

## Translating excellence in science into customer benefit

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- 9 litigation;
- 10 loss of key executives or other employees; and
- 11 adverse publicity and news coverage.

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## **Performance update**

**Strategy** 

**Update on oncology portfolio** 

**Summary** 



## **HY 2009: Group results**

## Core EPS grows significantly faster than sales

CHF bn	HY '08	HY '09	% cl CHF	hange local
Sales	22.0	24.0	+9	+10
Operating profit before exceptional items % of sales	7.0 <i>32.0</i>	8.0 <i>33.2</i>	+13 + <i>1.2 p</i>	+20
Operating profit % of sales	7.4 33.4	5.6 <i>23.4</i>	-24 -10.0 p	-17
Operating free cash flow % of sales	4.8 <i>21.8</i>	6.8 <i>28.2</i>	+41 +6.4 p	+52
Net financial income Exceptional financing costs	0.2	-0.6 -0.4	- -	
Tax rate in % (before exceptional items)	23.9	22.6	-1.3 p	
Net income % of sales	5.7 <i>26.0</i>	4.1 <i>16.9</i>	-29 <i>-9.1 p</i>	
Net income before exceptional items	5.5	5.7	+4	
Core EPS (CHF)	5.75	6.32	+10	+20



## YTD Sep 2009: Very solid growth for both divisions

## Momentum maintained well above market

CHF bn	YTD Sep 2008	<b>YTD Sep 2009</b>	% cha	nge in local
Pharmaceuticals	26.2	29.0	+11	+12
Diagnostics	7.1	7.4	+4	+8
Roche Group	33.3	36.4	+9	+11



### 2009: record year for clinical newsflow

Tarceva in 1L maintenance T-DM1 in 2L+ NSCLC SATURN

HFR2+ metastatic breast cancer

Herceptin in 1L gastric cancer **ToGA** 

Herceptin in adjuvant breast cancer-4yr follow-up

Avastin in 11 HFR2negative breast cancer **RIBBON-1 & AVADO** 

**BRAF** Inhibitor in advanced melanoma

T-DM1 in 3I + HER2+metastatic breast cancer

**HERA** 

Avastin in Adjuvant Colon Cancer NSABP C-08

Tarceva+Avastin in 11 NSCLC **ATLAS** 

Xeloda in early colon cancer **XELOXA** 

MabThera/Rituxan in follicular NHI maintenance **PRIMA** 

Avastin in 21 HFR2negative breast cancer RIBBON-2

O1'09

Q2'09

O3'09

Q4'09

Aleglitazar in Type 2 Diabetes **SYNCHRONY** 

> Lucentis for branch retinal vein occlusion BRAVO

Actemra in Rheumatoid Arthritis **LITHE** 

MabThera/Rituxan in ANCA-associated vasculitis

**RAVE** 

Lucentis for central retinal vein occlusion CRUISE

Taspoglutide for Type 2 diabetes

T-emerge 2

Actemra for systemic juvenile idiopathic arthritis

**TENDER** 

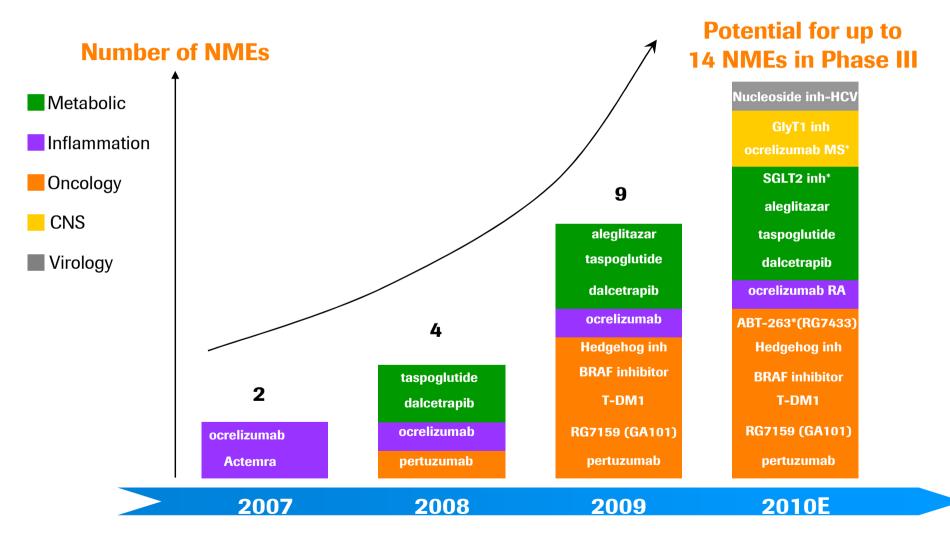
Taspoglutide for Type 2 diabetes T-emerge 1, 4

Valcyte for CMV disease **IMPACT** 



## **Building up the late-stage pipeline**

## Expanding into new therapeutic areas



<sup>\*</sup> Go/no-go decision for phase III pending



## **Performance update**

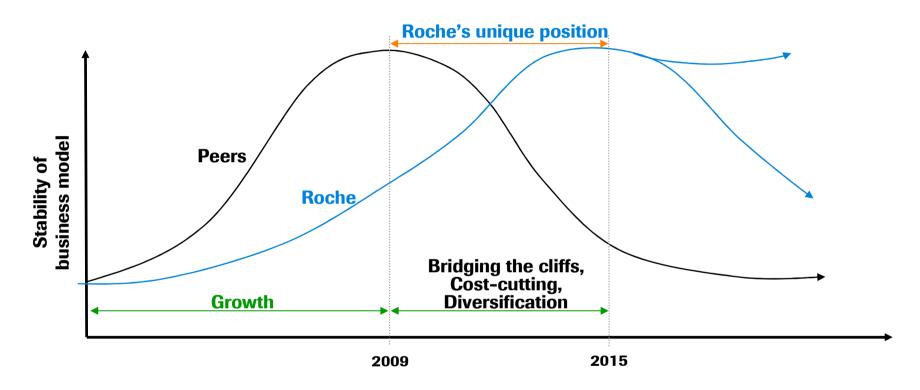
## **Strategy**

**Update on oncology portfolio** 

**Summary** 



### Roche's unique window of opportunity



### The industry

Low replacement power of current earnings levels

**Poor pipelines** 

**Cost cutting** 

#### **Roche**

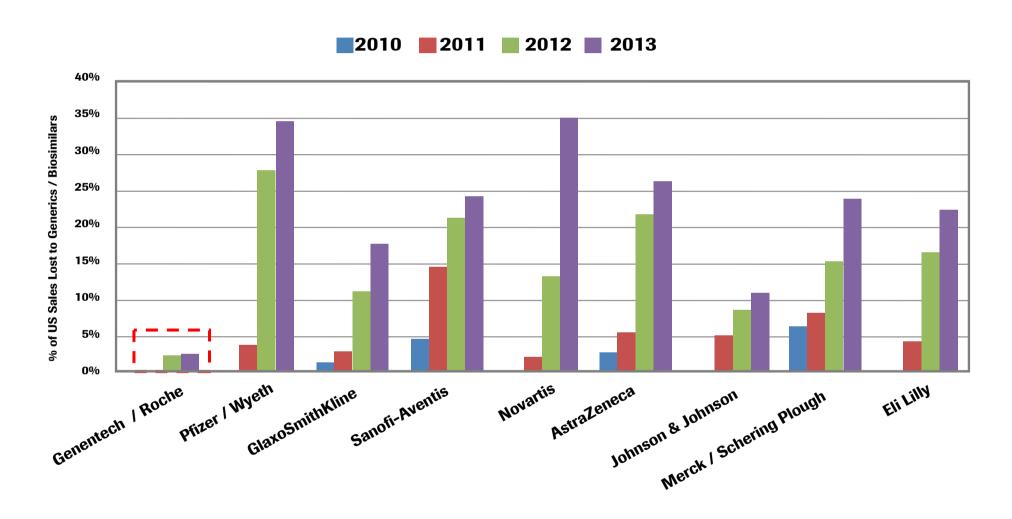
**Extended stability** 

Low generic exposure

**Investment into the future** 

## **Roche: Limited patent exposure**



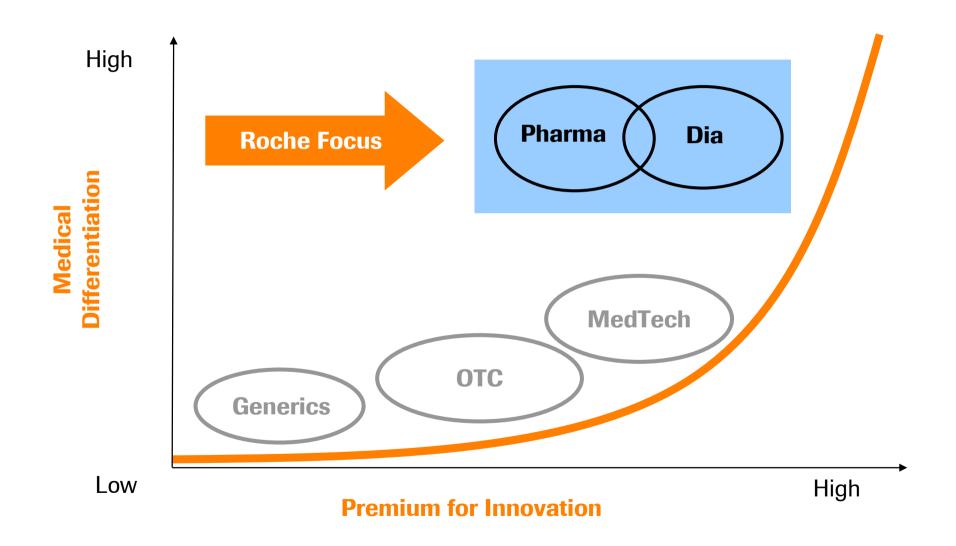


#### Notes:

<sup>•%</sup> Sales Lost calculated by subtracting given year sales ('10, '11, '12, '13) from full year sales from year prior to LOE.

### Focus on our core businesses







### **Our Focus**

# ... significant value capture from truly medically differentiated medicines

### Regulatory

• faster approval - improved efficacy/safety profile

### **Pricing**

- value to patients/physicians (e.g. US, Germany)
- reward of medical innovation (e..g. France, UK)

#### **Commercialization**

 faster and higher market penetration (efficacy & compliance drive sales



### **Roche Personalised Healthcare**

## A comprehensive portfolio of novel companion tests

			3 programs in CNS
			7 programs in metabolism
			3 programs in RA/ inflam.
		P53 gene mutation	16 programs in oncology
		MDM2 various markers	3 programs in virology
		EGFR gene copy number	
		EGFR protein expression (IHC)	
Bone markers (e.g. tP1NP)	anti-CCP antibodies	IGF-1R various markers	
CYP450	Rheumatoid Factor	HER2/HER3 RNA expression	
KRAS mutation	BRAF gene mutation		
EGFR mutation	Quantitative HBV sAG		
HER2 gene copy number (SISH)			Disease Biology areas:
HER2 protein expression (IHC)			CNS
HPV HR detection/typing			Metabolism/ CV
HCV viral load/genotyping			RA/ Inflammation Oncology
HBV viral load			Virology
CMV viral load		L	
HIV viral load			
On Hand	Late Stage Clinical Validation	Early Stage Clinical Validation	Exploratory Stage

Selection of key tests on the market and in clinical validation; only formalised programs included



### **Performance update**

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## **Understanding Biology to Improve Patient Outcomes**

Cancer Type	Marketed Products	Key Products in Development
Gastrointestinal	Avastin, Tarceva, Xeloda	Avastin, Herceptin, Xeloda, Hedgehog Pathway Inhibitor
Breast	Avastin, Herceptin, Xeloda	Avastin, pertuzumab, T-DM1, Xeloda
Lung	Avastin, Tarceva	Avastin, Apomab, dulanermin, Tarceva
Hematological	MabThera/Rituxan	Avastin, MabThera/Rituxan, GA101, dacetuzumab, Apomab, dulanermin, ABT-263
Genito-urinary	Avastin	Avastin, pertuzumab, Hedgehog Pathway Inhibitor
Skin & Soft Tissue		Hedgehog Pathway Inhibitor, PLX4032 (B-raf inhibitor), Apomab, Avastin
Brain	Avastin	Avastin
Childhood Cancers		Xeloda, Avastin



# What it takes to establish standard of care Aiming for first and best in class cancer medicines

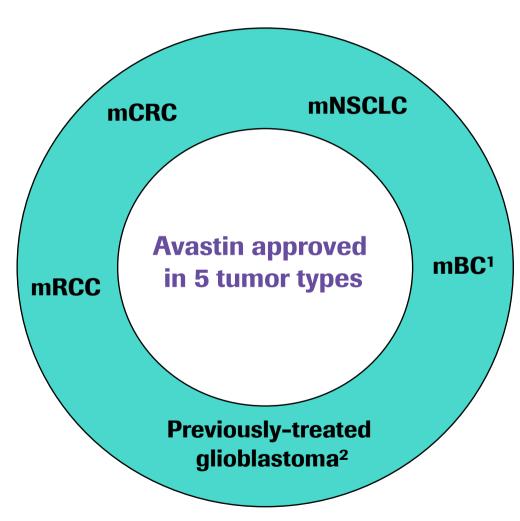
- Clinically meaningful and statistically superior benefit
- Broad combinability, especially with established backbones
- Positive risk-benefit profile, improving or maintaining quality of life
- Clinical data for all relevant settings and combinations
- Building trust through strong scientific rationale and breadth of clinical data, including phase IV and real-life experience

## Roche

### **Avastin: unique benefits**

## Overall survival benefit demonstrated in prospective studies

- Proven survival benefits in mCRC (1st and 2nd line) and mNSCLC (1st line)
- Broad combinability with commonly used chemotherapies
- On the market for >5 years –
   over 500,000 patients treated
- Data in the real-world setting supports results from the pivotal studies
  - mCRC (BEAT, BRiTE)
  - mNSCLC (SAiL, ARIES)
  - mBC (ATHENA)



<sup>&</sup>lt;sup>1</sup> accelerated approval in US, approved in EU; <sup>2</sup> accelerated approval in US, not approved in EU



## **Avastin: significant potential for additional indications in the metastatic setting**

## Important Phase III news flow over next 2 years

Indication	Study name	Status	Regulatory Submission
1 <sup>st</sup> -line advanced gastric cancer	AVAGAST	Expect data 2010	2010
Adjuvant colon cancer	AVANT	Expect data 2010	TBD
1 <sup>st</sup> -line metastatic ovarian	GOG-0218	Expect data 2010	2010
cancer	ICON-7	Expect data 2010	2010
Relapsed platinum-sensitive	OCEANS	Expect data 2010	2011
ovarian cancer	GOG-0213	Expect data 2013	2013
1 <sup>st</sup> -line hormone-refractory prostate cancer	CALGB 90401	Expect data 2010	2011
1 <sup>st</sup> -line metastatic HER2+ breast cancer	AVEREL (combo with Herceptin)	Expect data 2011	2011

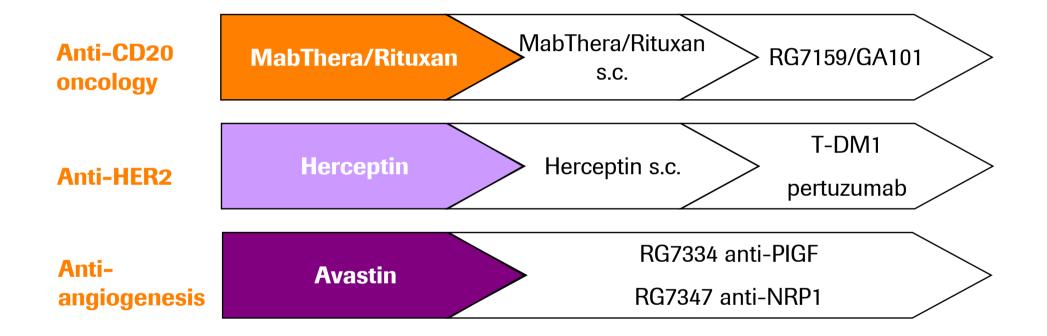


# **Avastin in Ovarian and Prostate Cancer: Summary of Phase II Results**

Indication	n	Prior regim.	Disease	setting	Study therapy	OR, %	SD, %	Median PFS, months	Median OS, months
Ovarian ca			Platinum sensitive	Platinum resistant					
Burger 2007	62	≤ <b>2</b>	✓	✓	SA Avastin	21	52	4.7	17
Cannistra 2007	44	2-3		✓	SA Avastin	16	25	4.4	
Micha 2007	20	0	Frontline	therapy	Avastin + carbo + paclitaxel	80	5	NR	NR
Campos 2007	58	0	Frontline	therapy	Avastin + carbo + paclitaxel => Avastin maint.	75		11	
Prostate ca						PSA RR/RR			
Di Lorenzo 2008	20		ا-Docetaxel hormone r		Avastin+ docetaxel	55/38		4	9
Picus 2003	<b>7</b> 9		Hormone-	refractory	Avastin+ docetaxel + estramustine	77/44		10.3	22.4
Ning 2008	60		Hormone-	refractory	Avastin+ docetaxel + thalidomide	90/64		18.2	-



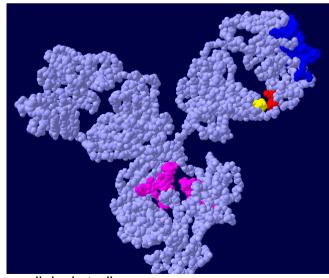
## **Next generation products to sustain our growth**

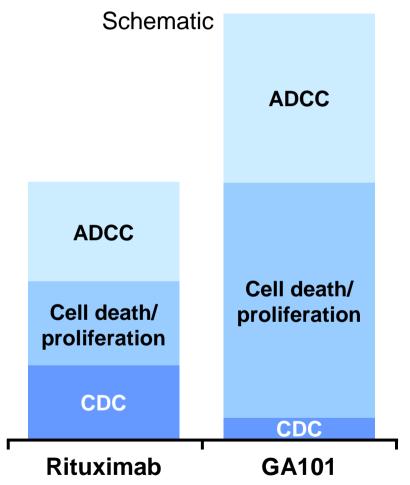




# RG7159/GA101: First glycoengineered, humanized, type II anti- CD20 antibody in clinical development

- First type II, glyco-engineered, humanised anti-CD20 antibody in clinical development
- Compared with rituximab, GA101 provides\*:
  - Enhanced direct cell-death induction<sup>1,2</sup>
  - Enhanced ADCC<sup>1,2</sup>





<sup>\*</sup>based on preclinical studies 1. Umaña P, et al. Blood 2006;108:Abstract 229

<sup>2.</sup> Umaña P, et al. Ann Oncol 2008;19 (Suppl. 4):Abstract 098



## The translation of science: GA 101 in NHL (MabThera /Rituxan pre-treated patients)

Population	Pre-treatment	Best response (%)
21 NHL patients various histology subtypes	Median 4 prior regimen (range 1-7)  Rituximab 95%  High dose therapy with autologous stem cell transplant 52%	4 CR, 5 PR (ORR=43%)

8 of 9 responses ongoing as of March 2009

Note: Preliminary data 12/08 Salles G, et al. Blood 2008;112: Abstract 234 22

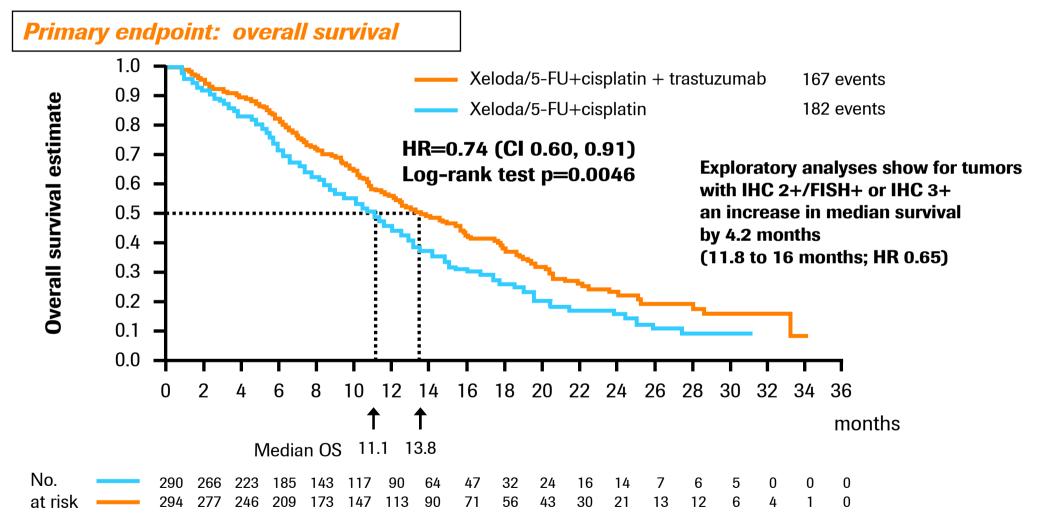


## GA101 (RG7159) development program

Patient Population	Relapsed Indolent Non-Hodgkin's Lymphoma	Indolent Non-Hodgkin's Lymphoma (NHL)	Relapsed or Ro CD20+ Hema Malignan	atologic	Indolent Non- Hodgkin's Lymphoma (Rituxan Refractory)	Front-line Chronic Lymphocytic Leukaemia
Phase/Study	Phase Ib	Phase I/II	Phase I/	<b>/II</b>	Phase III	Phase III
Phase/Siduy	(BO21000)	(BO21003)	(BO2099	9)	(GAO4573g)	(BO21004)
# of Patients	N=56	N=~200	N=133		N=340	N=780
Design	ARM A: GA101 plus fludarabine + cyclophosphamide     ARM B: GA101 plus CHOP	Phase II Cohort:  • ARM A: MabThera/Rituxan  • ARM B: GA101	Single agent		• ARM A: Bendamustine + GA101 • ARM B: Bendamustine	<ul> <li>ARM A: GA101 + chlorambucil</li> <li>ARM B: Chlorambucil alone</li> <li>ARM C: Rituxan + chlorambucil</li> </ul>
Status	• FPI Q1 2009	Initiated Q1 2008     FPI Phase II cohort Q3 2009     Phase I data submitted to ASH 2009	Initiated Q3 2007     Phase I NHL data pr ASH 2008; CLL data EHA and Pan Pacific June 2009     Data submitted to A     Phase II cohort:     Indolent and aggressive NHL arm enrolment	presented at Meetings	Expect FPI Q1 2010	• Expect FPI Q4 2009/Q1 2010



## The translation of science: the example of Herceptin in gastric cancer





### The translation of science: T-DM1

## Phase II data presented at SABCS

- Single agent T-DM1 demonstrated robust anti-tumor activity in a predefined patient population:
  - ORR: 32.7% IRF, 30% INV
  - CBR: 44.5% IRF, 40% INV
- Substantial clinical benefit was seen in this specific patient population that has not been previously studied
  - Previously treated with an anthracycline, a taxane, capecitabine, trastuzumab, and lapatinib
  - Received two HER2-directed regimens in the metastatic setting
  - Progressive disease on last regimen received
- T-DM1 is well tolerated by patients at the dose and schedule tested with no dose-limiting cardiotoxicity or new safety signals
  - One patient died from hepatic dysfunction
- The toxicities observed on this study are acceptable and manageable in this patient population



## **T-DM1 Development Program**

## Evaluating new treatment options in HER2+ mBC

	HER2-positive Metastatic Breast Cancer						
Patient Population	Patients Who Have Progressed on Herceptin- based Treatment	First-line Treatment	Third-line Treatment <sup>1</sup>	Second-line Treatment <sup>2</sup>			
Phase/Study	Phase lb/II	Randomised Phase II	Phase II	Phase III EMILIA			
# of Patients	N=60	N=120	N=110	N=580			
Design	Single ARM: T-DM1 plus pertuzumab	ARM A: T-DM1     ARM B: Herceptin plus docetaxel	Single agent study	<ul><li>ARM A: T-DM1</li><li>ARM B: Xeloda plus lapatinib</li></ul>			
Primary Endpoint	Safety and tolerability	Progression-free survival	Objective response     (assessed by independent radiologic review)	Progression-free survival			
Status	<ul> <li>FPI Phase Ib cohort Q2 2009</li> <li>FPI Phase II cohort Q3 2009</li> </ul>	• FPI Q3 2008	<ul> <li>Enrolment completed Q1 2009</li> <li>Data presented at SABCS 2009</li> </ul>	• FPI Q1 2009			

In collaboration with ImmunoGen

metastatic setting.

Additional Phase Ib and Phase II studies ongoing.

FPI = First patient in; SABCS = San Antonio Breast Cancer Symposium.

<sup>&</sup>lt;sup>1</sup> Patients must have received prior treatment with an anthracycline, trastuzumab, a taxane, lapatinib, and capecitabine in the neoadjuvant, adjuvant, locally advanced, or metastatic setting and prior treatment with at least two lines of therapy (a line of therapy can be a combination of two agents or single-agent chemotherapy) in the metastatic setting.

<sup>2</sup> Patients must have received prior treatment which included both: a taxane, alone or in combination with another agent, and trastuzumab in the adjuvant, locally advanced, or



### The translation of science: Pertuzumab

## First in a new class of HER dimerization inhibitors

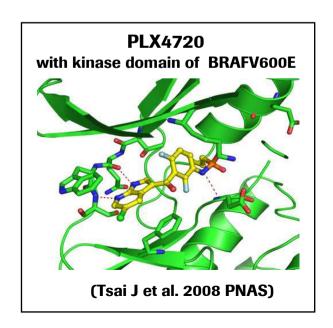
Patient Population	Second-line Metastatic Non-small Cell Lung Cancer	Neoadjuvant HER2- positive Breast Cancer	Neoadjuvant HER2- positive Breast Cancer	Second-line HER2- positive Metastatic Breast Cancer	First-line HER2- positive Metastatic Breast Cancer	Platinum-resistant Ovarian Cancer (Low HER3 Biomarker)
Phase/Study	Phase II	Phase II TRYPHAENA (BO22280)	Phase II NeoSphere (WO20697)	Phase II PHEREXA	Phase III CLEOPATRA	Phase III
# of Patients	N=52	N=225	N=400	N=450	N=800	TBD
Design	Single ARM:     Pertuzumab plus     Tarceva	ARM A: FEC followed by Taxane with Herceptin and pertuzumab (H+P given concurrently)     ARM B: FEC followed by Taxane with Herceptin + pertuzumab (H+P given sequentailly)     ARM C: TCH + pertuzumab (H+P given concurrently)	ARM A: Herceptin plus docetaxel     ARM B: Herceptin, docetaxel plus pertuzumab     ARM C: Herceptin plus pertuzumab     ARM D: Pertuzumab plus docetaxel	ARM A: Xeloda plus Herceptin     ARM B: Xeloda plus Herceptin plus Pertuzumab	ARM A: Herceptin and docetaxel     ARM B: Pertuzumab plus Herceptin and docetaxel	ARM A: Gemcitabine plus placebo     ARM B: Gemcitabine plus Pertuzumab
Primary Endpoint	Day 56 FDG-PET scan assessment	Safety	Pathologic response rate	Progression-free survival	Progression-free survival	Progression-free survival
Status	• FPI Q1 2009	• FPI Q4 2009	FPI Q1 2008     Expect data ASCO 2010	FPI pending	• FPI Q1 2008	Phase II study completed Phase III study under consideration

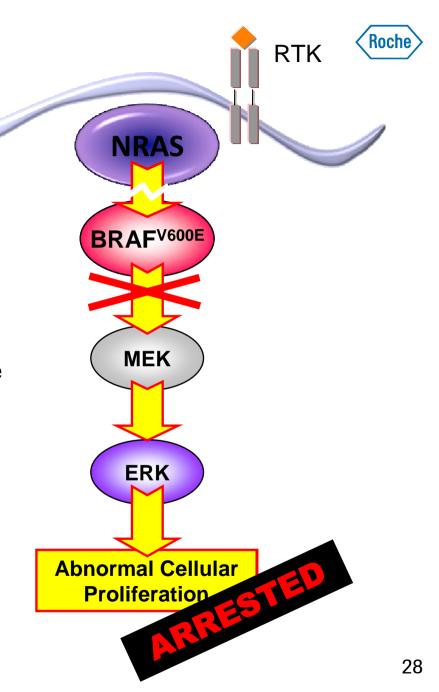
FDG = Fluoro-2-deoxy-D-glucose; PET = Positron Emission Tomography; FPI = first-patient-in; FEC = Fluorouracil, Epirubicin, and Cyclophosphamide; TCH = Docetaxel, Carboplatin, Herceptin.

## The Translation of science: B-raf inhibitor RG7204

### **Malignant Melanoma**

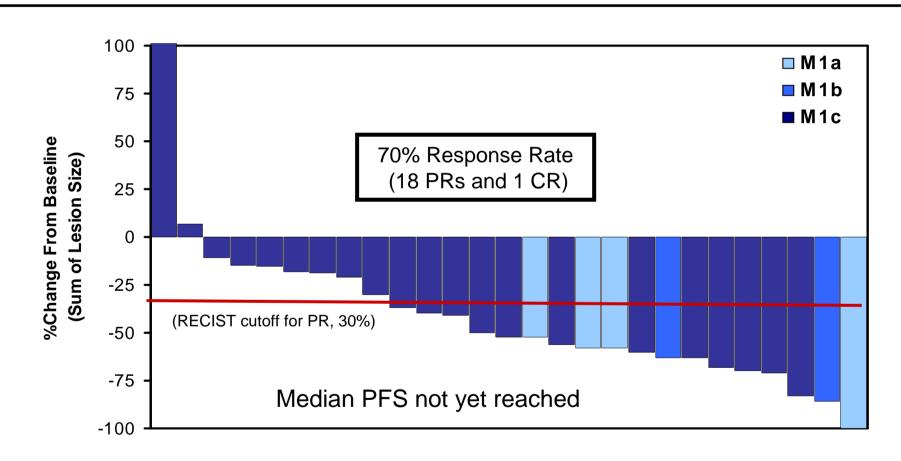
- Very limited treatment options
- High unmet medical need
- PFS in metastatic melanoma 2-3 months
- 5 year OS in metastatic melanoma < 5%
- Incidence (stage IV) in US and Top 5 EU is about 21k, ~50% of them mutated and eligible







# RG7204: Interim best overall response in extension cohort patients



n=27 evaluable patients
As of 8/21/09

## **Key Oncology Milestones in 2010**



#### **Avastin Phase III Data**

- CALGB 90401 for 1L hormone-refractory prostate cancer
- AVAGAST for 1L advanced gastric cancer
- GOG-218 and ICON-7 for 1L metastatic ovarian cancer
- OCEANS for relapsed platinum-sensitive ovarian cancer
- AVANT adjuvant colon cancer

#### **Other Potential Oncology Data Results in 2010**

- Xeloda Phase III NO17629 in adjuvant BC
- T-DM1 Phase II in 1L HER2+ metastatic breast cancer
- Pertuzumab Phase II in HER2+ neoadjuvant breast cancer

#### **Potential Oncology Regulatory Submissions**

- Avastin
  - RIBBON-2 in 2L metastatic breast cancer
  - AVAGAST metastatic gastric cancer
  - GOG218/ICON-7 in 1L ovarian cancer
  - AVANT adjuvant colon cancer
- ToGA: Herceptin in HER2+ gastric cancer in the US
- PRIMA: MabThera/Rituxan in indolent NHL maintenance (1L)
- ATLAS: Tarceva + Avastin in NSCLC maintenance (1L)
- XELOXA: Xeloda in adjuvant colon
- AVANT: Xeloda + oxaliplatin + Avastin in adjuvant colon cancer

#### **Potential Oncology Approvals**

- SATURN: Tarceva in 1L maintenance therapy for advanced NSCLC
- ToGA: Herceptin in HER2+ gastric cancer in the EU
- Rituxan 1L/relapsed CLL (US)
- Avastin RIBBON-1/AVADO (US), RIBBON-1 (EU)



**Performance update** 

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**Update on oncology portfolio** 

## **Summary**



## Q3 2009: Raising our outlook for 2009

Sales growth (in LC)	2009: Pharma: <b>at least high single-dig</b> Diagnostics: well above market	jit
Synergies	2009: CHF 300 m 2010: CHF 800 m 2011: CHF 1,000 m	
Core EPS growth (in LC)	<ul><li>2009: Double-digit</li><li>2010: Double-digit</li></ul>	
Debt	<ul><li>2010: 25% debt reduction</li><li>2015: Aim to return to net cash position</li></ul>	
3 yr Dividend outlook	Maintained (as announced in 2008)	



## Roche: A unique investment case

### **Clear and focused strategy**

- Medically differentiated products
- Leader in Personalised Healthcare

### **Attractive risk profile**

Low generic risk; lowest among European large-cap players

### **Assets in place for sustained success**

- World market leader in Oncology
- Emerging Rheumatology/Autoimmune and Metabolic franchises

### **Industry-leading organic growth**

Unique high-tech healthcare investment



## We Innovate Healthcare