

Active Biotech AB



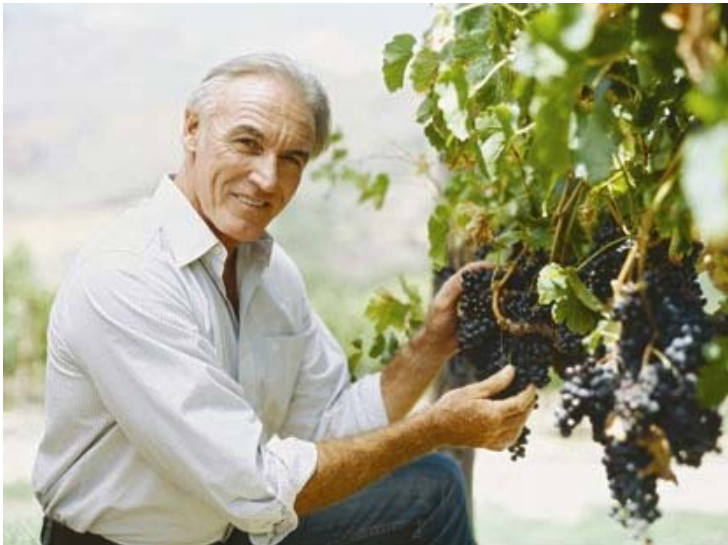
September, 2009

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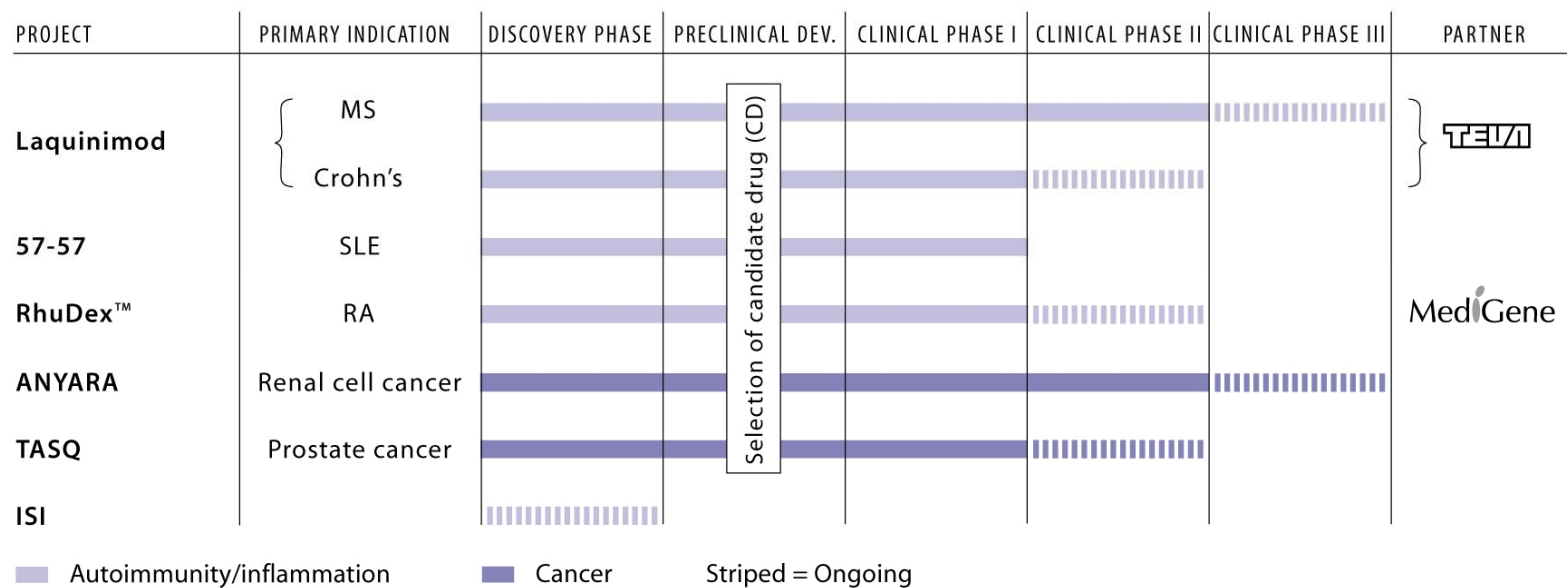
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- Swedish Biotechnology Company
- **Five** Projects in **Clinical Development**
- Focus on **Autoimmune/Inflammatory** diseases and **Cancer**
- Spin out from Pharmacia
- Listed since 1997
(NASDAQ OMX Nordic: **ACTI**)
- Market Cap SEK **3,395** M (MUSD 475)
as of August 31, 2009
- A total of **90** employees
- Key competences:
 - Development, Regulatory, Biology, Chemistry & Pharmaceuticals, Preclinical Development

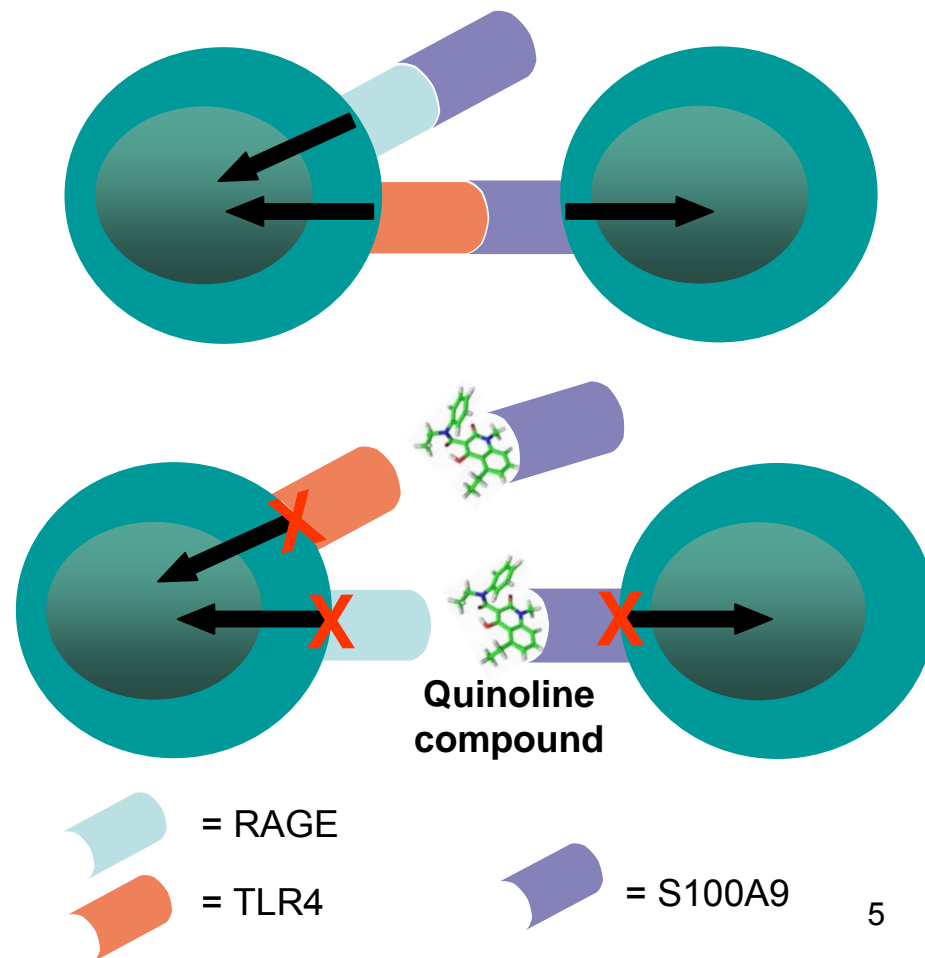
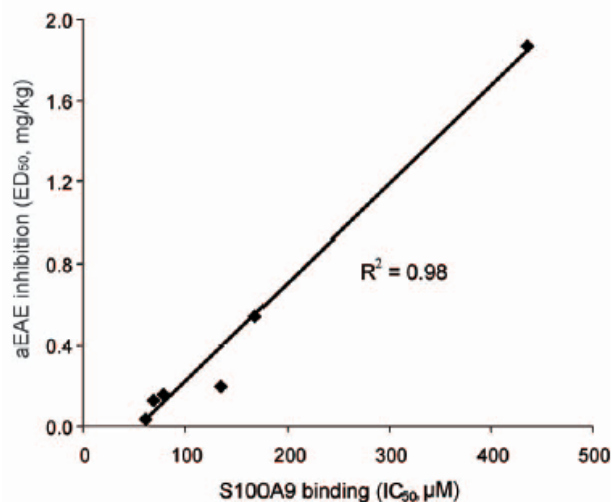
Active Biotech Pipeline



Active Biotech's Quinoline Technology

- S100A9 a unique molecular target

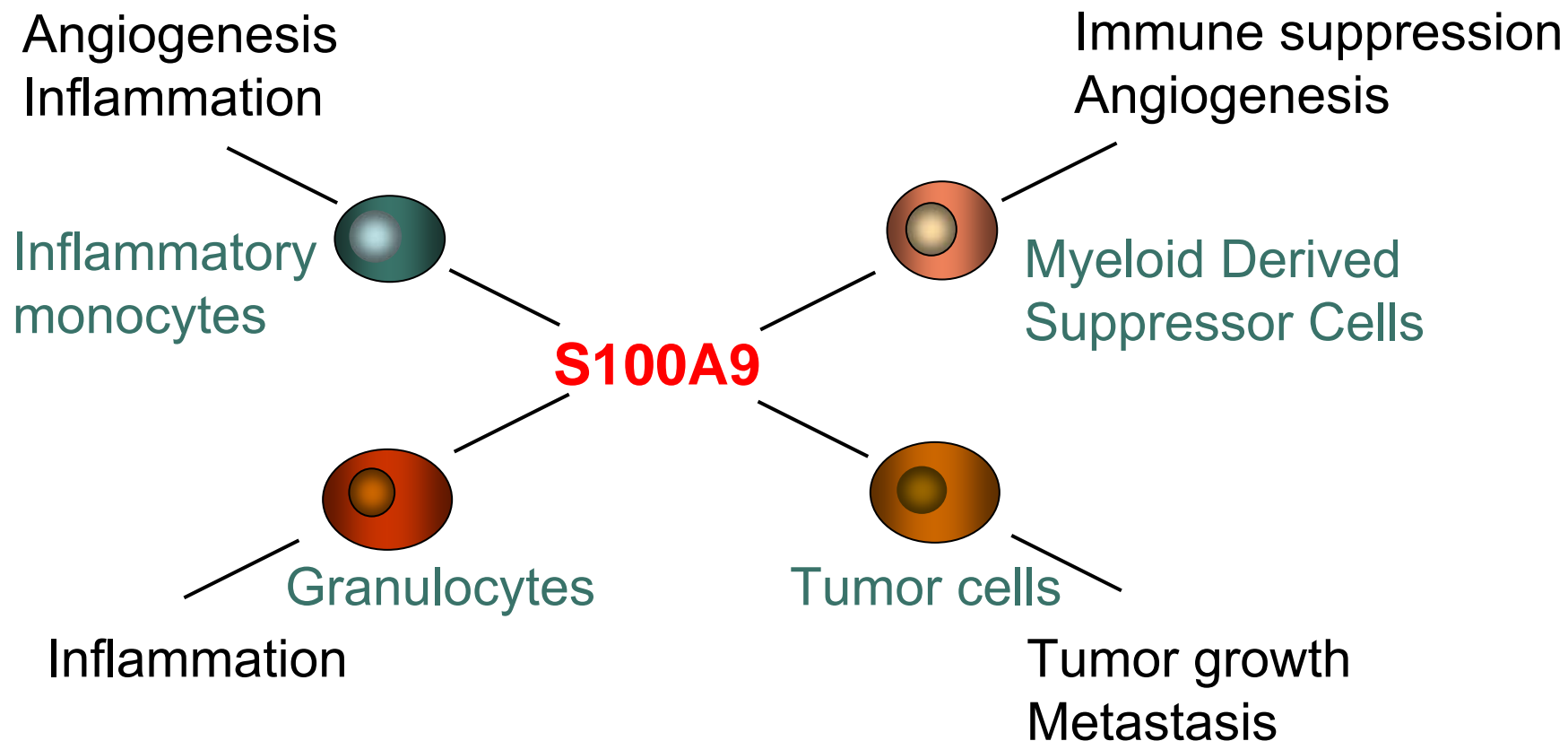
- First in class S100A9 binder
(PLoS Biology April 2009, Vol 7, Issue 4, p. 800-812)
- Interferes with early stages of immune activation
- Structure Activity Relationship
- binding to molecular target and efficacy in experimental in vivo model



Active Biotech's Quinoline Technology

- S100A9 a unique molecular target

S100A9 as a target for autoimmune/inflammatory diseases and cancer



Laquinimod: Chronic Oral Treatment for Autoimmune Diseases

- **Two global Phase III studies** in MS patients **ongoing**
- data followed by launch late 2011
- **Fast Track** status granted by **FDA**
- Small molecule – **one tablet a day** dosing
- Phase II program in Crohn's Disease ongoing

Laquinimod development highlights

- Phase II study demonstrated that 0.3 mg laquinimod daily was well tolerated and reduced the formation of active lesions in RRMS
- Phase IIb study¹⁾ in 306 patients: 0.6 mg laquinimod daily, reduced MRI disease activity by 60 percent vs placebo in RRMS patients. Reduction of annual relapse rates and number of relapse-free patients
- Over 1000 MS patients have received laquinimod
- Novel data on the immunomodulatory mechanism of action (MOA) of laquinimod presented at AAN 2009
- Several presentations at ECTRIMS September 10-11 2009
 - extensive data on neuroprotection
 - update on Phase IIb extension study

¹⁾ *Comi et al, Lancet 2008, 371:2085-92*

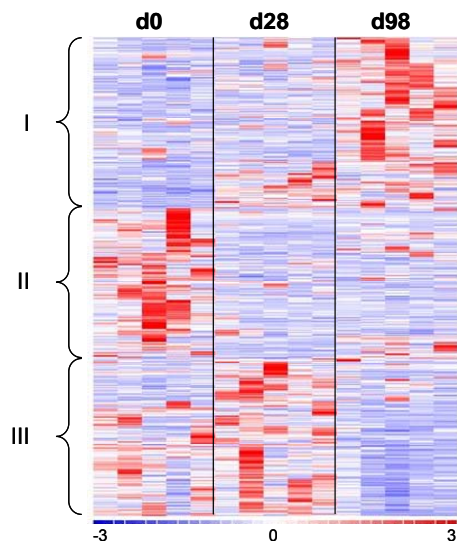
Active Biotech - Autoimmunity/Inflammation



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

57-57: Chronic Oral Treatment of SLE

- Completed **Phase Ib** study confirms previous data and **strengthens 57-57** for further **clinical development**
- Small quinoline molecule intended for chronic **oral** treatment of systemic lupus erythematosus (SLE)
- Blocks S100A9 interactions with RAGE/TLR4
- SLE is a chronic autoimmune disorder with a **high medical need**
- **Exploratory clinical study** ongoing



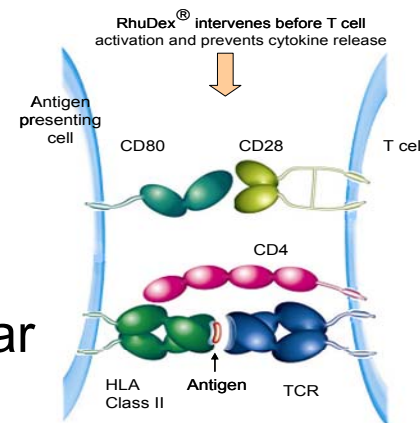
57-57 induces changes in gene expression patterns in PBMC of SLE patients.

RNA was prepared from PBMCs from five SLE patients receiving 57-57 and subjected to microarray analysis. An overall analysis identified three major clusters of genes with different expression patterns (I-III).

- Clinical Phase Ib: Effect on gene expression patterns in SLE patients
- Exploratory clinical study ongoing

RhuDex™ - Chronic Oral Treatment of RA

- Licensed to MediGene AG 2002
- Small molecule **CD80 inhibitor** for rheumatoid arthritis (RA)
- Clinical **Phase IIa** in RA patients **concluded** June 2008
- Upon approval of results from preclinical studies, clinical development may be resumed before the end of this year



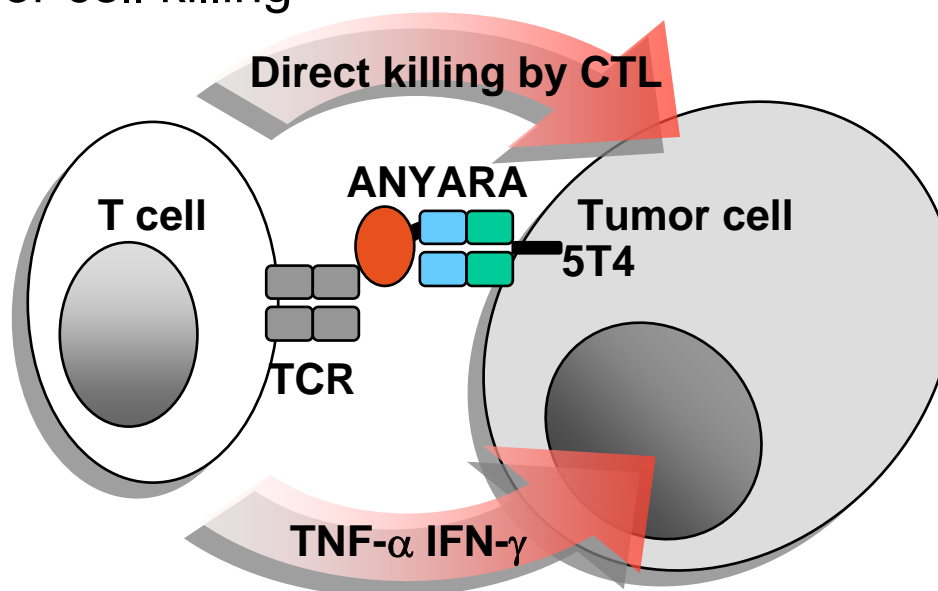
ANYARA: Increasing survival for patients with advanced cancer

- Pivotal **Phase III** studies for **renal cell cancer** (RCC) fully recruited, - **overall survival** data late 2010/early 2011
- Fusion protein targeting the 5T4 tumor antigen
- Encouraging results from Phase I trial in NSCLC, RCC and pancreatic cancer (Borghaei et al 2009, J Clin Oncol 27:4116-4123)
- **Orphan drug status** granted in Europe (July 2007)

ANYARA: Tumor Targeted Superantigen (TTS)

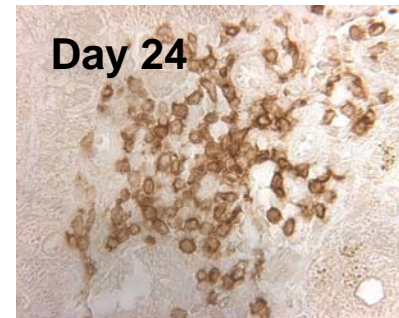
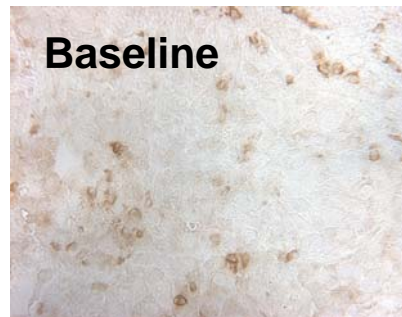
Therapeutic principle

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

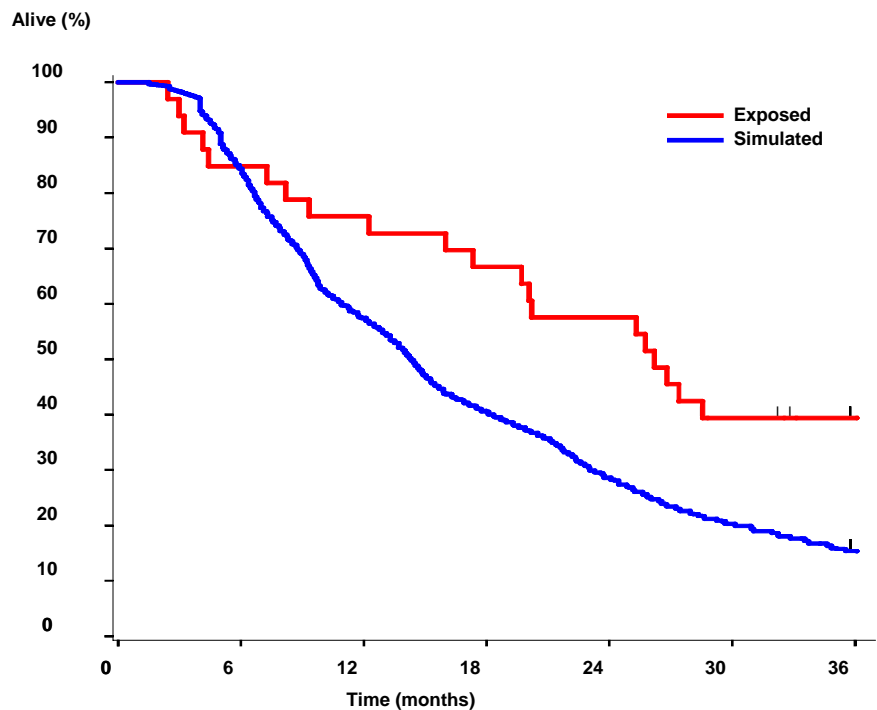


ANYARA: Concept Validation in Patients

- Specific uptake and retention of ANYARA in tumor (PET)
- Potent stimulation of immune system
- Expansion of ANYARA specific T cells
- Targeting of T cells into liver metastases of patient with NSCLC:



Promising Median Survival in RCC



Median survival 26.2 vs 14.3 months
(33 patients)

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

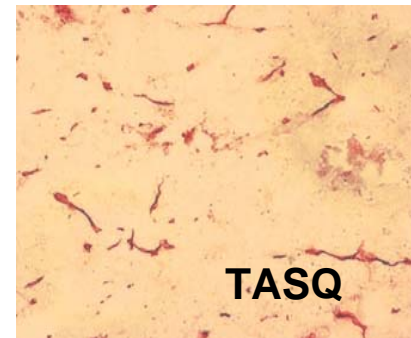
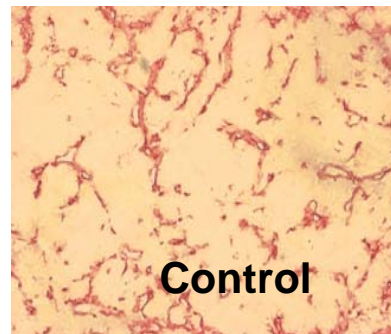
Number of patients	> 500, enrollment completed June 2009
Randomization	IFN α vs ANYARA+IFN α
Countries	UK, Ru, Uk, Bu, Ro (50 sites)
Primary endpoint	Overall survival
Secondary endpoints	Progression free survival, objective response rates, safety etc.
Analyzed at	384 of 512 patients

TASQ: Delay onset of prostate cancer symptoms

- **Phase II** placebo controlled clinical trial fully recruited
 - data by end 2009/early 2010
- Positive outcome from **DSMB** safety evaluation
- Small molecule – **one tablet a day** dosing
- Anti-angiogenic activity, **S100A9 one molecular target**
- **Positive** results from Phase I study
 - well-tolerated & preliminary efficacy encouraging

S100A9, MDSC (Myeloid Derived Suppressor Cells) and angiogenesis

- S100A9 is only a target at certain conditions e.g. found in the tumor environment
- S100A9 seem to be important for MDSC function
- Accumulation of immune suppressive MDSCs is one of the major immunological abnormalities in cancer
- MDSC impair T cell effector function
- VEGF implicated in generation of MDSC
- MDSC stimulate tumor angiogenesis

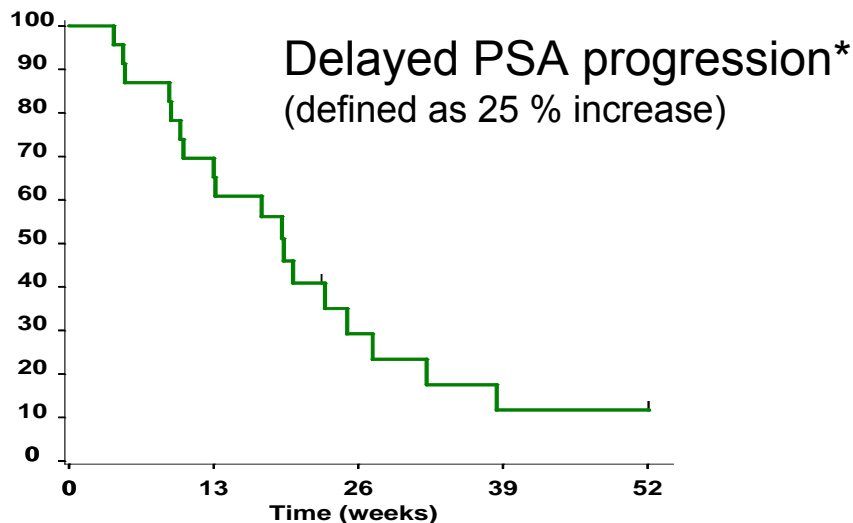


References; S100A9 in cancer

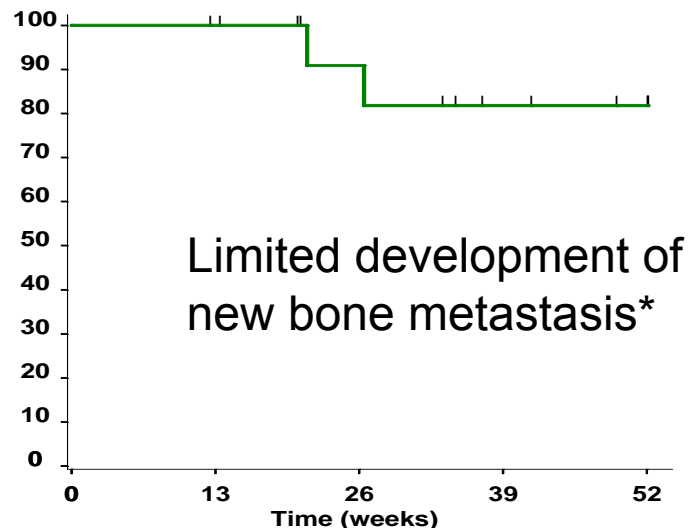
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TASQ - Phase Ib Efficacy in HRPC

No progression (%)



No progression (%)



- Patients with and without bone metastases
- 32 patients evaluated for safety
- 23 patients evaluated for efficacy (PSA)
- 15 patients evaluated with bone scan

- Phase Ib data strongly supported development in hormone refractory prostate cancer patients with metastatic disease

* 19.3 weeks (median)

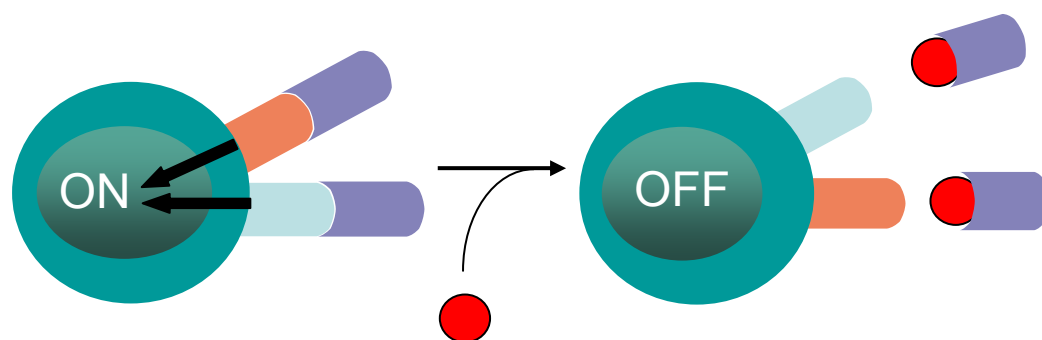
Benchmark refs: *Small et al, J Clin Oncol 2006, Carducci et al, J Clin Oncol 2003*

TASQ – Ongoing Phase II Study



- 200 patients with asymptomatic metastatic hormone refractory prostate cancer
- Performed at centers in the US, Canada and Sweden
- 2:1 randomization 1.0 mg TASQ vs placebo
- Primary endpoint: Proportion of patients with disease progression at 6 months
- Placebo patients can cross over to TASQ after 6 months
- Fully recruited - Results late 2009/early 2010

The ISI Project - Inhibition of S100 Interactions

- S100A9 interacts with the pro-inflammatory RAGE and TLR4 receptors
- Lead compounds blocks S100A9 – RAGE/TLR4 interactions



 = RAGE
 = TLR4

 = S100A9
 = lead compound

RAGE

- Type I diabetes
- MS
- Alloimmune responses
- Atherosclerosis
- Cancer

TLR4

- Acute infection - pathogen clearance
- Sustained responses to microbial antigens
- Autoimmune disease – endogenous ligands or neoepitopes
- Cancer

Active Biotech Projected News Flow

- TASQ - Controlled Phase II data late 2009/early 2010
- 57-57 - Results Exploratory study 2010
- RhuDex™ - Phase IIb study start in RA patients
- ISI - Patent filing and CD selection 2010
- ANYARA - Phase III overall survival data late 2010/early 2011
- Laquinimod - Phase III data followed by launch late 2011

Company Overview & Financial Highlights



Capital Structure



Symbol

ACTI.ST

Exchange

**NASDAQ OMX Nordic Exchange
in Stockholm**

Shares Outstanding

64,052,238

Price

SEK 53.00 (as of August 31, 2009)
\$ 7.41

Market Capitalization

SEK 3,395 M (as of August 31, 2009)
~\$ 475 M

* 1 \$ = 7.15 SEK

Commercial Development and Marketing Agreements

Laquinimod and Teva

- Teva has global exclusive rights to develop, register, manufacture and commercialize laquinimod since 2004
- Active Biotech retains commercial rights to Nordic/Baltic market
- 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

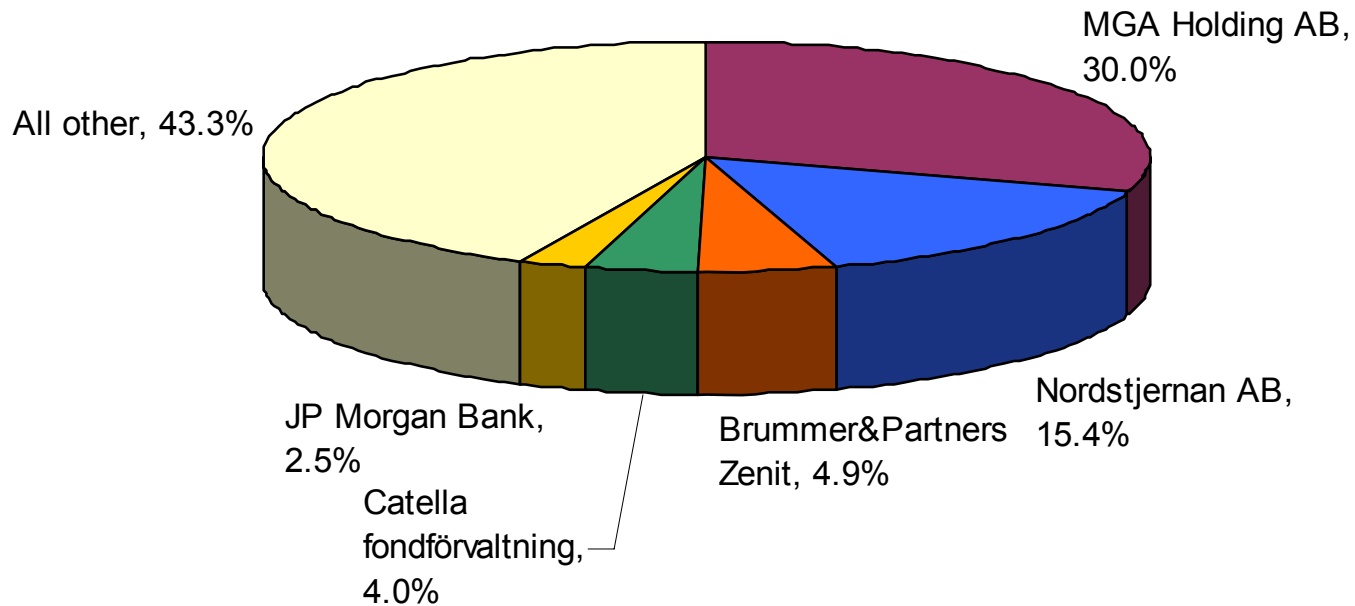
RhuDex™ and MediGene

- MediGene has global exclusive rights to develop, register, manufacture and commercialize RhuDex™ since 2002
- MediGene conducts and funds further clinical development of drug
- Active Biotech will receive pre-agreed milestone payments of GBP 6 million. In addition, low single digit royalties on future sales

Financials January – June 2009

- Net sales SEK 5.2 million (5.8)
- Operating loss SEK 118.5 million (loss: 104.7)
- Loss after tax SEK 118.6 million (loss: 99.3)
- Cash on hand SEK 259.5 million (June 30, 2009)

Ownership Structure – July 31, 2009





www.activebiotech.com

