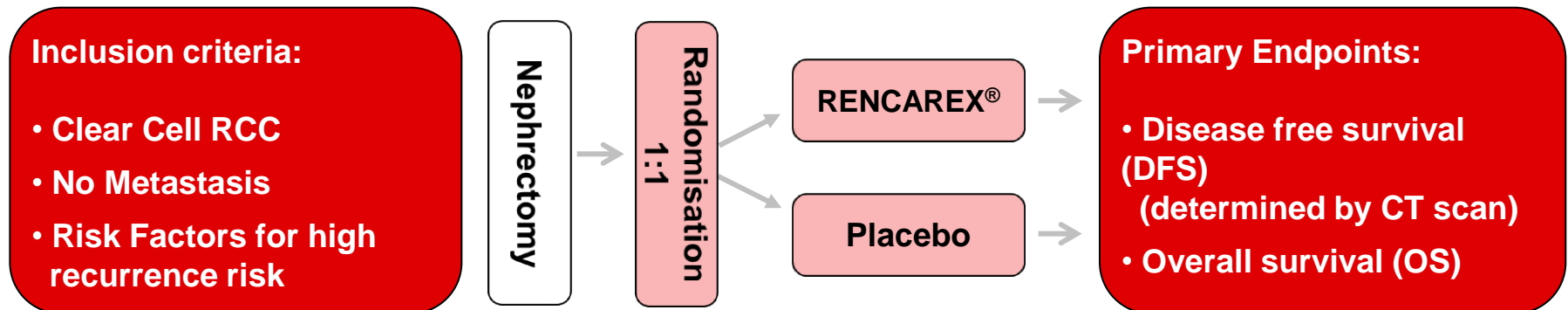
- **Monoclonal antibody for therapeutic use**
 - INN: Girentuximab
 - Specifically binds to the antigen CA IX on tumour cells
 - Validated mechanism of action (ADCC*)
- **High medical benefit**
 - Targets micro-metastases to delay onset of metastatic disease
- **No drug approved by FDA / EMA in non-metastatic 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

→ **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



RENCAREX®: Original planned regulatory path

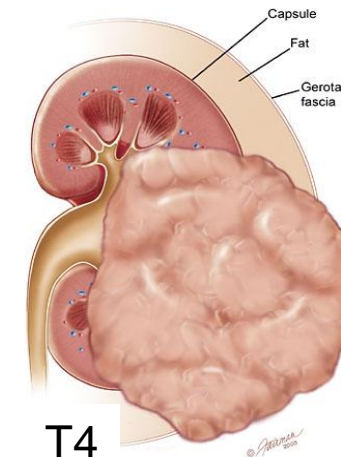
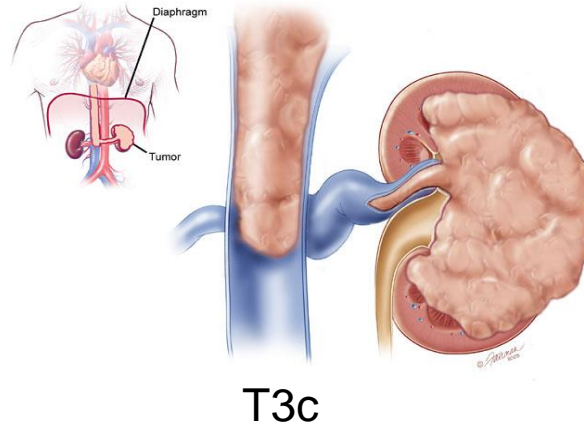
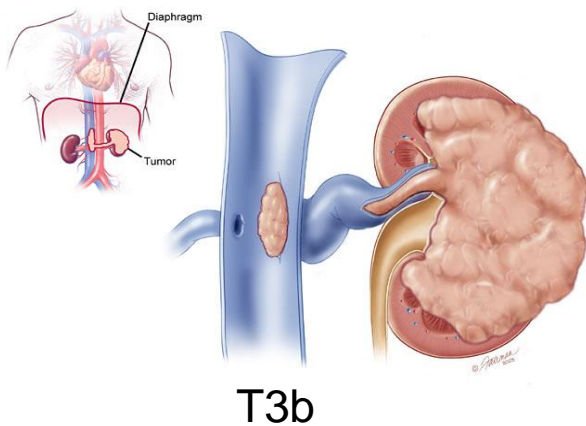
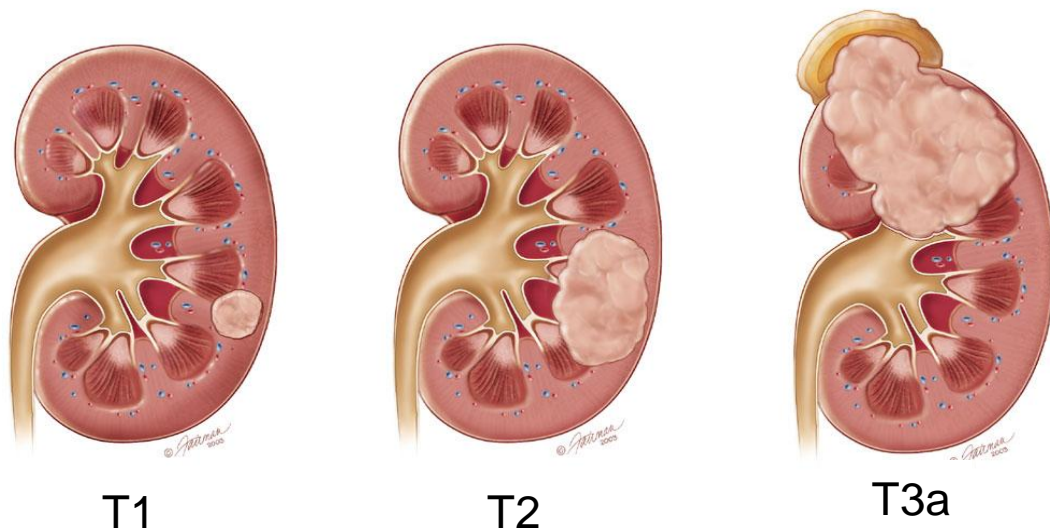
	Conducted at	Date	Outcome / Options
<i>Interim analysis for futility</i>	<i>100 events DFS</i>	<i>Dec 2007</i>	<i>IDMC recommended “continue trial”</i>
<i>All patients enrolled</i>	<i>864 patients</i>	<i>July 2008</i>	<i>6 months medication completed, Follow-up CT-scans</i>
Interim analysis for efficacy	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 received October 2011
- IDMC recommendation H2 2011

Patients with high risk for relapse



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

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.

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Bloomberg: WL6G.GR