

# Jefferies 2011 Global Healthcare Conference



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Tomas Leanderson  
President & CEO  
Active Biotech



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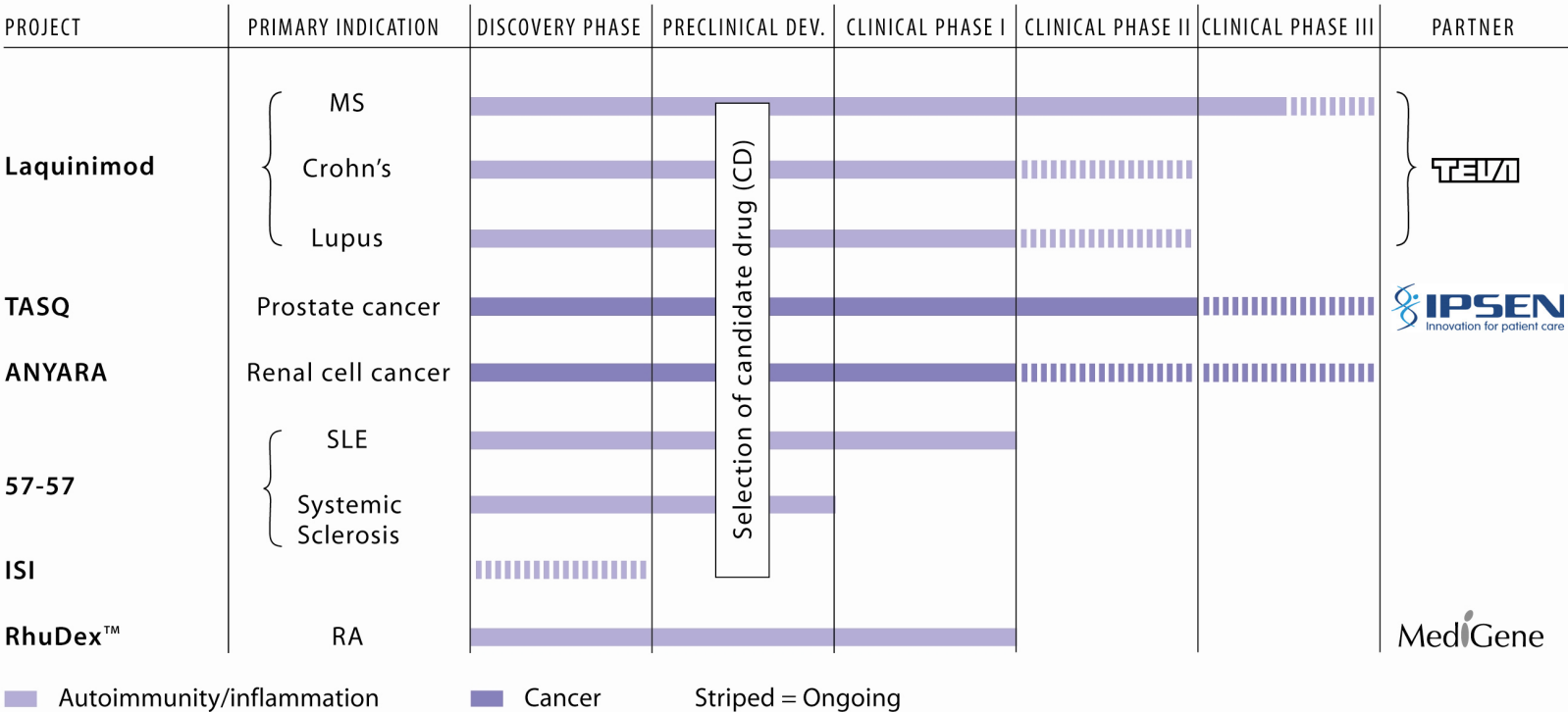
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## Company overview

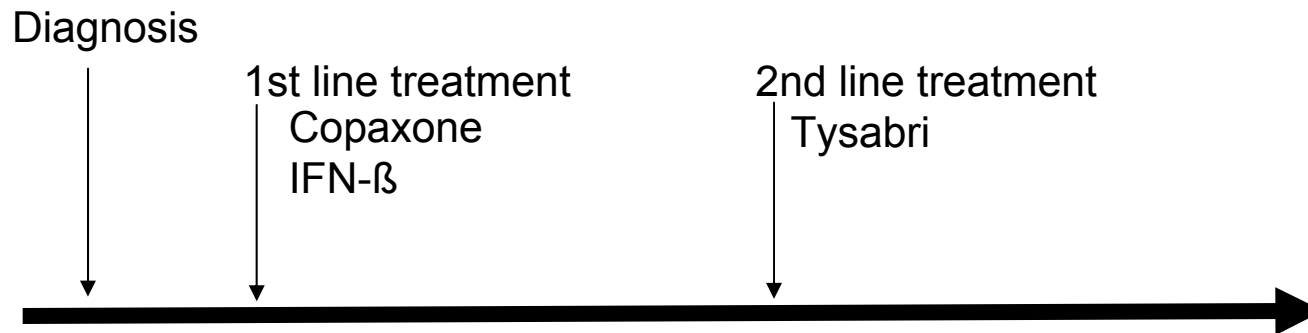
- Swedish Biotechnology Company
- Core competence in **Autoimmune/Inflammatory** diseases and **Cancer**
- Spin out from Pharmacia 1998
- Listed company NASDAQ OMX Nordic: **ACTI**
- Share price SEK 88.25 (14.0 USD), market cap **SEK 6.1 B** (962 MUSD) as of May 30, 2011
- A total of **82** employees

# Active Biotech Pipeline



## Multiple sclerosis

- Over 1 million people affected worldwide, total market 2009 – 10.2 BUSD<sup>1)</sup>
- Inflammatory and neurodegenerative components of the disease
- Current treatments:
  - injectables: Copaxone, Avonex, Rebif, Betaseron and Tysabri
  - orals: Gilenya (US, EU, RUS) and Cladribine (AUS, RUS)



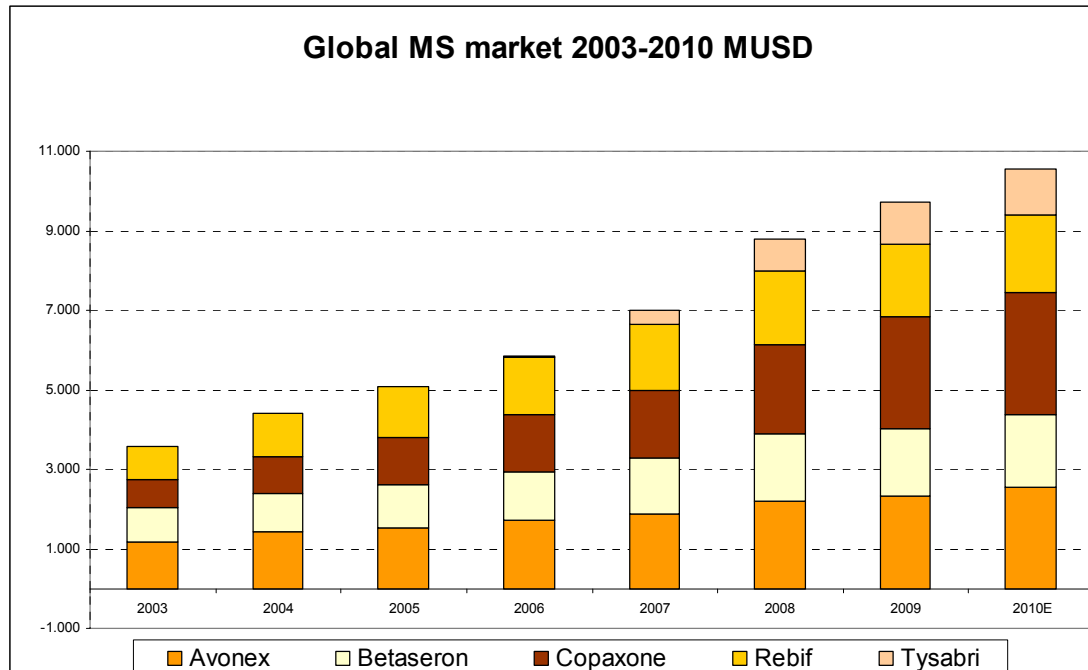
## Laquinimod

- Oral disease-modifying treatment of MS<sup>2)</sup> ; one tablet a day dosing
- Efficacy and safety data position laquinimod as first line therapy

<sup>1)</sup> Cowen Therapeutic Categories Outlook March 2010

<sup>2)</sup> Comi et al *Mult Scler Sep 2010*

# Current Multiple Sclerosis Treatment Landscape



Source: Morgan Stanley June 2010

	Injectable	Oral
Immunosuppressant	<ul style="list-style-type: none"> <li>• Campath (Phase III)</li> <li>• Daclizumab (Phase III)</li> <li>• Tysabri (Mkt)</li> </ul>	<ul style="list-style-type: none"> <li>• Gilenya (Mkt)</li> <li>• Cladribine (Ph III)</li> <li>• Teriflunomide (Ph III+)</li> </ul>
Immunomodulator	<ul style="list-style-type: none"> <li>• Copaxone (Mkt)</li> <li>• Interferon (Mkt)</li> <li>• PEG-interferon (Phase III)</li> </ul>	<ul style="list-style-type: none"> <li>• Laquinimod (Ph III+)</li> <li>• BG-12 (Ph III+)</li> </ul>

## MS Market Landscape – Marketed And Phase III Drug Categorization

# Primary endpoint met in ALLEGRO Phase III (AAN)

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1,106 MS patients; 0.6 mg laquinimod daily for 24 months

- 23 % reduction ( $p=0.0024$ ) in annualized relapse rate (primary endpoint)
- 36 % reduction ( $p=0.0122$ ) in sustained disability progression by EDSS (Expanded Disability Severity Scale)
- 33% reduction ( $p<0.0001$ ) in brain atrophy
- Safe & well tolerated

# Laquinimod – Phase III trials



<b>Objective</b>	Effect of 0,6 mg vs placebo on Relapse rate & Disability	Effect of 0,6 mg vs placebo on Relapse rate & Disability, Comparative Risk/Benefit – Laquinimod vs Avonex®
<b>Patients</b>	~1000 RRMS patients (2x500)	~1200 RRMS patients (3x400)
<b>Countries</b>	United States, Canada, Europe and Israel	United States, Europe, Israel and South Africa
<b>Treatment Duration</b>	24 Months	24 Months
<b>Dose</b>	Daily oral LAQ 0,6 mg & Placebo	Daily oral LAQ 0,6 mg & Placebo Weekly im Avonex® 30 µg
<b>Primary Endpoint</b>	Number of relapses during Rx phase	Number of relapses during Rx phase
<b>Secondary Endpoints</b>	Time to confirmed progression EDSS, MRI parameters	Time to confirmed progression EDSS, MRI parameters
<b>Status</b>	Positive complete results presented April 2011	Fully recruited June 2009 Results Q3 2011

# Laquinimod – ongoing Phase II clinical program

Indication	Crohn's disease	Lupus Nephritis	Lupus Arthritis
<b>Objective</b>	Safety and effect of daily oral <b>laquinimod</b>	Safety and effect of daily oral <b>laquinimod</b>	Safety and effect of daily oral <b>laquinimod</b>
<b>Patients</b>	~180 patients with active moderate to severe Crohn's disease	~45 active Lupus Nephritis patients	~90 active Lupus Arthritis patients
<b>Countries</b>	Europe, Israel and South Africa (45 sites)	United States, Canada, France, Russia, UK (28 sites)	United States, Canada (25 sites)
<b>Treatment Duration</b>	8 weeks	24 weeks	12 weeks
<b>Dose</b>	Daily oral LAQ 0.5 mg/day up to 2 mg/day or Placebo in sequential dose groups	Daily oral LAQ 0.5mg/day and 1 mg/day or Placebo in combination with standard of care treatment (mycophenolate mofetil and corticosteroids)	Daily oral LAQ 0.5mg/day and 1 mg/day or Placebo
<b>Primary Endpoint</b>	Safety, Tolerability, Clinical Effect - proportion of subjects in clinical remission and subjects who respond to treatment	Safety, Tolerability, Effect on protein to creatinine ratio	Safety, Tolerability, Change in swollen and tender joint counts
<b>Status</b>	Recruiting	Recruiting	Recruiting

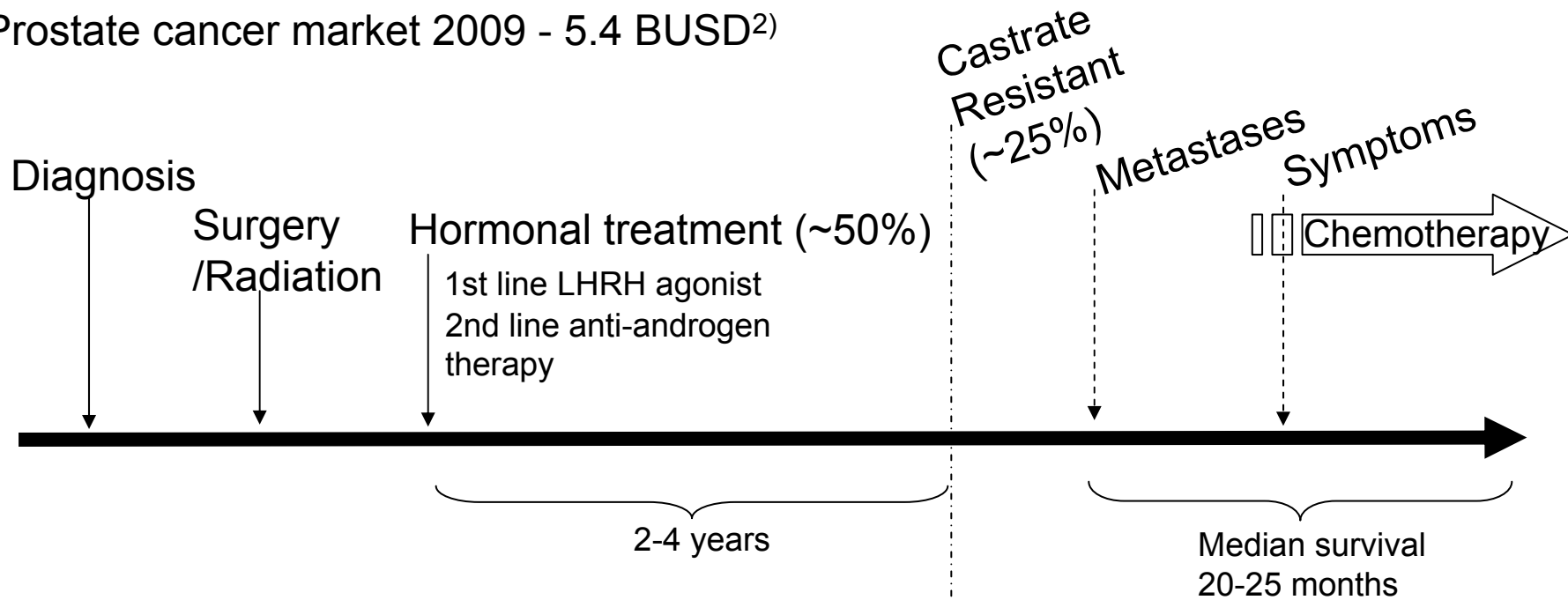
# Laquinimod Commercial Development and Marketing Agreement

## Teva Pharmaceutical Industries

- Teva has global exclusive rights to develop, register, manufacture and commercialize laquinimod since 2004
- Teva conducts and funds further clinical development of drug
- Expected to generate USD 92 million in overall milestones whereof USD 17 million received so far
- Active Biotech to receive tiered double digit royalties on future sales
  - 15 year royalty period on country-by-country basis
  - Higher royalty level in the Nordic/Baltic territory

# Active Biotech - Oncology

- TASQ development currently focused on registration in metastatic castrate resistant prostate cancer (CRPC)
- Small molecule – one capsule a day dosing
- Broader use envisaged
- Number of prostate cancer patients exceeds 400,000<sup>1)</sup>
- Prostate cancer market 2009 - 5.4 BUSD<sup>2)</sup>



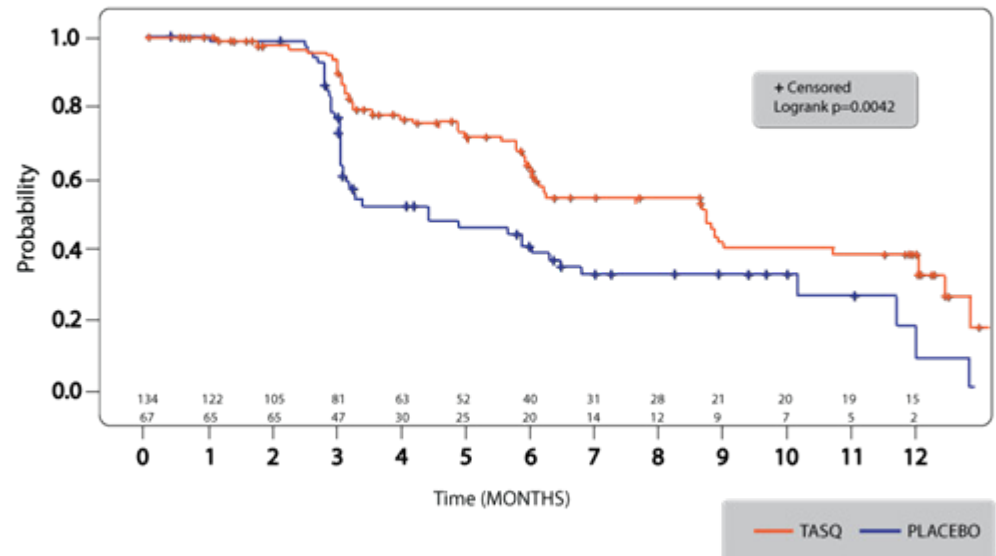
<sup>1)</sup> Datamonitor, 7 Major Markets forecast 2009. US; 262,207

<sup>2)</sup> GlobalData 2010

***Delay chemotherapy<sub>1</sub>***

# TASQ randomized Phase II met primary endpoint

- 206 asymptomatic metastatic CRPC patients in the US, Canada and Sweden
  - Disease progression: bone scan or CT scan, cancer pain, pathological event
  - 2:1 randomization 1.0 mg TASQ vs placebo
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- 69 % (93/134) of TASQ patients vs 34 % (23/67) of placebo patients had not progressed at 6 months ( $p < 0.0001$ ) (CMH). Relative risk for progression 0.47
  - Median Progression Free Survival (mPFS) 7.6 vs 3.3 months ( $p = 0.0042$ )



# Ongoing TASQ Phase III Trial

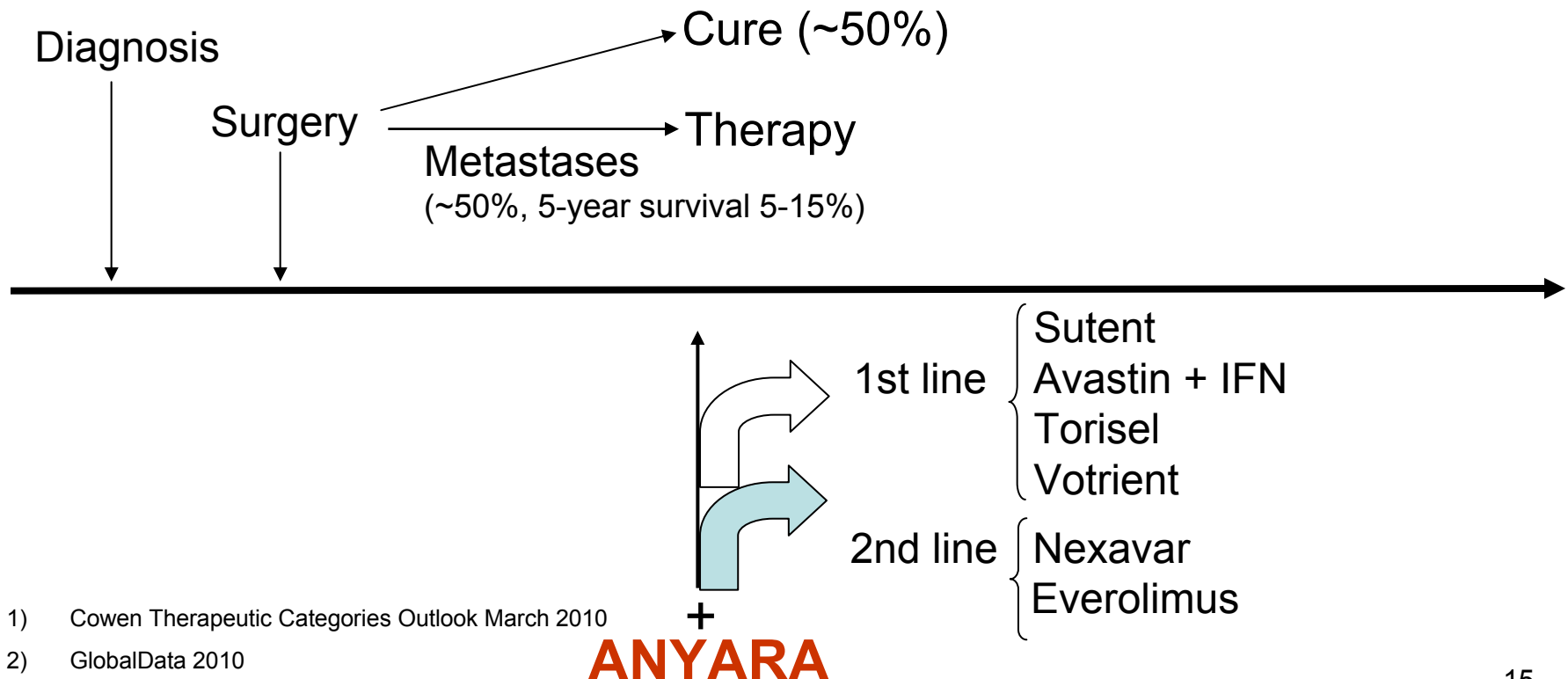
<b>Indication:</b>	Metastatic castrate resistant prostate cancer (CRPC) pre-chemo
<b>Primary endpoint:</b>	Radiographic Progression Free Survival (PFS)
<b>Study design:</b>	Randomized, double-blind placebo-controlled
<b>Regions:</b>	Global including US/Canada, Europe & China
<b>No. of patients:</b>	1,200 (powered for overall survival)
<b>Study start:</b>	Patient recruitment initiated March 2011
<b>Study duration:</b>	24-30 months
<b>Coordinating investigator:</b>	Michael A. Carducci, Johns Hopkins University, Baltimore, US

# TASQ Co-development with Ipsen

- Partnership announced April 18, 2011
- Up to 200 M€ including 25 M€ upfront, and additional payments (clinical, regulatory and commercial milestones)
- Ipsen will pay Active Biotech progressive double-digit royalties on its net sales
- Active Biotech will be responsible for and finance the ongoing phase III trial
- Ipsen will conduct and fund a European supportive study in prostate cancer patients
- Active Biotech granted Ipsen exclusive rights to commercialize TASQ worldwide, except for North and South America and Japan where Active Biotech retains all commercial and marketing rights.

## Renal Cell Carcinoma

- 180,000 new cases worldwide each year<sup>1)</sup>
- Renal cancer market 2009 – approx 1 BUSD<sup>2)</sup>



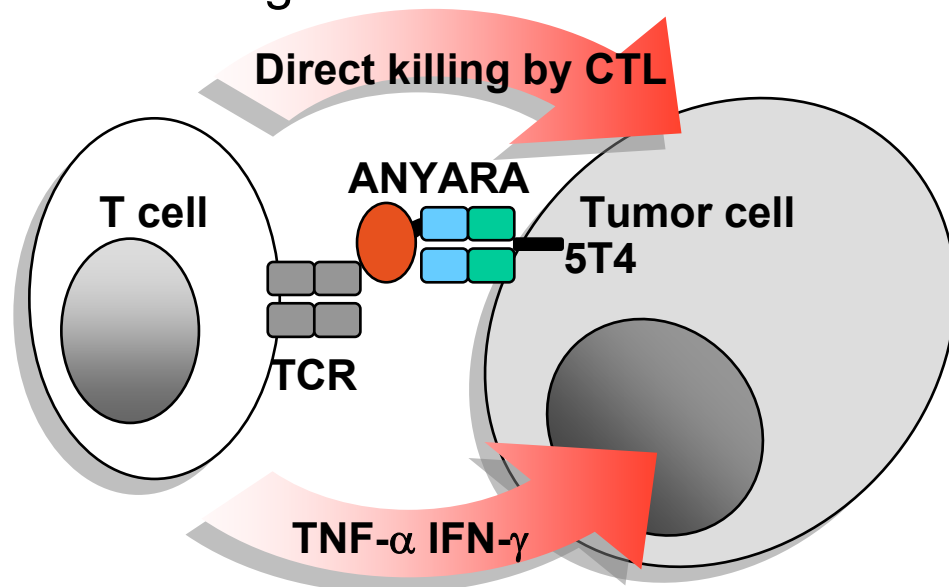
1) Cowen Therapeutic Categories Outlook March 2010

2) GlobalData 2010

## ANYARA: Tumor Targeted Superantigen (TTS)

### Therapeutic principle

- Selective drug retention in tumor tissue
- Activation and targeting of effector T cells
- Direct and indirect tumor cell killing



# ANYARA in Pivotal Phase III trial in RCC

- Study on-going since January 2007
- Positive interim analysis of safety and efficacy May 2008
- ANYARA currently in pivotal Phase III stage in Europe

Number of patients	> 500, enrollment completed June 2009
Randomization	IFN $\alpha$ vs ANYARA+IFN $\alpha$
Countries	UK, Ru, Uk, Bu, Ro (50 sites)
Primary endpoint	Overall survival
Secondary endpoints	Progression free survival, objective response rates, safety etc.
Analyzed at	384 of 512 patients

# Active Biotech - Autoimmunity/Inflammation

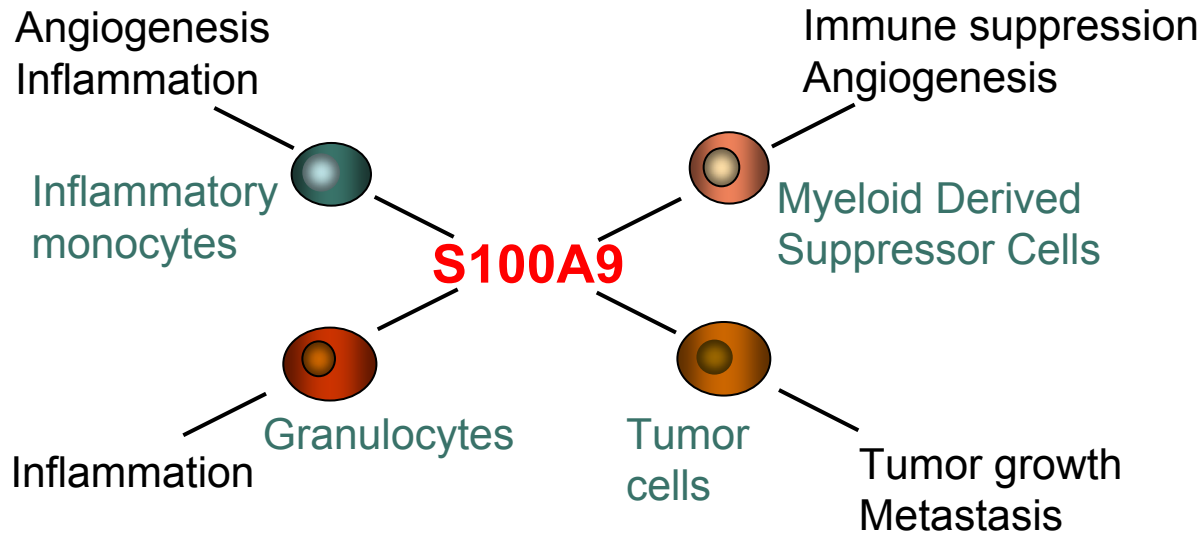


## 57-57: Chronic Oral Treatment

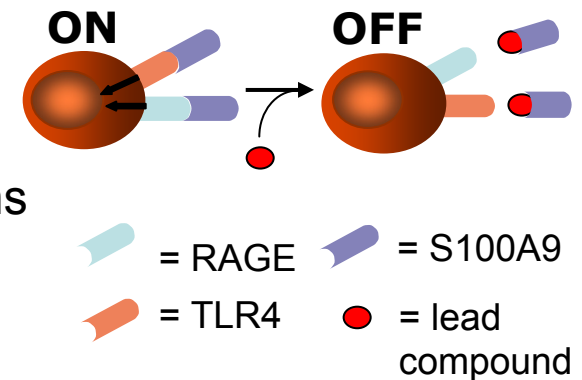
- Completed Phase Ib and exploratory clinical studies in SLE confirms previous data and **strengthens** 57-57 for further **clinical development**
- Positive effects observed in SLE patients
- Small quinoline molecule intended for chronic **oral** treatment
- Blocks S100A9 interactions with RAGE/TLR4
- Development in Systemic Sclerosis/Scleroderma initiated;  
Orphan Medicinal Product status granted in the EU

# The ISI Project - Inhibition of S100A9 Interactions

- Quinolines first in class S100A9 binders (PLoS Biology April 2009, Vol 7, Issue 4, p. 800-812)
- S100A9 interacts with the pro-inflammatory RAGE and TLR4 receptors



- The **ISI Project** - Inhibition of **S100A9** Interactions
- Lead compounds block S100A9-RAGE/TLR4 interactions
- First indication oncology



# Active Biotech Projected News Flow

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Laquinimod - Phase III data BRAVO Q3 2011

TASQ - Phase III results 2013

ANYARA - Phase III overall survival data 2012

57-57 - Start of SSc exploratory clinical study 2011

ISI - CD selection 2011/2012

# Company information



# Financials January – March 2011

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- Net sales SEK 2.7 million (2.8)
- Operating loss SEK 70.9 million (loss: 51.0)
- Loss after tax SEK 69.3 million (loss: 53.5)
- Cash on hand SEK 411.3 million (March 31, 2011)

EUR 25 million upfront payment received from Ipsen (April 2011)



[www.activebiotech.com](http://www.activebiotech.com)

