

Active Biotech



Capital Markets Day - June 10, 2010

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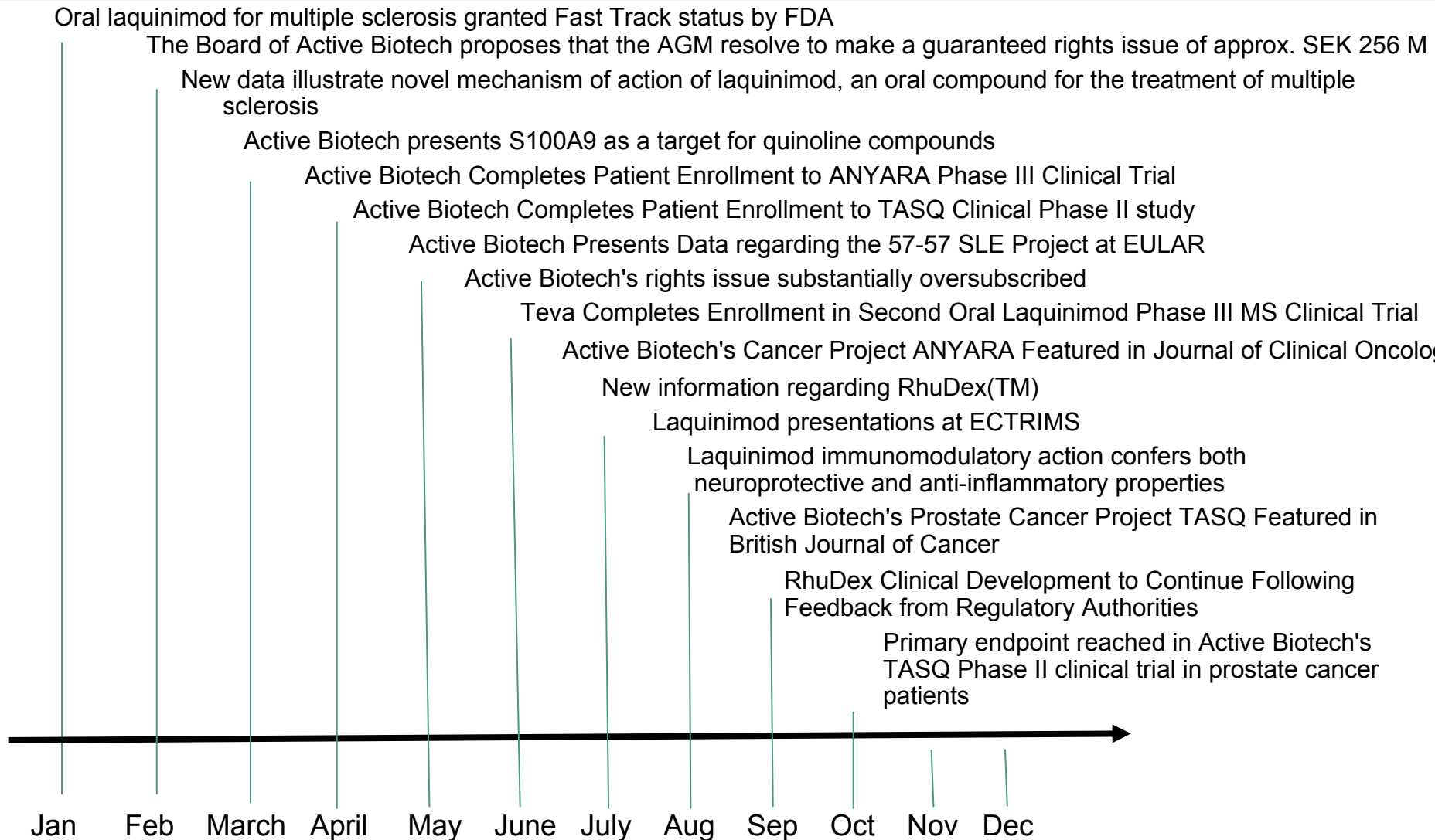
Capital Markets Day - Agenda

14:00 – 14:05	Welcome and introduction	Tomas Leanderson
14:05 – 14:40	Project portfolio	Tomas Leanderson
14:40 – 14.45	Q & A	
14:45 – 15:25	TASQ Phase II	Göran Forsberg
15:25 – 15:35	Q & A	
15:35 – 15:45	TASQ Phase III outline	Tomas Leanderson
15:45 – 15:55	Active Biotech going forward	Tomas Leanderson
15:55 – 16:00	Q & A	

Welcome and introduction



The year that passed - 2009



The year that passed - 2010

Teva acquires marketing rights for oral laquinimod in the Nordic and Baltic regions

Exploratory data presented for Active Biotech's ANYARA project

Active Biotech raises SEK 149 million through a directed share issue

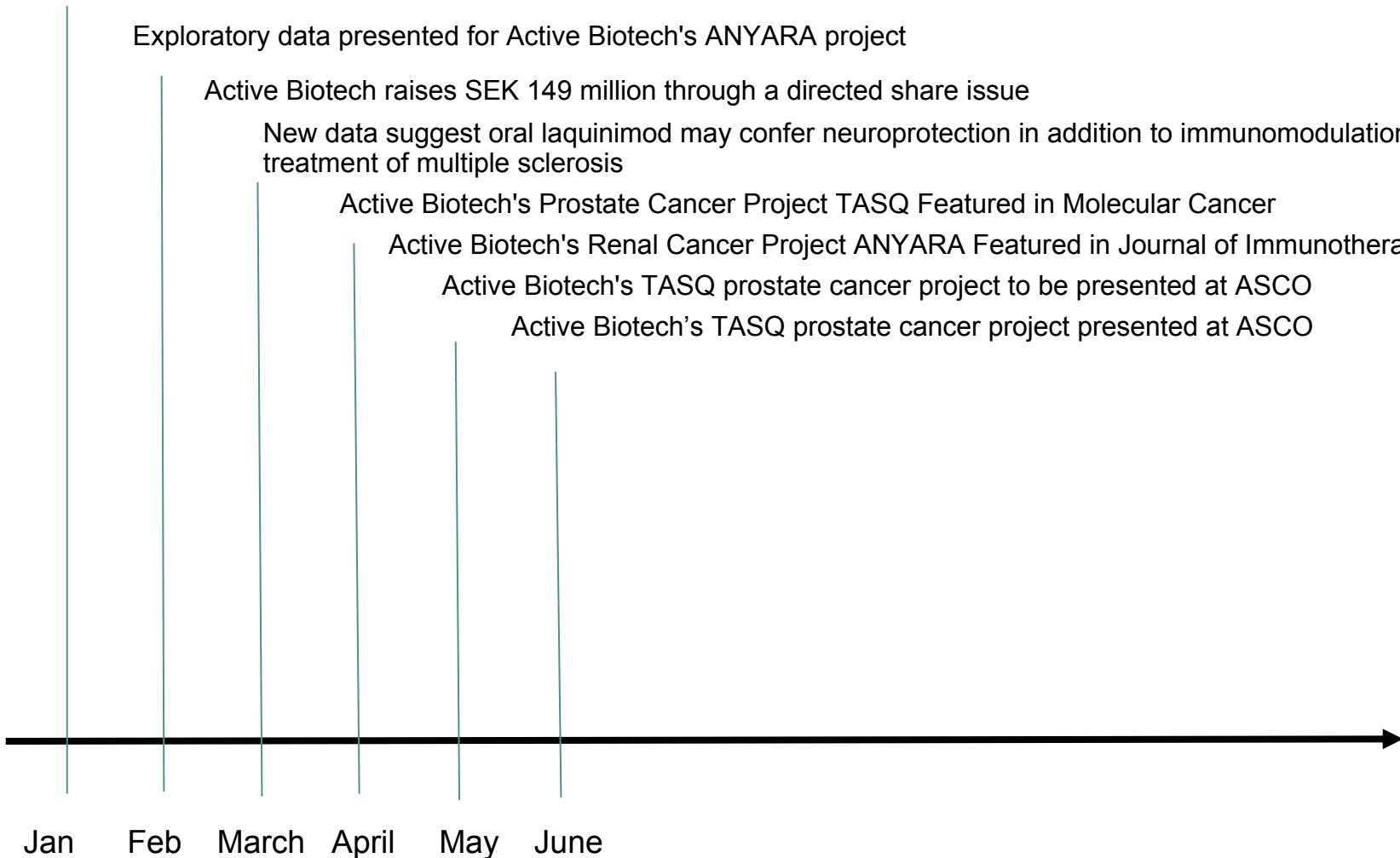
New data suggest oral laquinimod may confer neuroprotection in addition to immunomodulation in the treatment of multiple sclerosis

Active Biotech's Prostate Cancer Project TASQ Featured in Molecular Cancer

Active Biotech's Renal Cancer Project ANYARA Featured in Journal of Immunotherapy

Active Biotech's TASQ prostate cancer project to be presented at ASCO

Active Biotech's TASQ prostate cancer project presented at ASCO



Share development since Jan 2009



Symbol

ACTI.ST

Exchange

**NASDAQ OMX Nordic
Exchange in Stockholm**

Shares Outstanding

65,670,925

Price

**SEK 118.50 \$14.81
(as of June 8, 2010)**

Market Capitalization

**SEK 7,782 M
(as of June 8, 2010)
~\$ 973 MUSD**

Financials



Financials January – March 2010

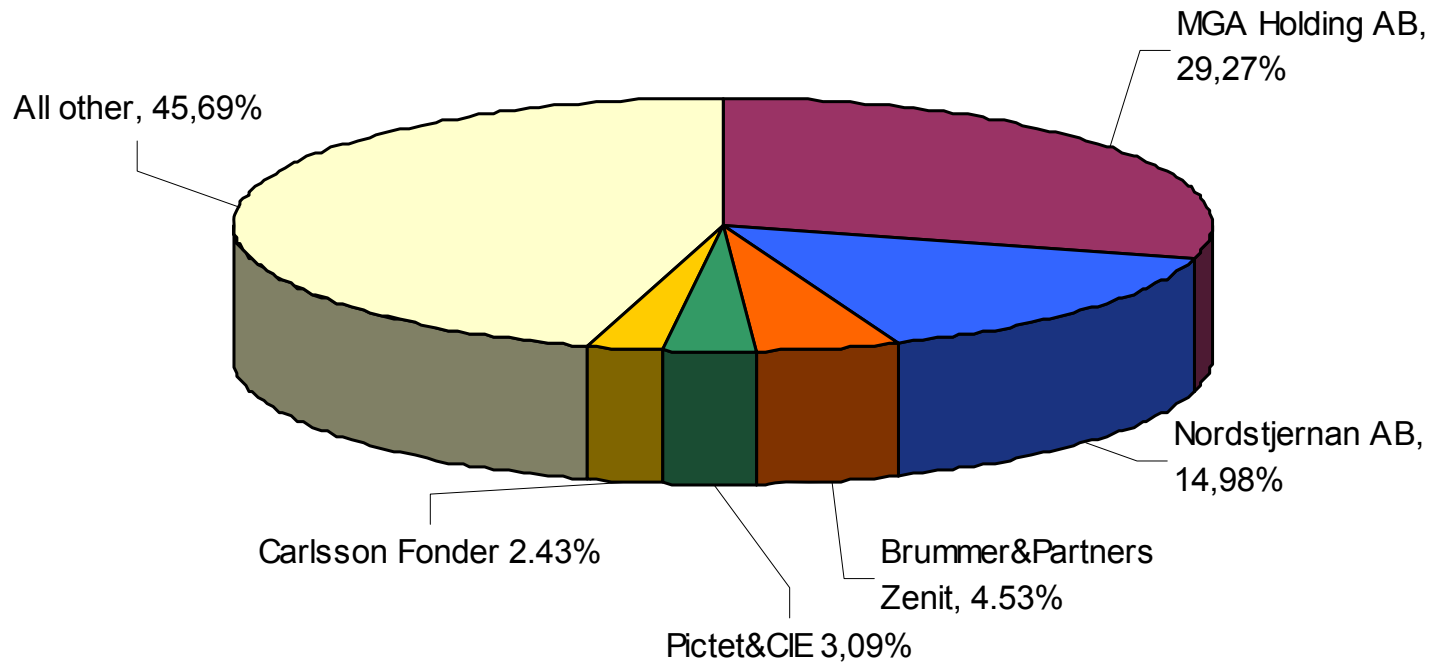
	MSEK	MUSD
Net sales	SEK 2.8 (2.2)	0.4 (0.3)
Operating loss	51.0 (63.7)	6.6 (8.2)
Loss after tax	53.5 (62.2)	6.9 (8.0)

Cash on hand March 31, 2010 (excluding directed share issue on April 1, 2010)

- SEK 110.6 million (MUSD 14.3)

Directed share issue on April 1, 2010 to Sectoral Asset Management, a specialized investor in the healthcare sector. 1 418 000 shares, subscription price of SEK 105 per share, total proceeds appr. SEK 149 million (MUSD 19.2).

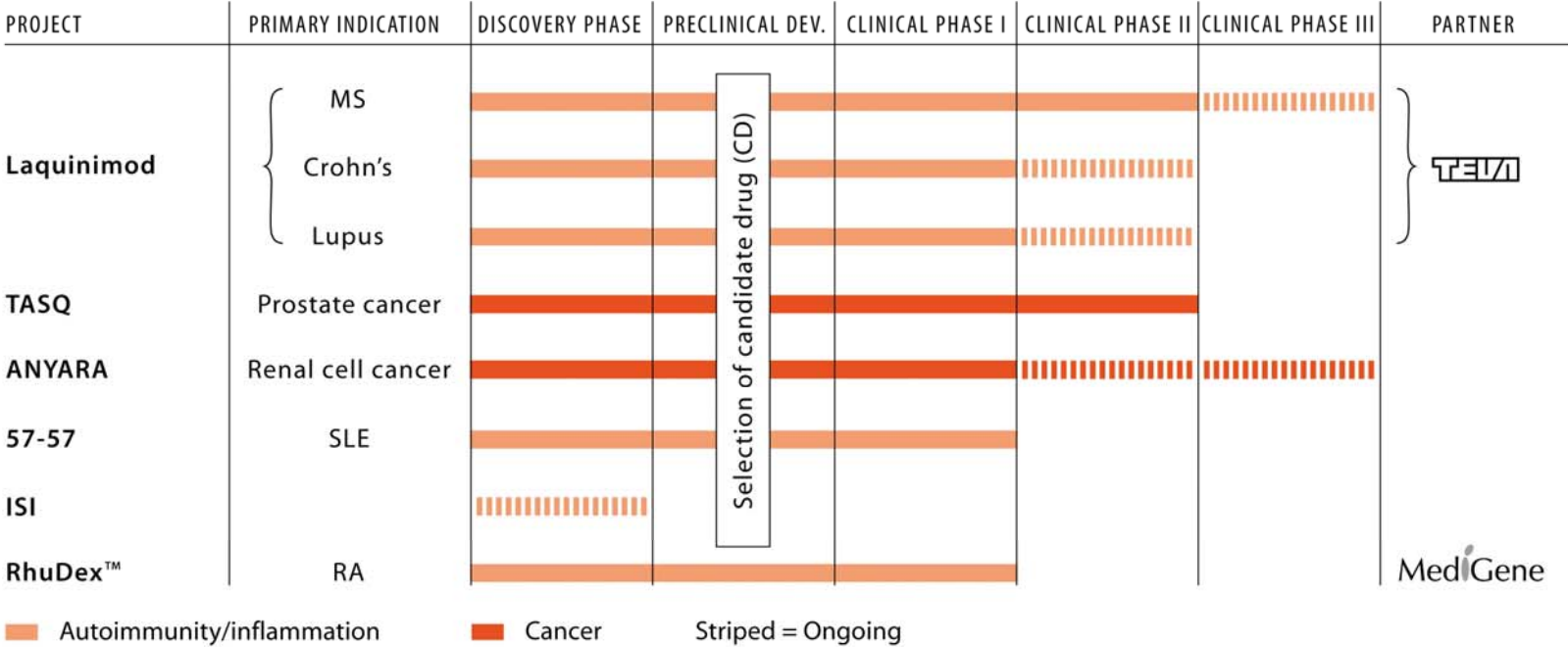
Active Biotech shareholding – May 31, 2010



R&D projects



Active Biotech Pipeline



...focused on high-potential market opportunities in autoimmunity and cancer

Indication	Market size	Market value
Multiple sclerosis (“MS”)	Affects over 1 million people every year ⁽¹⁾	~ USD 10 billion ⁽¹⁾ (total market for MS pharmaceuticals)
Systemic lupus erythematosus (“SLE”)	Estimated 1 million people in Europe and the US are affected by SLE ⁽²⁾	~ USD 6 billion ⁽²⁾
Rheumatoid arthritis (“RA”)	Affects over 2 million people in the US alone ⁽¹⁾	~ USD 6 billion ⁽¹⁾
Renal cell cancer (“RCC”)	Appr. 200,000 people diagnosed annually whereof > 35000 in the US ⁽¹⁾	~ USD 1 billion ⁽³⁾
Prostate cancer	>400,000 new cases diagnosed annually, whereof > 260 000 in the US ⁽⁴⁾	> USD 5.4 billion ⁽⁵⁾

(1) Therapeutics Categories Outlook, Cowen & Co., 2010

(2) Company estimate

(3) Companies reported sales

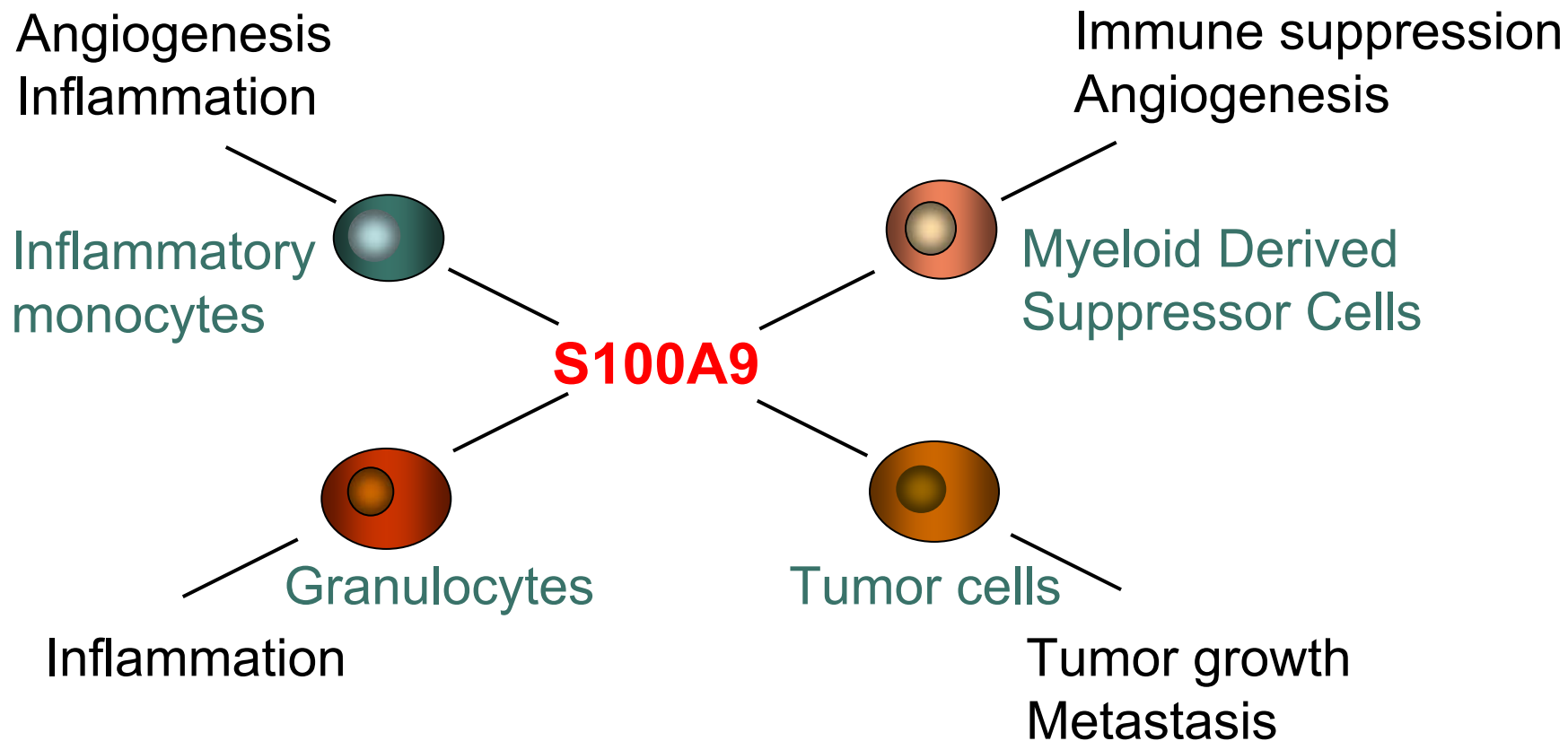
(4) Datamonitor, 7 major markets forecast 2009

(5) Global Data 2010

S100A9 as a target for autoimmune/ inflammatory diseases and cancer

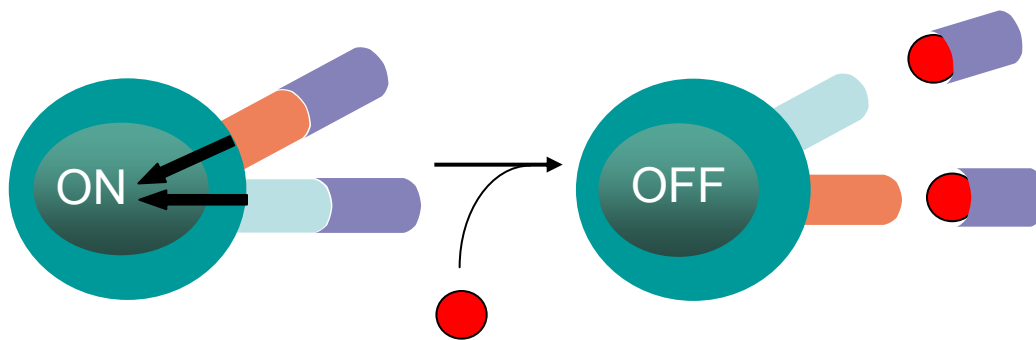
Quinolines first in class S100A9 binders

(PLoS Biology April 2009, Vol 7, Issue 4, p. 800-812)





The ISI Project - Inhibition of S100 Interactions

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



 = RAGE
 = TLR4

 = S100A9
 = lead compound

RAGE

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

TLR4

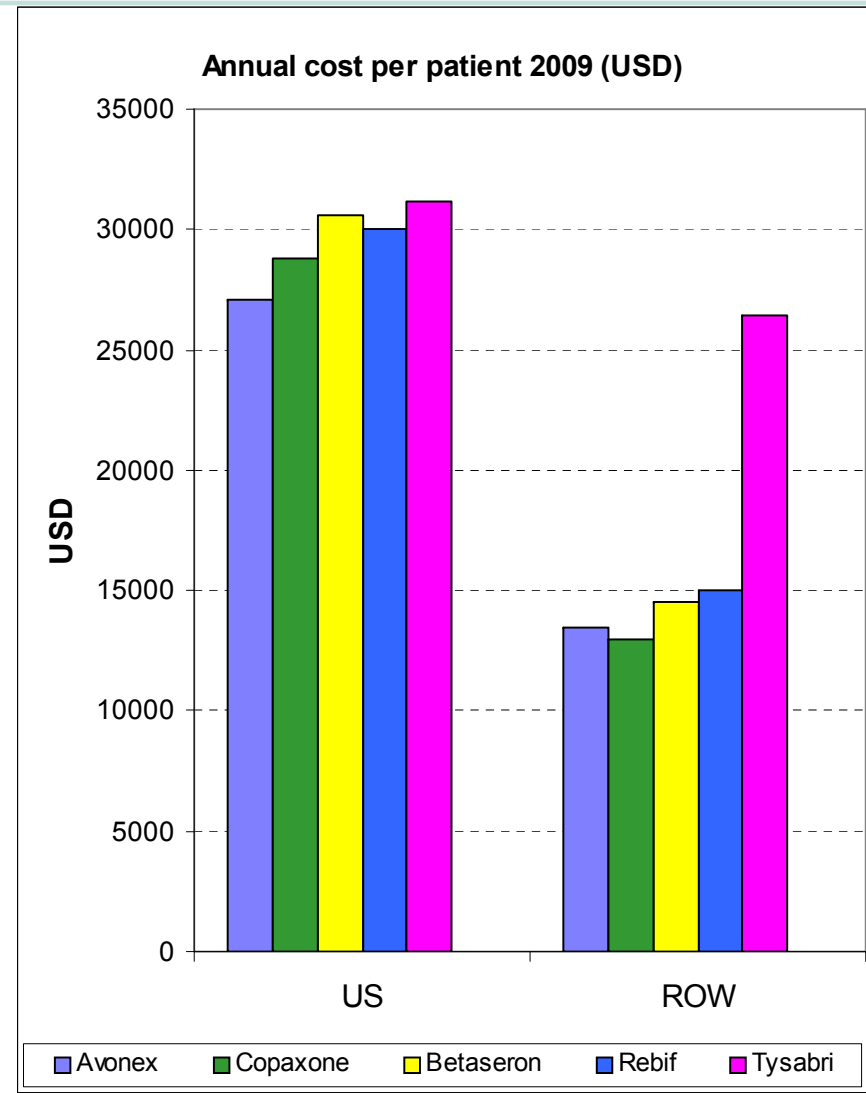
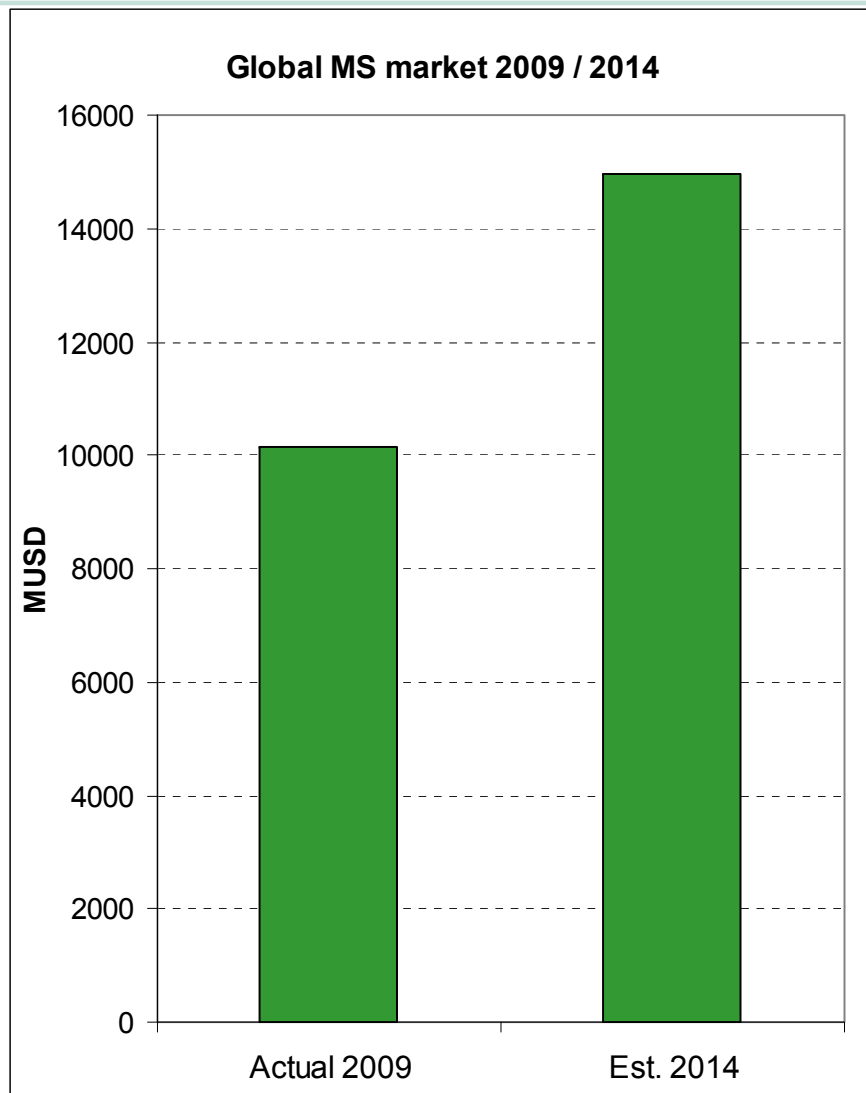
- Acute infection - pathogen clearance
- Sustained responses to microbial antigens
- Autoimmune disease – endogenous ligands or neoepitopes
- Cancer

The laquinimod project

Market opportunity and positioning of laquinimod

- MS is a chronic disease, often with insidious progression, affecting the CNS
- Primarily affects young and middle-aged people, often first appearing between 20 and 50 years old with twice as many women affected as men
- Total market for registered MS drugs amounted to USD 10 billion (2009 data)
 - Of the US's existing MS patients, about 80 percent are assumed to be under treatment
 - The figure for Europe is lower (about 50 percent)
- Oral administration a significant benefit over existing therapies
- Unlike most other oral products in development, laquinimod does not display immune suppression - may have important safety advantages

MS Market and Competition



MS Market – Existing Products

Drug	Company	Administration	Sales MUSD 2009	% of total
Copaxone	Teva	injectable	2826	28%
Avonex	Biogen Idec	injectable	2323	23%
Rebif	Merck-Serono	injectable	2143	21%
Betaseron	Bayer	injectable	1800	18%
Tysabri	Biogen Idec	injectable	1058	10%
Total sales			10150	100%
Projected sales 2014			appr 15000	

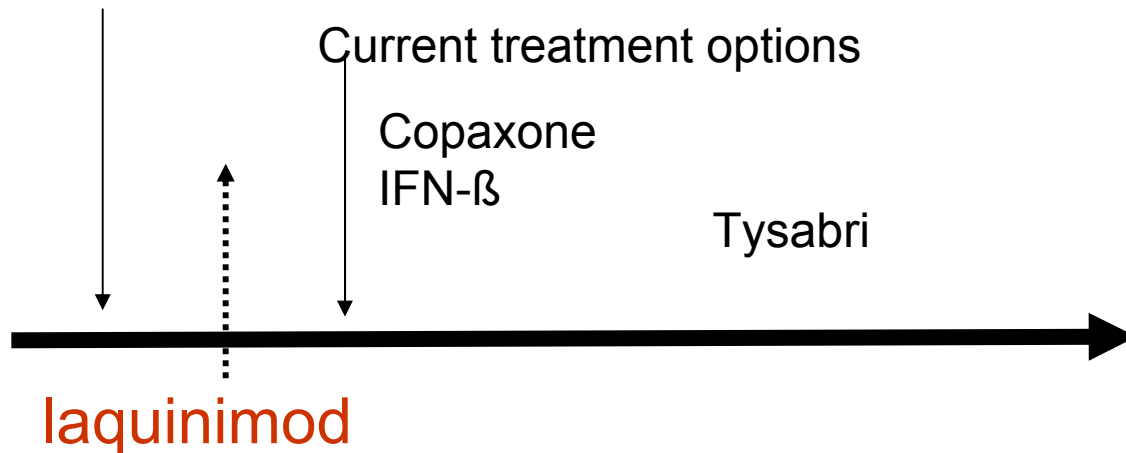
Source: Cowen Therapeutic Categories Outlook March 2010

Competition – MS drugs under development

Drug	Company	Filing/Launch	Comment
Gilenia®/Fingolimod	Novartis	Filed 2009 (EMA/FDA) Launch planned for 2010	FDA review extended to 09/2010. Advisory Committee Meeting June 10, 2010 Two ongoing phase III studies
Cladribine/Mylinax	Merck-Serono	Filed 2009 (EMA/FDA) Re-submitted June 2010 (FDA) Launch planned for 2011	Applications still pending Two ongoing phase III studies
Panaclar/BG-12	Biogen Idec	Filing/Launch 2011/2012	Two ongoing phase III studies First phase III data 2011
Teriflunomide	Sanofi-Aventis	Filing/Launch 2012/2013	Five ongoing phase III studies First phase III data 2010
Campath®/ Alemtuzumab	Genzyme/ Bayer Schering	Filing/Launch 2012	Two ongoing phase III studies First phase III results 2011
Zenapax®/Daclizumab	Biogen Idec/ Abbott	Filing/Launch 2014	Ongoing pivotal phase IIb and phase III. Results 2011 and 2013
Ocrelizumab	Roche/ Biogen Idec	Filing/Launch 2015	One ongoing phase II study (results 2011). Tested for RA – halted 2010

Active Biotech - laquinimod

Diagnosis



- Efficacy in Phase II¹⁾²⁾ clinical trials;
 - reduced MRI disease activity by 60 percent¹⁾ vs placebo in RRMS patients
 - reduction of annual relapse rates, number of relapse-free patients
 - favorable safety profile

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

2) Polman et al, *Neurology* 2005;64:987-991

Laquinimod – ongoing Phase III RRMS trials



Objective	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®
Patients	1000 RRMS patients (2x500)	1200 RRMS patients (3x400)
Countries	United States, Canada, Europe and Israel	United States, Europe, Israel and South Africa
Treatment Duration	24 Months	24 Months
Dose	Daily oral LAQ 0,6 mg & Placebo	Daily oral LAQ 0,6 mg & Placebo Weekly im Avonex® 30 µg
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 Nov 2008	Fully recruited June 2009

Laquinimod Clinical Program in New Indications

Indication	Crohn's disease (Phase II)	Lupus Nephritis (Phase II)	Lupus Arthritis (Phase II)
Objective	Safety and effect of daily oral laquinimod	Safety and effect of daily oral laquinimod	Safety and effect of daily oral laquinimod
Patients	~180 patients with active moderate to severe Crohn's disease	~45 active Lupus Nephritis patients	~90 active Lupus Arthritis patients
Countries	Europe, Israel and South Africa (45 sites)	United States, Canada, France, Russia, UK (28 sites)	United States, Canada (25 sites)
Treatment Duration	8 weeks	24 weeks	12 weeks
Dose	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
Primary Endpoint	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
Status	Recruiting	Study start June 2010	Study start July 2010

Laquinimod Commercial Development and Marketing Agreement

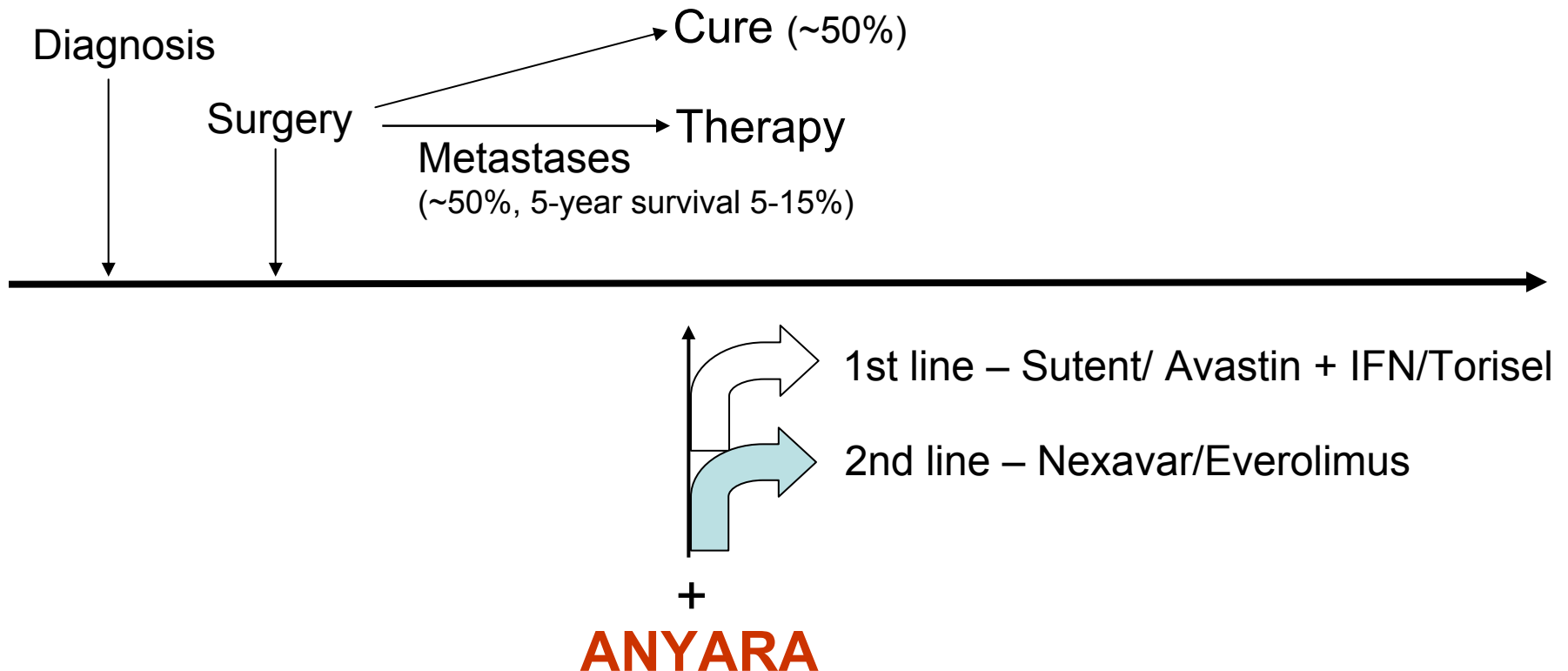
Teva Pharmaceutical Industries

- Teva has global exclusive rights to develop, register, manufacture and commercialize laquinimod since 2004
- Active Biotech retained 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
- New agreement February 2010 including the Nordic and Baltic regions previously held by Active Biotech
 - substantially higher royalty rate on sales in these territories compared to the royalty rate signed in 2004 for ROW sales

TASQ: Delay tumor progression

- **Primary endpoint** met in **Phase II** controlled clinical trial in prostate cancer December 2009
- General mechanism; not restricted to prostate cancer
- Small molecule – **one capsule a day** dosing
- Anti-angiogenic activity, **S100A9 one molecular target**

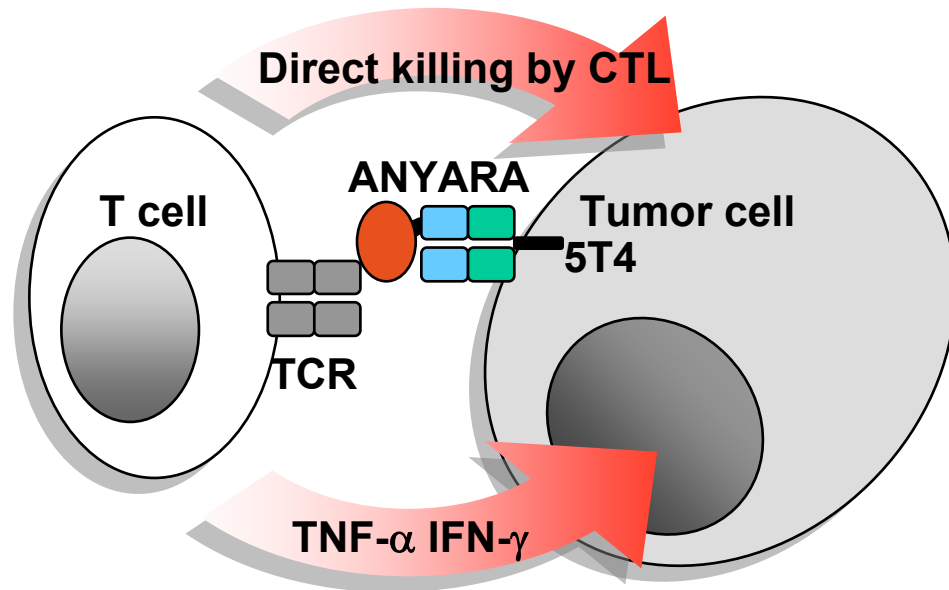
ANYARA in Renal Cell Carcinoma



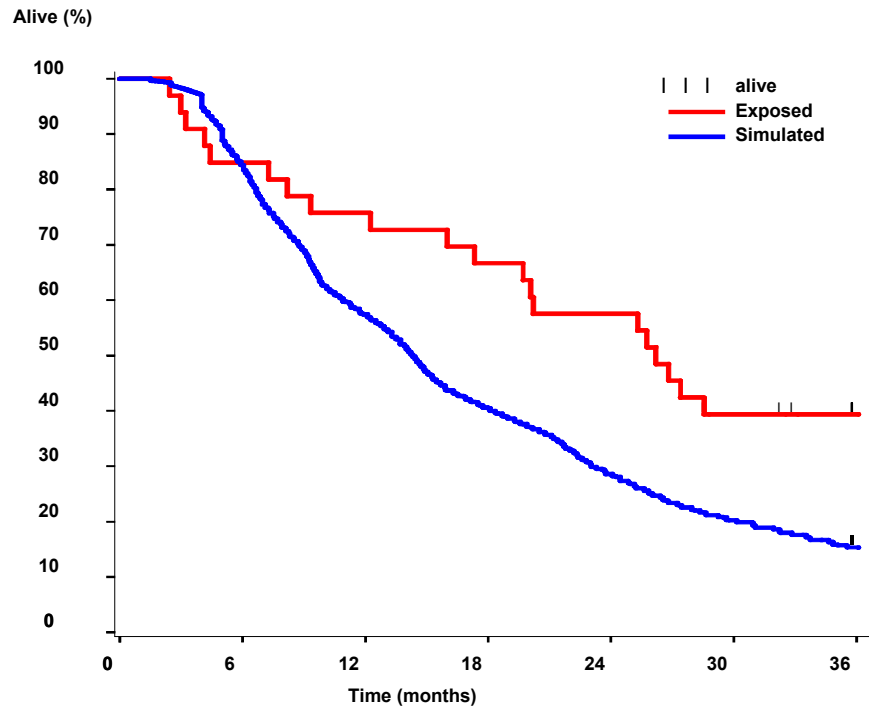
ANYARA: Tumor Targeted Superantigen (TTS)

Therapeutic principle

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



ANYARA - 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

Active Biotech - 57-57



57-57: Chronic Oral Treatment of SLE

- SLE is a heterogeneous autoimmune disorder with a **high medical need**
- 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

57-57 — Strategic options

Laquinimod in development for SLE

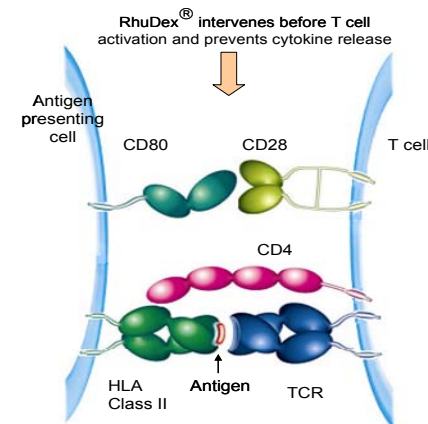
- Exploratory study ongoing
- Potential future options:
 - continue SLE development in selected regions
 - development in orphan indication
 - project closure

Active Biotech - RhuDex



RhuDex™ - Chronic Oral Treatment of RA

- Additional **Phase II** studies to start 2010/2011
- Clinical **Phase IIa** in RA patients concluded
- Small molecule **CD80 inhibitor** for rheumatoid arthritis (RA)
- Preclinical studies ongoing
- Licensed to MediGene AG 2002



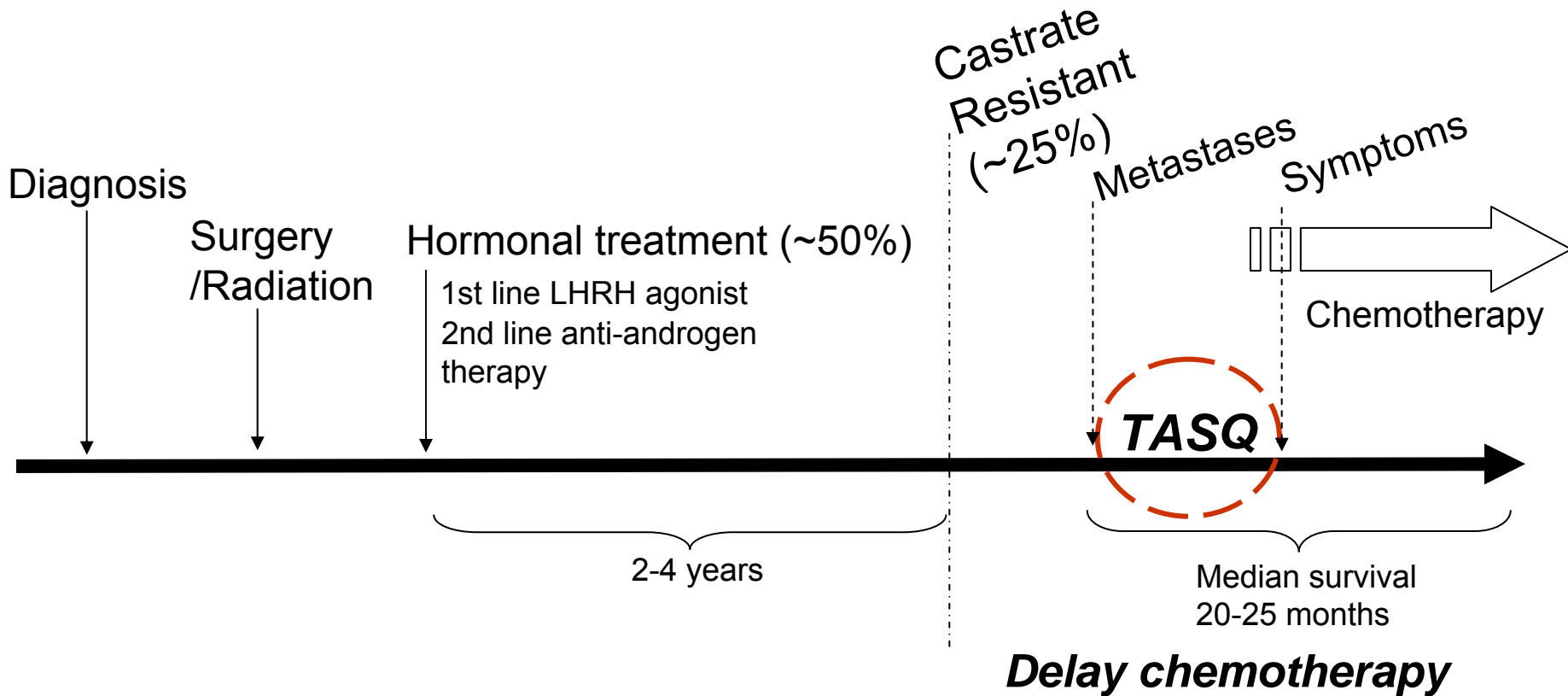
TASQ – Prostate Cancer Treatment



TASQ: Delay tumor progression

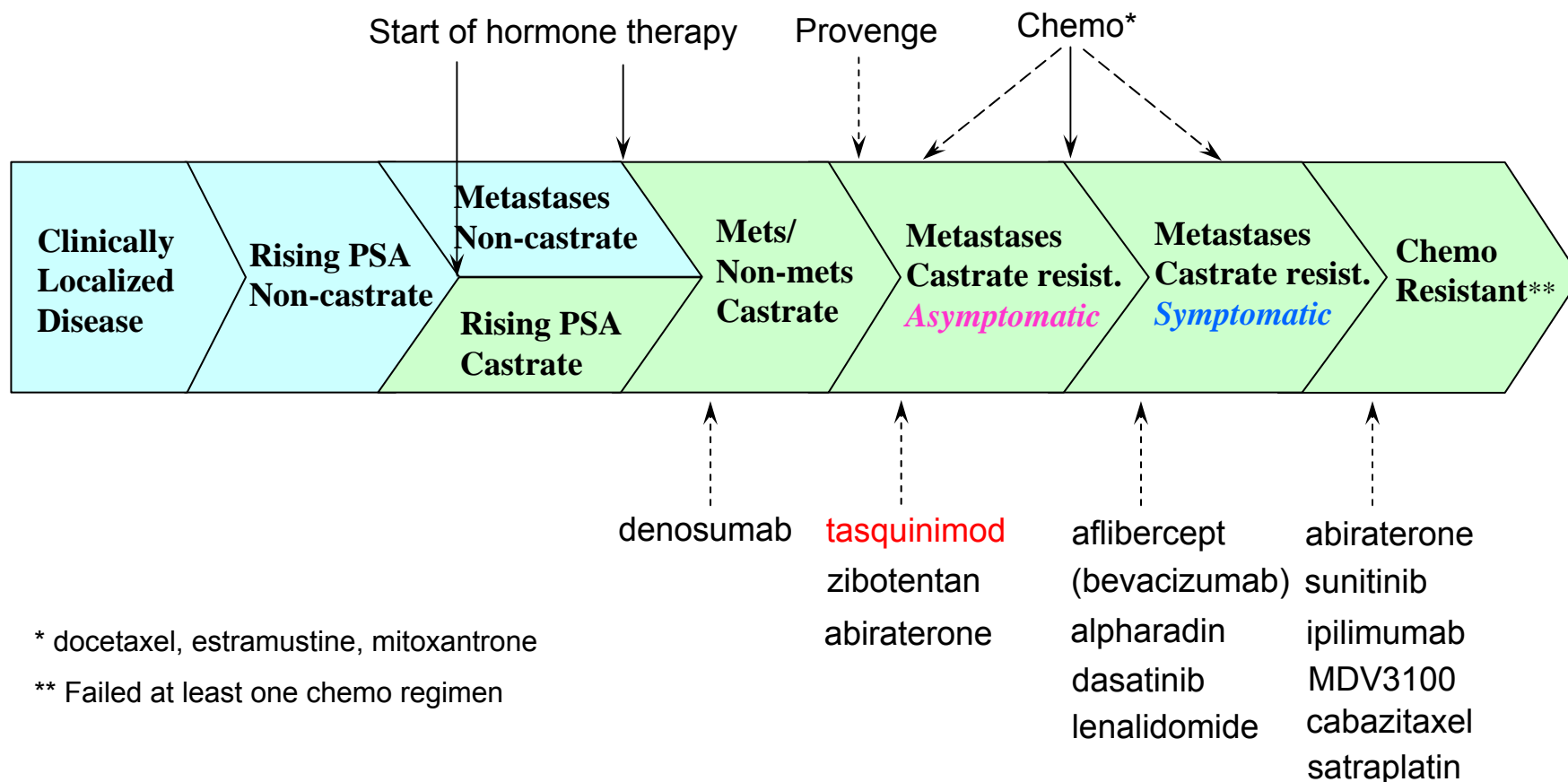
- Small molecule – one capsule a day dosing
- Anti-angiogenic activity

Active Biotech – TASQ Regulatory Strategy



- TASQ development currently focused on registration in asymptomatic metastatic CRPC
- Broader use envisaged

Emerging Treatments in Prostate Cancer



* docetaxel, estramustine, mitoxantrone

** Failed at least one chemo regimen

Sunday, June 6, 2010

11:45 AM A randomized, multicenter, international phase II study of tasquinimod in chemotherapy-naïve patients with metastatic castrate-resistant prostate cancer (CRPC). (Abstract #4510)

R. Pili, M. Häggman, W. M. Stadler, J. R. Gingrich, V. J. Assikis, A. Björk, G. Forsberg, M. A. Carducci, A. J. Armstrong

12:00 PM A randomized, double-blind, placebo-controlled phase III trial comparing docetaxel, prednisone, and placebo with docetaxel, prednisone, and bevacizumab in men with metastatic castration-resistant prostate cancer (mCRPC): Survival results of CALGB 90401. (Abstract #LBA4511)

W. K. Kelly, S. Halabi, M. A. Carducci, D. J. George, J. F. Mahoney, W. M. Stadler, M. J. Morris, P. W. Kantoff, J. P. Monk III, E. J. Small, Cancer and Leukemia Group B

Discussion

12:15 PM William L. Dahut, MD (Abstracts #4510–LBA4511)

National Cancer Institute

Angiogenic Targeting in Castration-resistant Prostate Cancer

Monday, June 7, 2010

7:30 - 9:00 AM

HIGHLIGHTS OF THE DAY

7:40 Prostate Cancer

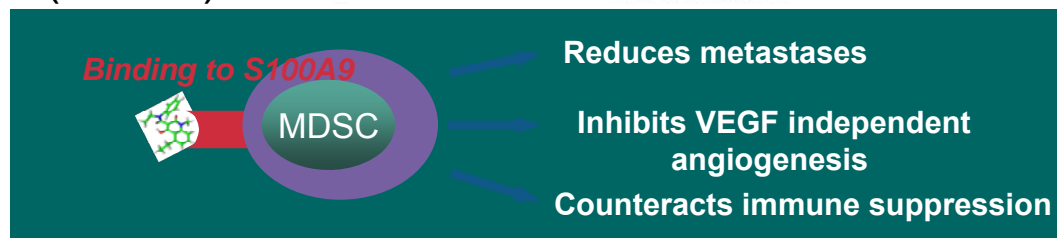
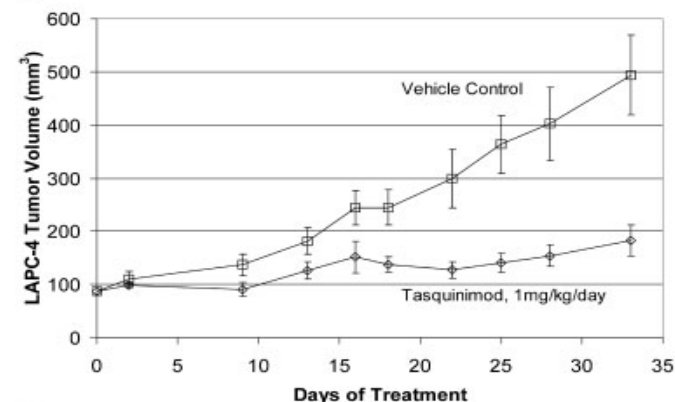
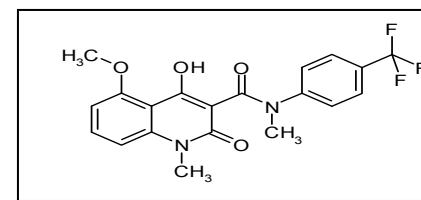
Nicholas J. Vogelzang

A randomized multicenter international Phase II study of tasquinimod in chemotherapy naïve patients with metastatic castrate-resistant prostate cancer (CRPC)

R. Pili, M. Häggman, W.M. Stadler, J.R. Gingrich, V. Assikis, A. Björk, G. Forsberg, M.A. Carducci, A.J. Armstrong

Tasquinimod (TASQ)

- Tasquinimod is a quinoline-3-carboxamide optimized for tumor therapy
- Inhibition of tumor growth in several prostate cancer models
- Antiangiogenesis effects in *in vitro* and *in vivo* assays
- Upregulates TSP-1, downregulates HIF-1 α and VEGF
- Tasquinimod binds to S100A9 (MRP14) on myeloid derived suppressor cells (MDSC)



Isaacs et al. *Prostate* 66, 1768-78, 2006

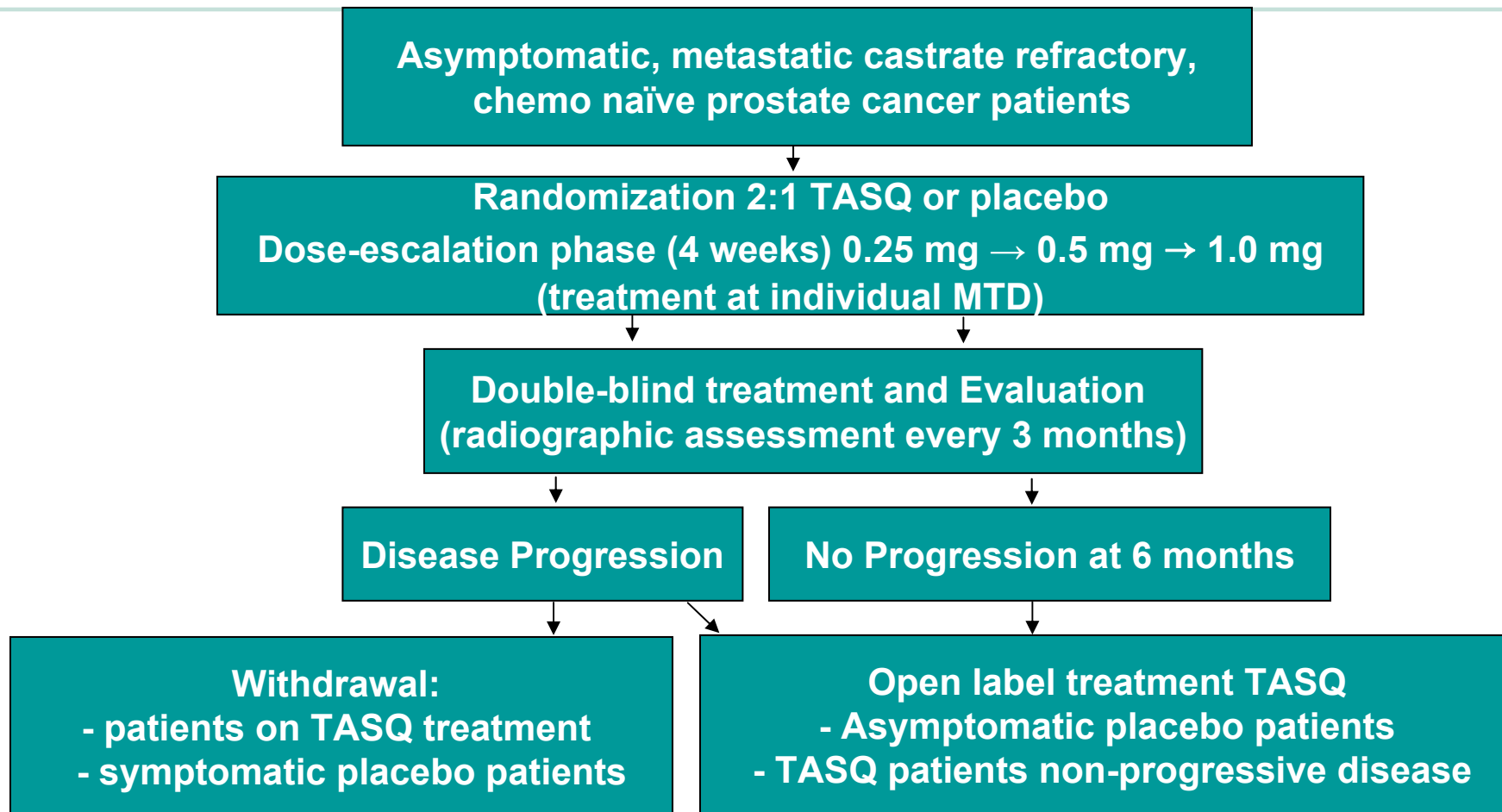
Olsson et al *Mol Cancer* 9:107, 2010

Björk et al *PLoS Biology*, April 2009 7:4, p. 800-812

Phase I in castrate resistant prostate cancer patients

- 32 patients with CRPC (with/without mets) evaluated for safety
- AEs were generally mild and transient; most frequent muscle and joint pain, and fatigue
- Asymptomatic transient changes in laboratory parameters such as increased amylase
- 2 DLT-s; hyperamylasemia and sinus tachycardia
- Recommended phase II dose: 1 mg daily preceded by dose escalation
- 3/15 patients at 0.5 mg/day developed new metastases (bimonthly bone scan evaluation, 8 months median follow-up)

Schematic Phase II Study Design



	TASQ	Placebo	Total
No. enrolled :	136	70	206
No. analyzed (ITT):	134	67	201
No. open label phase:	35	41	76

Main Inclusion & Exclusion Criteria

Main Inclusion Criteria

- Asymptomatic metastatic CRPC (VAS* pain score ≤ 3)
- Evidence of metastatic disease from CT or Bone scan
- Evidence of progressive disease after castration levels of testosterone
 - *Increased serum prostate-specific antigen (PSA) levels*
 - *Progression of soft tissue or bone disease*
- Karnofsky score 70-100

Main Exclusion Criteria

- Prior chemotherapy within 3 years
- Anticancer therapy (biologics or vaccines) last 6 months (bevacizumab not allowed)
- Concurrent use of other anti-cancer agents or treatments (stable doses of LHRH agonists, bicalutamide (e.g. Casodex) or other antiandrogens allowed)

* VAS = Visual analogue scale

Primary endpoint

Proportion of patients with disease progression (DP) at 6 months

(one or more of the following):

- Onset of tumor-related cancer pain
 - Narcotic analgesics or Radiation required for control of tumor-related pain
 - VAS [pain] rating >4 due to cancer pain on two consecutive ratings
- Measurable disease progression
 - RECIST
- Bone metastases
 - PCWG2* (2 or more skeletal lesions not consistent with tumor flare. DP at 3 months confirmed by second scan with at least one additional lesion observed in the confirmatory scan.)
- Need for radiotherapy or surgery for pathological fracture or spinal cord compression

Baseline Demographics

Demographic Variable	TASQ (N = 134)	Placebo (N = 67)
Race:		
Black / African American	20 (15%)	2 (3%)
White / Caucasian	110 (82%)	63 (94%)
Other	4 (1%)	2 (3%)
Ethnicity:		
Hispanic / Latino	6 (4%)	2 (3%)
Not Hispanic / Latino	128 (96%)	65 (97%)
Mean age (range) (years):	72.3 (49-89)	73.2 (48-89)
Age groups:		
46–65	33 (25%)	13 (19%)
66–89	101 (75%)	54 (81%)
Mean Karnofsky performance score:	94.7	95.2
Median Gleason score	7	7
Median Serum PSA concentration (µg/L)	29	19.2
Median PSA doubling time (months)	4.2	5.0

PCWG2 Prognostic groups

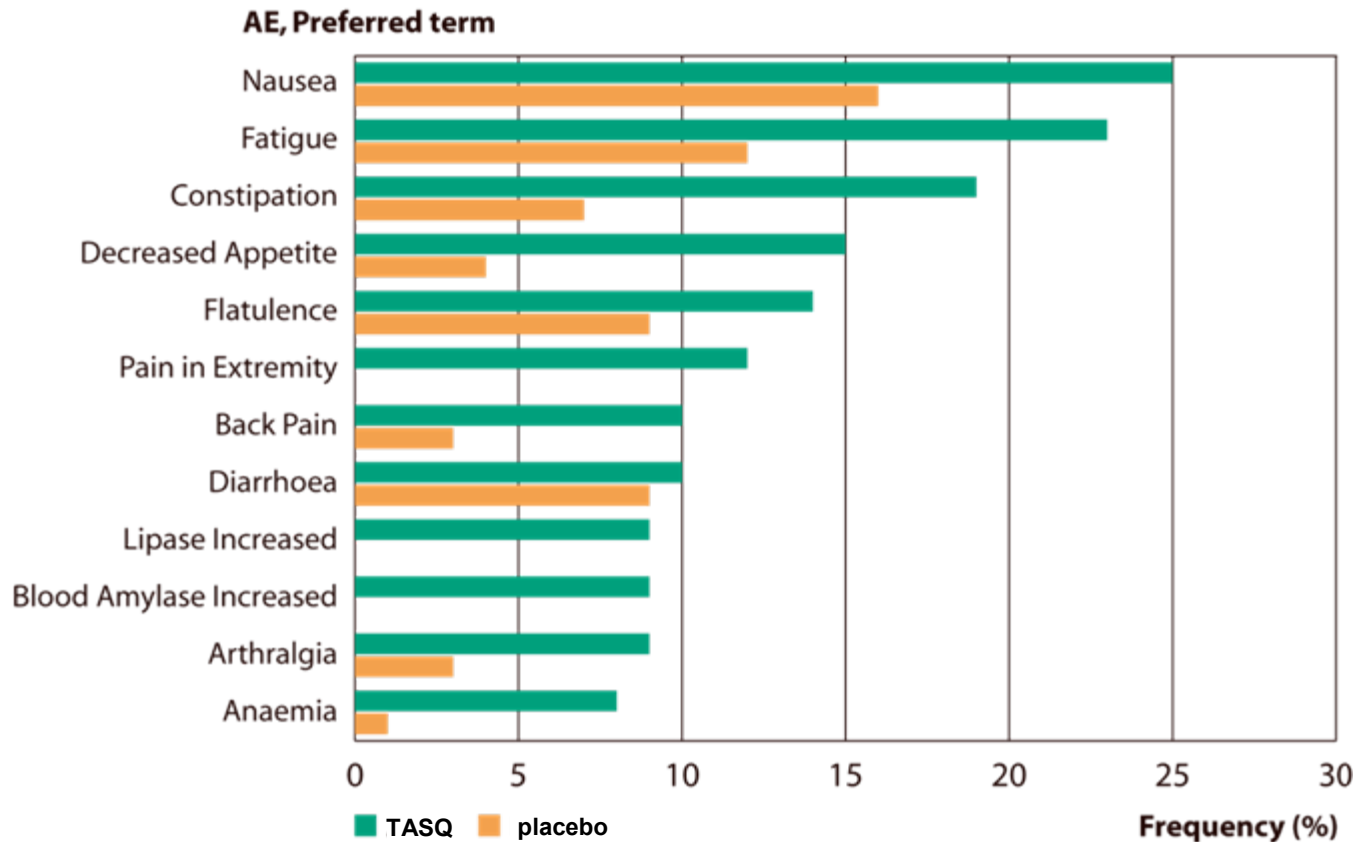
PCWG2 - Prostate Clinical trials Working Group 2 –
New standard criteria for evaluation of clinical trials

PCWG2 Prognostic Groups	TASQ (N = 134)	Placebo (N = 67)
Visceral (lung, liver) metastases ^a Worst prognosis	32 (24%)	10 (15%)
Bone metastases ^b Intermediate	92 (69%)	44 (66%)
Lymph node only Best prognosis	9 (7%)	12 (18%)
No metastases	1 (1%)	1 (1%)

^a) Including patients both with and without bone or lymph node lesions

^b) Including patients with lymph node, but not visceral lesions at baseline

Most common related adverse events



- Total number of related AEs; TASQ 534, placebo 135
 - Total number of SAEs; TASQ 77, placebo 12
 - Majority of AEs grade 1 or 2

Grade 3-5 toxicities during double-blind phase

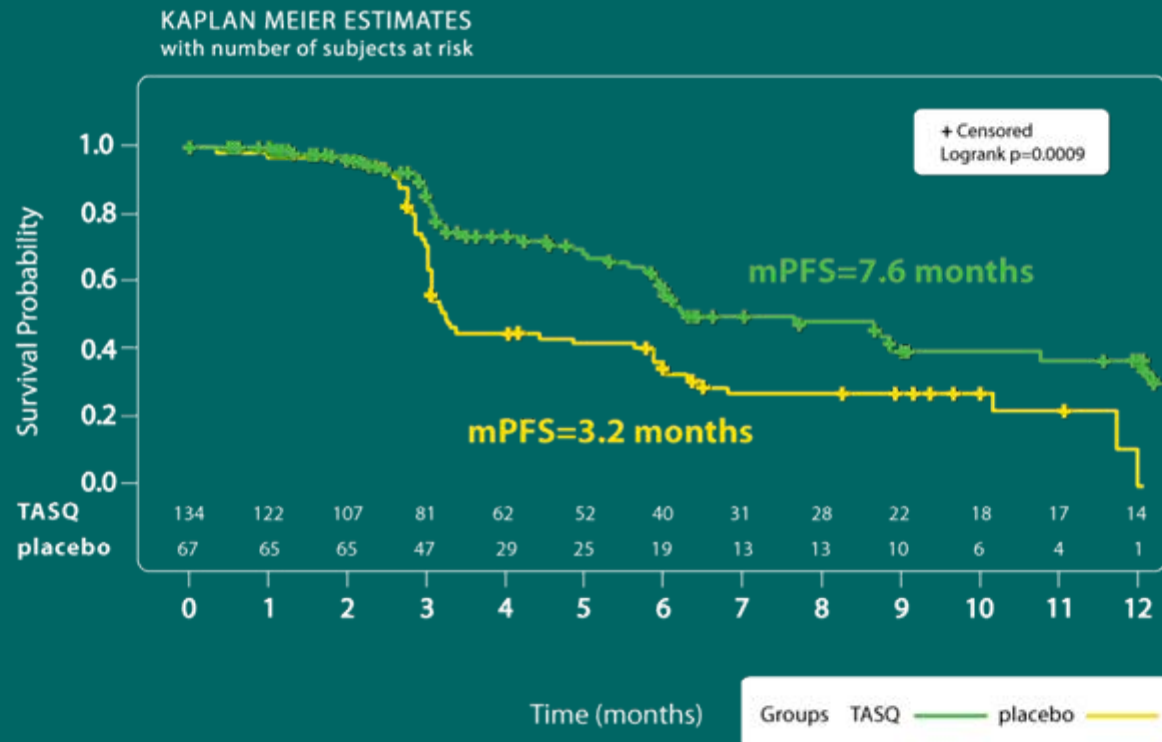
	TASQ (N = 134)	Placebo (N =67)
Investigations	10%	0%
<i>Increased lipase or amylase</i>	6 %	0%
Musculoskeletal And Connective Tissue Disorders	9%	3%
<i>Muscular weakness</i>	4%	0%
<i>Pain (eg muscle or joint)</i>	5%	1%
Gastrointestinal Disorders	7%	0%
<i>Nausea</i>	1%	0%
<i>Constipation</i>	1%	0%
Renal And Urinary Disorders	7%	3%
<i>Renal failure</i>	4%	1%
Vascular Disorders*	5%	0%
<i>Deep Vein Thrombosis</i>	4%	0%
Blood And Lymphatic System Disorders	4%	1%
<i>Anemia</i>	3%	1%
Cardiac Disorders*	4%	3%
<i>Cardiac failure</i>	1%	0%

* 1 MI recorded during blinded phase and 1 stroke during open label phase for TASQ treated patients

• 82 % of Grade 3-5 AEs were of Grade 3 46

Primary endpoint and median Progression Free Survival (mPFS)

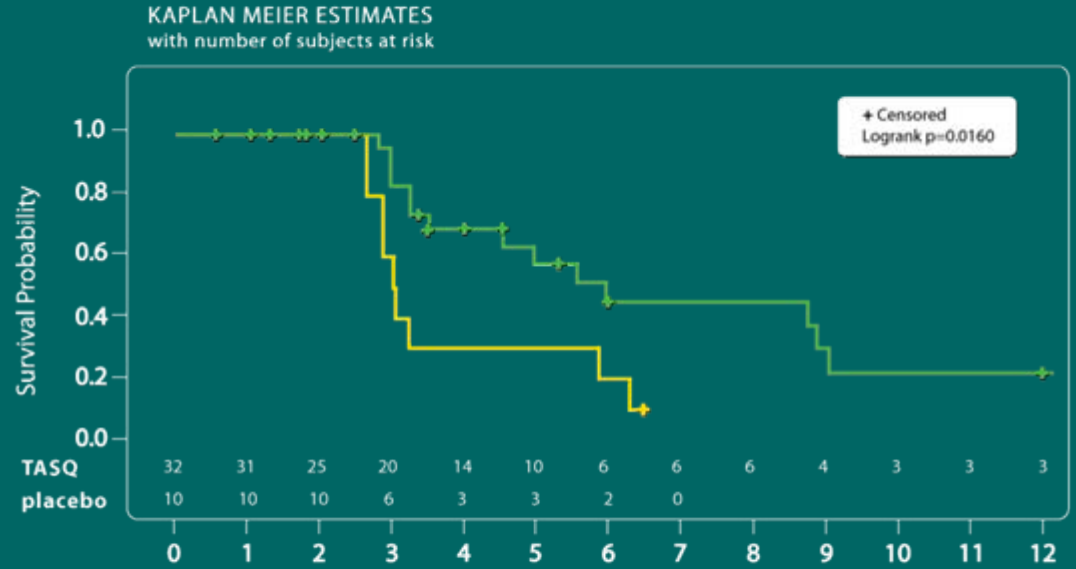
- 69 % (93/134) of TASQ treated patients vs 34 % (23/67) of placebo treated patients had not progressed at 6 months ($p < 0.0001$) (CMH). Relative risk for progression was 0.47
- Median PFS was 7.6 vs 3.2 months ($p = 0.0009$) and HR 0.52 (Logrank)



PFS PCWG2 Subgroup analysis

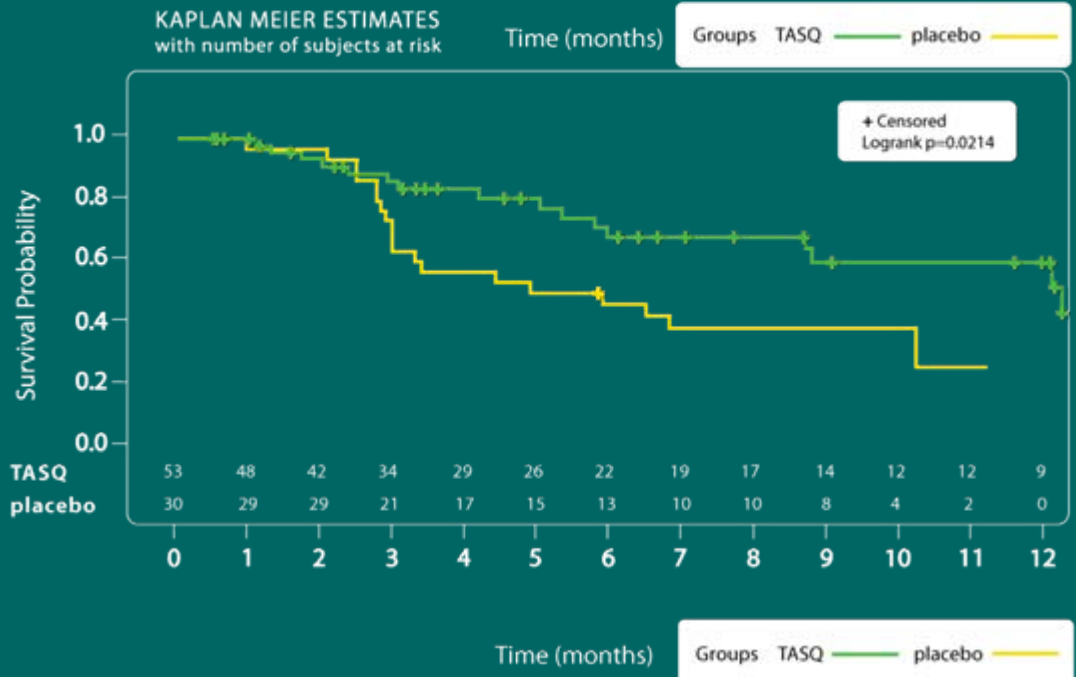
Visceral

mPFS 6.0 vs 3.0 months
 $p=0.0160$ HR=0.36



Bone only

mPFS 12.2 vs 5.4 months
 $p=0.0214$ HR=0.45



Central review of scans

- CT and bone scans from 143 patients fully analyzed
- Significant difference in median PFS remained
- The central review identified fewer events which led to lower p-value
- Results of central review (including local review of remaining patients); Median PFS 8.4 vs 3.8 months $p=0.0045$ HR=0.52



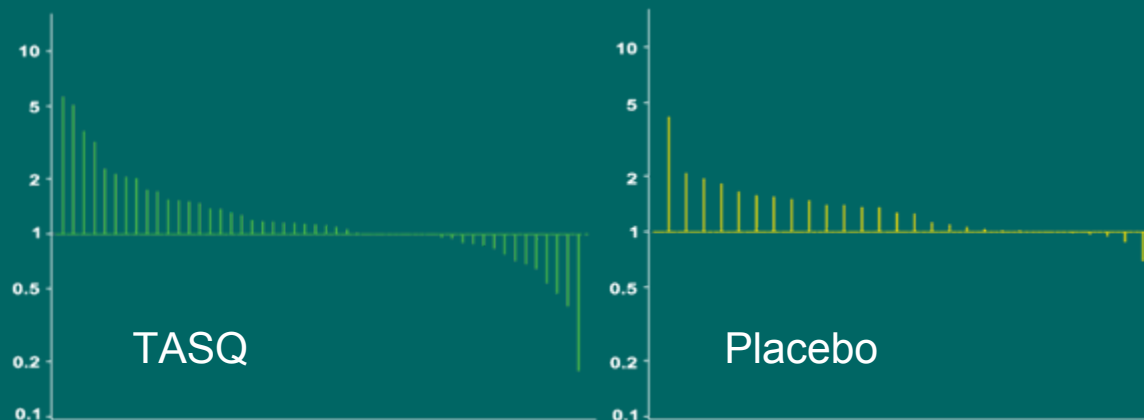
RECIST Evaluation

Response	TASQ (n=134)	Placebo (n=67)	Total (n=201)
Partial response*	4 (6%)	-	4 (4%)
Stable disease	36 (55%)	13 (31%)	49 (46%)
Progressive disease	25 (38%)	29 (69%)	54 (50%)
No measurable disease	69 (-)	25 (-)	94 (-)

* Including not confirmed responses

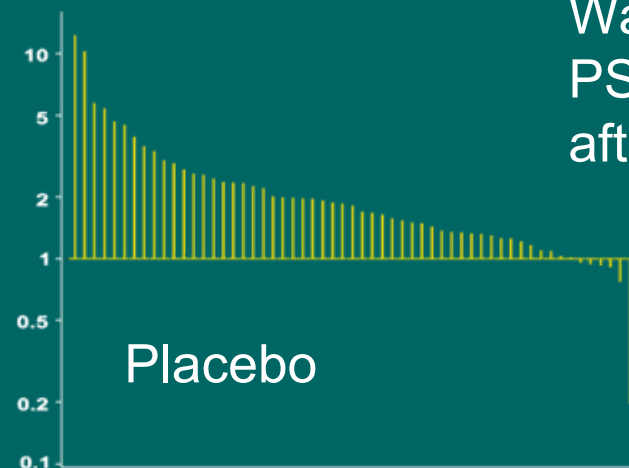
- Tumor shrinkage in 15/65 (23 %) TASQ and 5/42 (12 %) placebo

Waterfall plot
(target lesions)
relative change vs
baseline



PSA Analysis

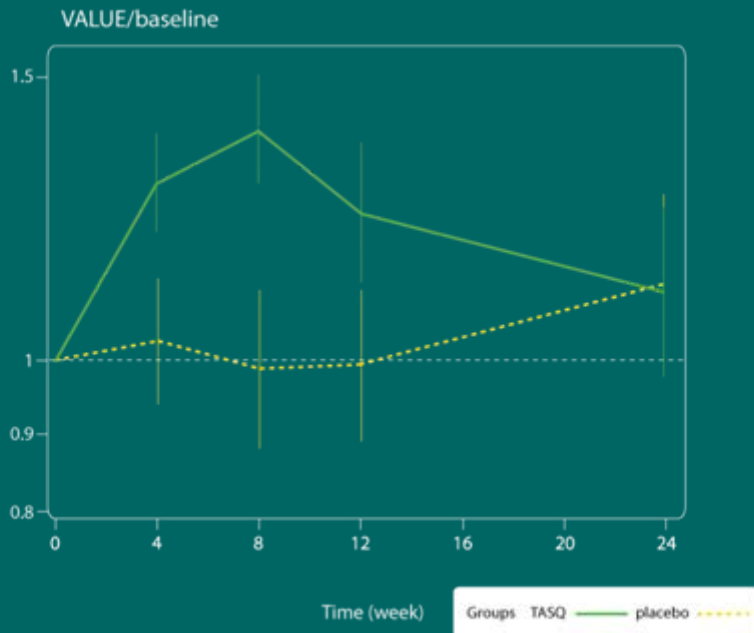
- TASQ treatment had a minor effect on PSA



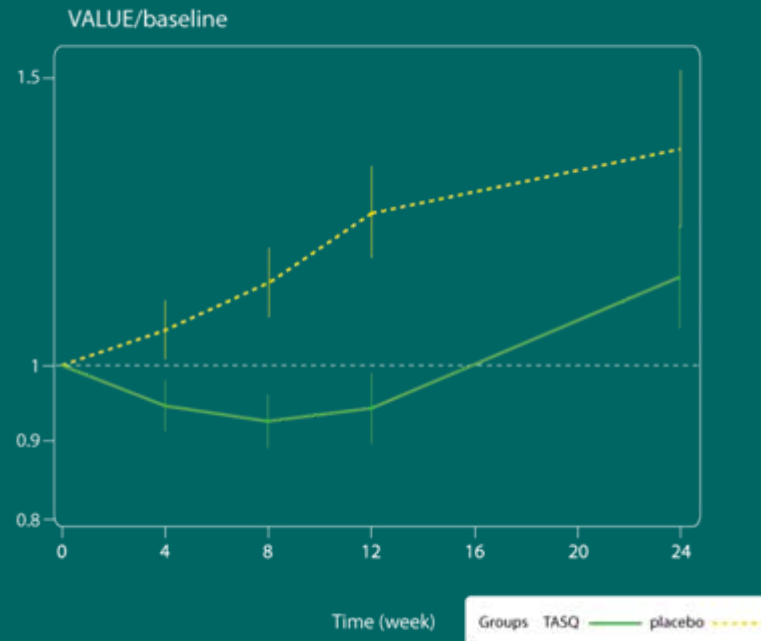
Waterfall plot
PSA change
after 3 months

Biomarker VEGF & Bone Alk Phos (BAP)

VEGF Total



Bone Alk Phos Total



- Baseline levels of VEGF (45.2 vs 40.2 pg/ml), Bone Alkaline Phosphatase (BAP) (20.9 vs 21.3 $\mu\text{g}/\text{ml}$) were similar in both groups
- VEGF levels increased with 23 % (TASQ) vs 1 % decrease (placebo) at 3 months
- BAP levels decrease 6 % (TASQ) vs 24 % increase (placebo) at 3 months

ASCO Summary

- Primary endpoint reached with 69 % (TASQ) vs 34 % (placebo) of patients progression free at 6 months and significant improvement in median PFS (7.6 vs 3.2 months)
- First controlled trial to demonstrate an improvement in median PFS using PCWG2-defined radiological criteria
- Using a dose escalation strategy, TASQ was generally well tolerated at individualized dose levels
- TASQ is a promising new agent for the treatment of advanced prostate cancer
- Phase III trial in the pre-docetaxel setting in preparation

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Kaiser Permanente Medical Group, Fontana

*Department of Defense - Prostate Cancer Clinical Trials Consortium

TASQ further development

- **Prostate cancer**
 - priority on initiating Phase III trial
- **Other indications**
 - general mechanism of action applicable to several cancer indications
 - promising preclinical data e.g. in breast cancer, colon cancer and melanoma
 - further development to be discussed with future partners

Proposed Phase III Trial

- **Coordinating investigator:** Michael A. Carducci, Johns Hopkins University, Baltimore, US
- **Placebo control:** Survival benefit appears to be independent of timing of docetaxel initiation
- **Progression criteria:** Radiological (CT or bone scan) progression as defined by RECIST1.1 and PCWG2
- **Primary endpoint:** Progression Free Survival (PFS)
- **Key secondary endpoints:** Overall survival and time to symptomatic progression

Proposed Phase III Trial

- Indication:** Asymptomatic, metastatic castrate resistant prostate cancer (CRPC)
- Study design:** Randomized, double-blind placebo-controlled
- Regions:** US/Canada, Europe, additional regions TBD
- No. of patients:** 1000-1200 (powered for overall survival)
- Study start:** early 2011
- Study duration:** 24-30 months

Trial currently discussed with regulatory authorities in the US and Europe.

Conclusions and closing remarks



Conclusions

- Exceptional last twelve months
- Continued strong news flow expected:
 - potential outlicensing of TASQ
 - initiation of Phase III development for TASQ (early 2011)
 - Phase III results from laquinimod studies (2011)
 - laquinimod regulatory filing (2011)
 - Phase III results from ANYARA studies (H1 2011)
 - CD selection for ISI (2011/2012)

Looking around the corner



Looking around the corner

1. Exit - Trade sale
2. Optimize earnings - Down-size to a royalty machine
3. Build “Active Biotech Turbo”

Looking around the corner

If 3. - What type of company?

- R&D?
- Sales & marketing?
- Selected territories?

The sky is the limit



Photo: Peter Korkala



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