



# Novartis Oncology Pipeline – Molekular Zielgerichtete Therapieentwicklung“

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# Novartis Oncology: A global leader in Oncology

We discover, develop and commercialize products to protect and improve the health and well-being of patients with cancer

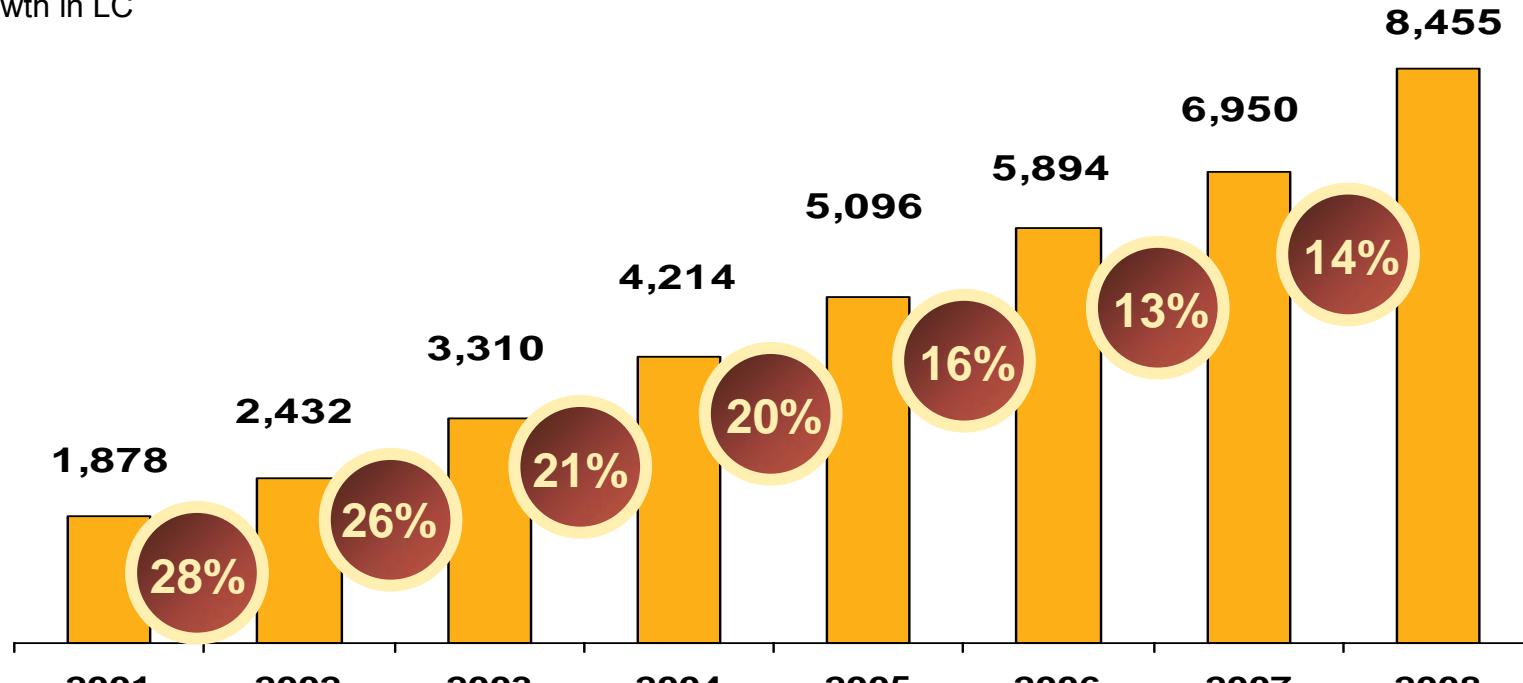


- Unique Business Unit model created in 2000 to focus on Oncology & Hematology
- Major sites in Florham Park (US), Basel (CH), Cambridge (US), Emeryville (US)
- Key growth driver for Novartis Pharma
- More than 5,200 employees worldwide

# “Business Unit” Structure: The power and resources of big pharma with the passion and speed of biotech

In USD millions

Growth in LC

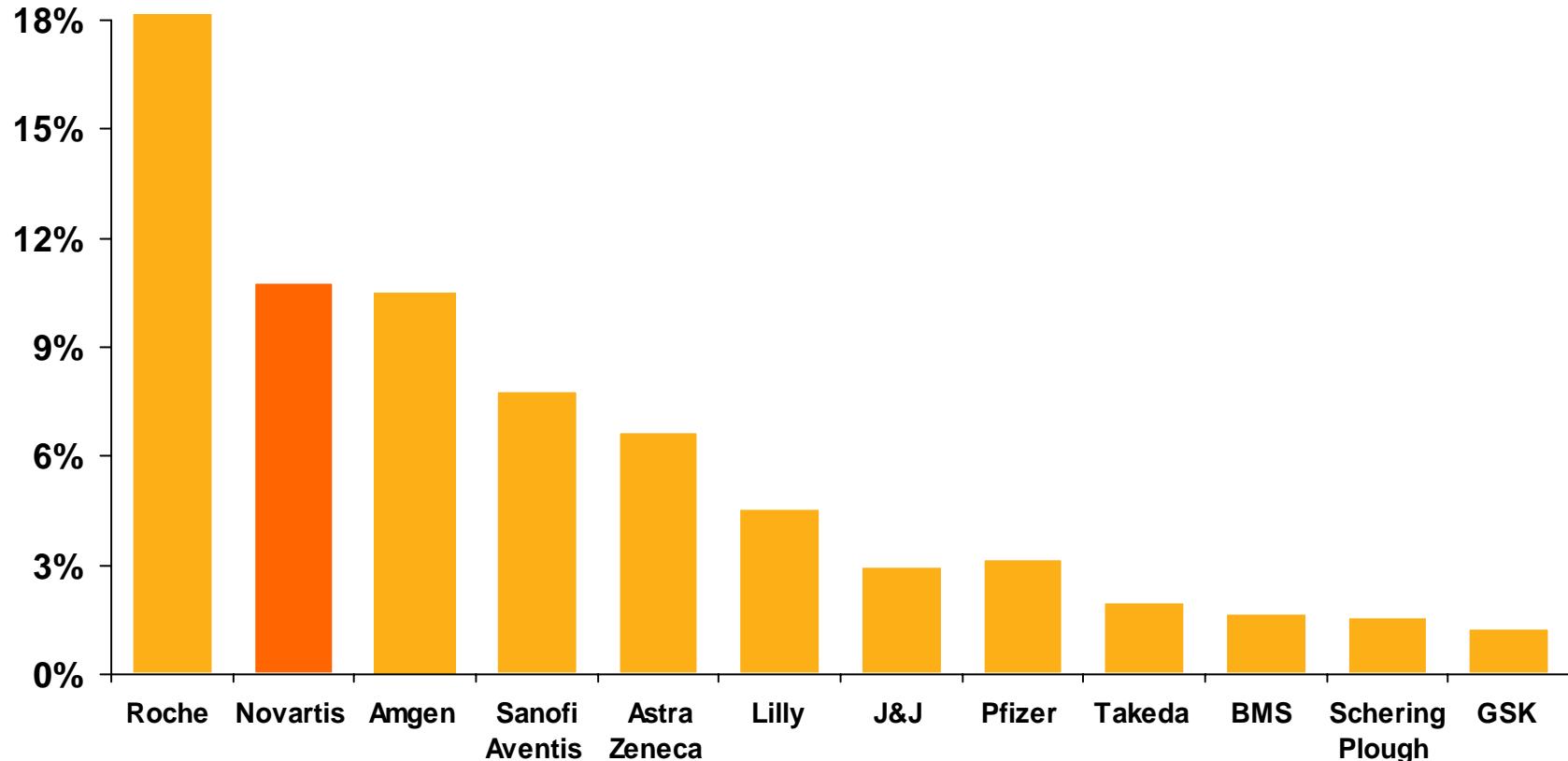


<sup>1</sup> Q4 2001   <sup>2</sup> Q1 2009

Source: Novartis Oncology; IMS PADDS

# Novartis Oncology is the world's second largest Oncology business

Global Oncology market segment share

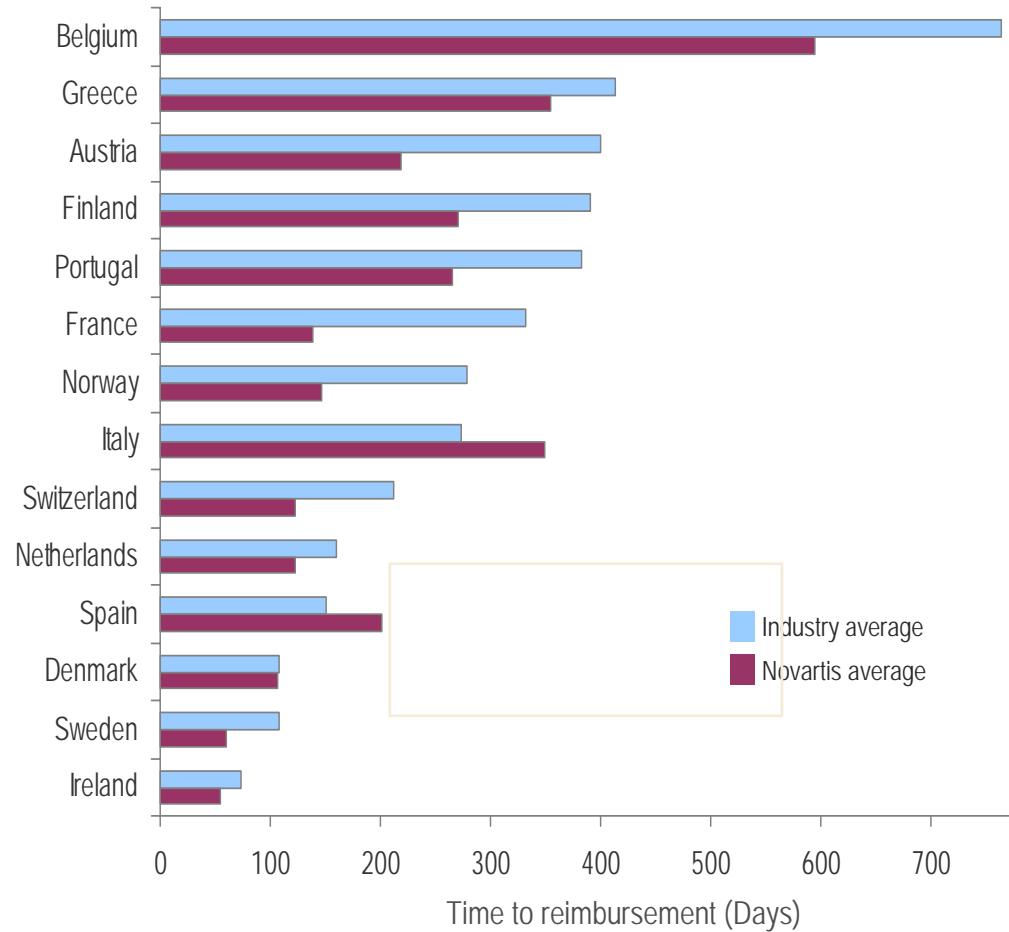


Worldwide Market Share as of MAT Q1 2009 based on IMS MIDAS Data

Source: IMS MIDAS

# Novartis Succeeds in Accessing European Markets at a Faster Pace Than Industry Average

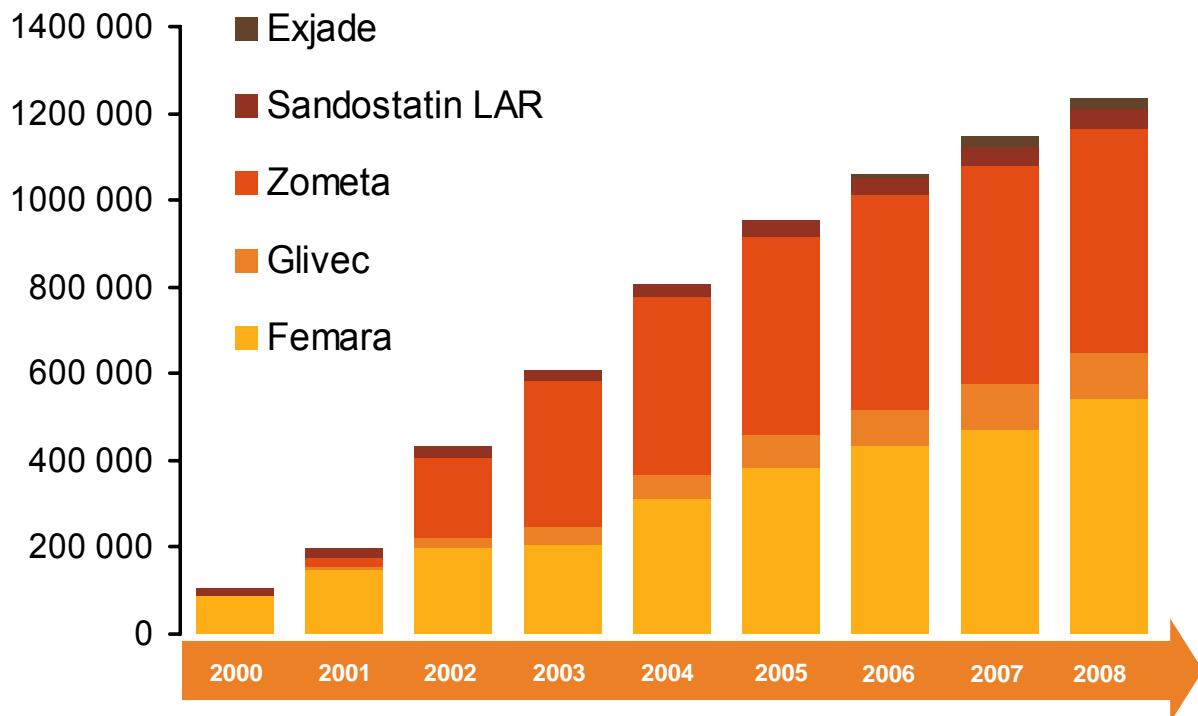
- There are significant delays in getting reimbursement approval in the EU
- Delays in reimbursement are costly to pharmaceutical companies
- Timely market access at optimal prices has become more challenging
- treatments for unmet needs no longer immune from access pressures
  - In the UK, Avastin and Erbitux rejected on cost-effectiveness grounds
  - In Italy, Sutent and Nexavar not reimbursed until patient shows response
- Companies challenged to be increasingly creative in demonstrating value



Source: Internal survey performed by IMS-Cambridge Pharma Consultancy

# Over 1.2 million cancer patients were treated with Novartis Oncology drugs in 2008

Number of Treated Patients



# Key oncology and hematology projects

Exploratory	Confirmatory		Registration
	Phase I/II	Phase III	
HCD122 Hem. tumors	LBH589 Hodgkin's lymphoma	ASA404 NSCLC <sup>3</sup>	Afinitor® RCC <sup>7</sup>
TKI258 Solid tumors	PKC412 ASM <sup>1</sup>	EPO906 Ovarian cancer	
RAF265 Solid tumors	EPO906 Solid tumors	SOM230 Cushing's disease	
BEZ235 Solid tumors	Exjade® Hered. hemochromatosis	PKC412 AML <sup>4</sup>	
AUY922 Solid tumors	LBH589 Hemat. & solid tumors	Afinitor® pNET <sup>2</sup> and Carcinoid	
BHQ880 Solid tumors	Afinitor® Solid tumors	Afinitor® TSC <sup>5</sup>	
BGT226 Solid tumors		Afinitor® ER+ Breast Cancer	
BKM120 Solid tumors		SOM230 Acro and Carcinoid Syndrome	
LCL161 Solid tumors		Tasigna® GIST <sup>8</sup> / newly diagnosed CML <sup>6</sup>	
LDE225 Solid tumors		Zometa® Adjuvant breast cancer	
HSP990 Solid tumors			

<sup>1</sup> Aggressive systemic mastocytosis

<sup>2</sup> Pancreatic neuroendocrine tumor

<sup>3</sup> Non small cell lung cancer

<sup>4</sup> Acute myeloid leukemia

<sup>5</sup> Tuberous sclerosis complex

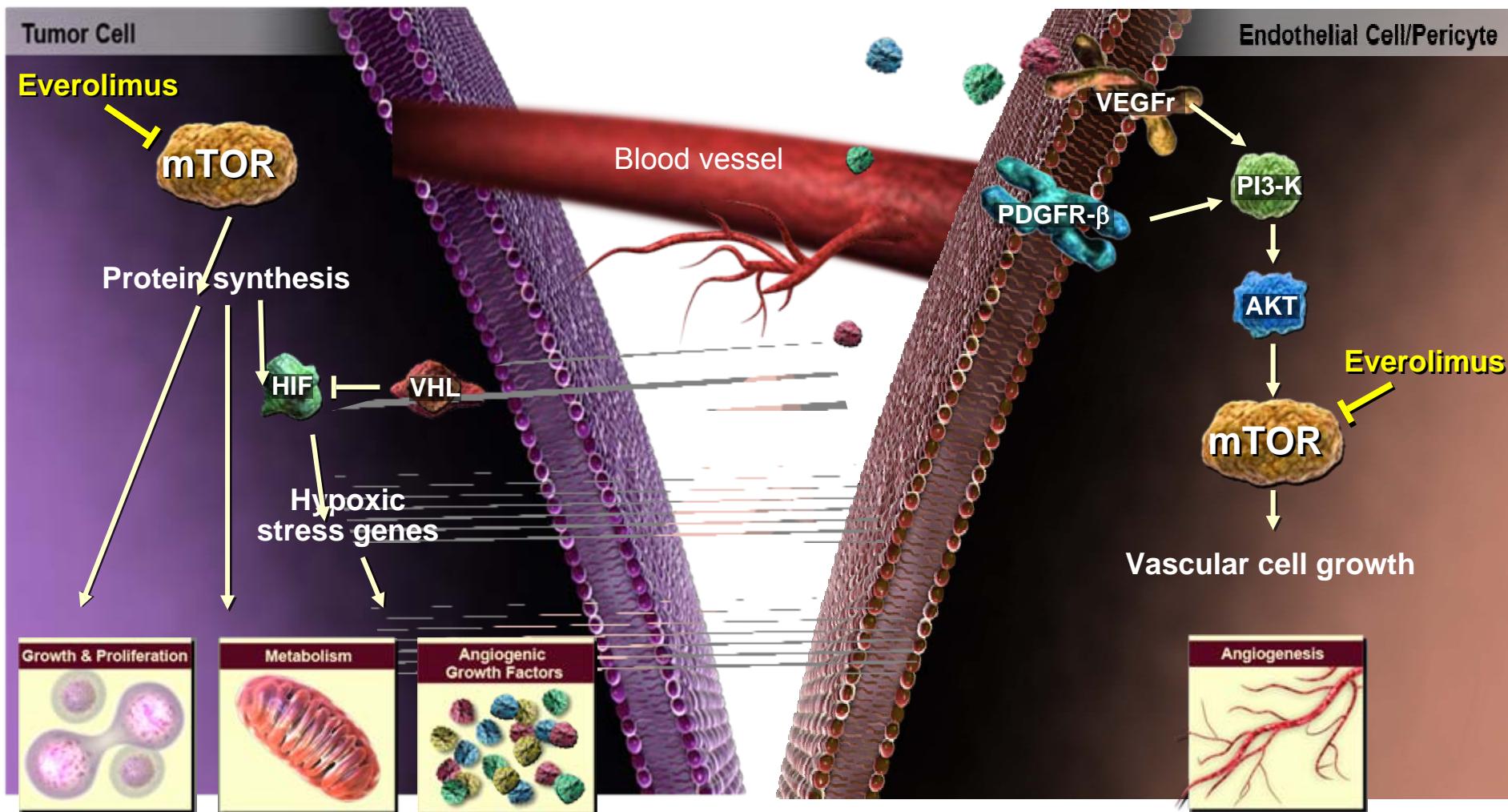
<sup>6</sup> Chronic myeloid leukemia

<sup>7</sup> Renal cell carcinoma

<sup>8</sup> Gastrointestinal stromal tumor



# Everolimus inhibits mTOR in tumour cells and endothelial cells



# Broad Development Plan for Afinitor in 2009-2010

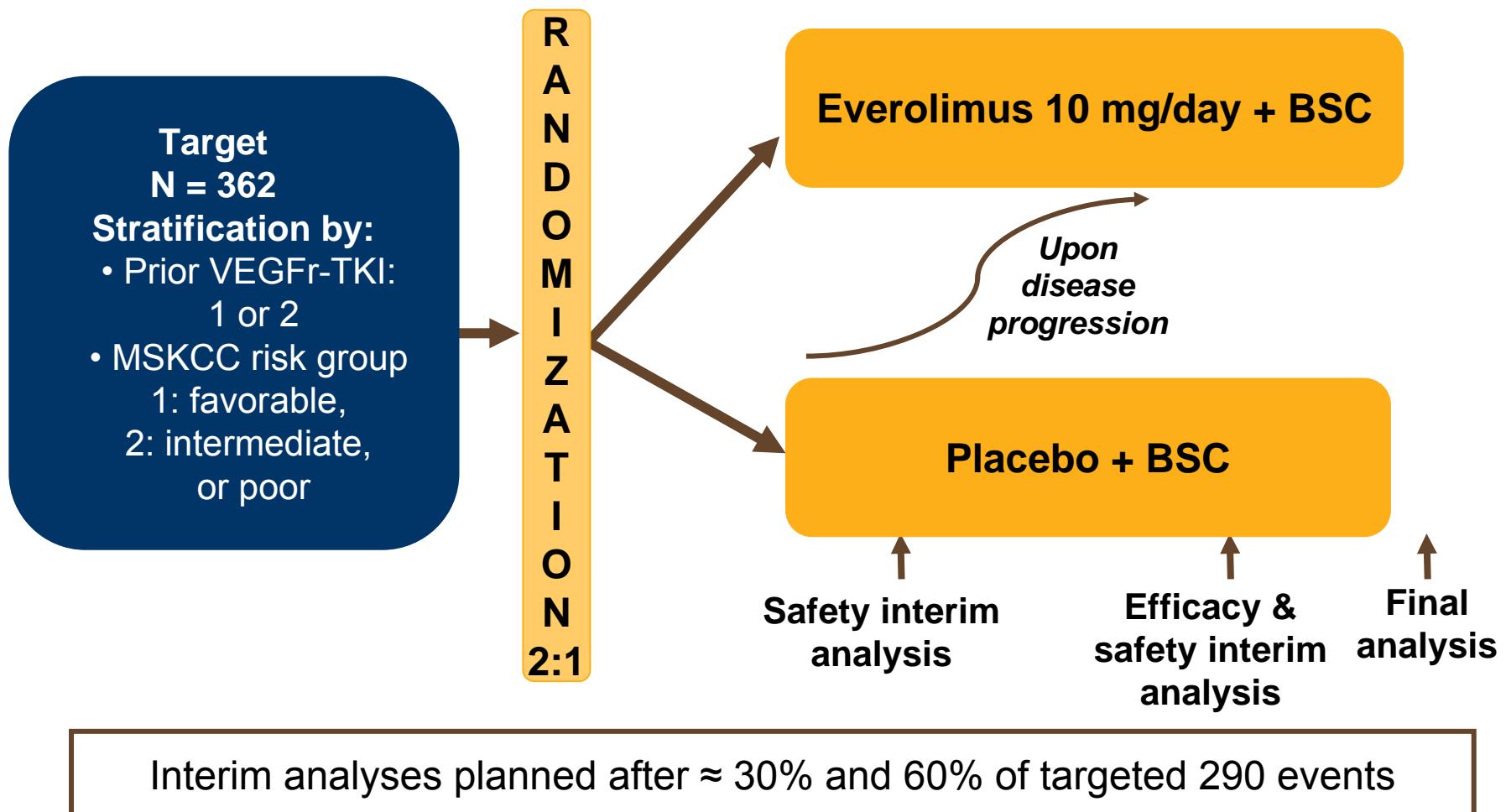


Tumor	Ph	Status
RCC 2 <sup>nd</sup> /3 <sup>rd</sup>	Ph 3	Approved
Carcinoid	Ph 3	Enrolled
piCT 1 <sup>st</sup> line	Ph 3	Enrolled
TSC AML	Ph 3	Enrolling
TSC SEGA	Ph 3	Enrolling
Gastric 2nd/3rd	Ph 3	Enrolling
Breast ER+	Ph 3	Enrolling
HCC	Ph 3	2010
Breast HER2+ (1 <sup>st</sup> )	Ph 3	Enrolling
Breast HER2+ (2 <sup>nd</sup> /3 <sup>rd</sup> )	Ph 3	2009
DLBCL	Ph 3	Enrolling

<sup>1</sup> Worldwide Initiative to Develop Everolimus;

9 | PharmaForum , Frankfurt 03.Nov.2009 | Jens Brauburger, Novartis

# RECORD-1 – Afinitor in mRCC / Study design

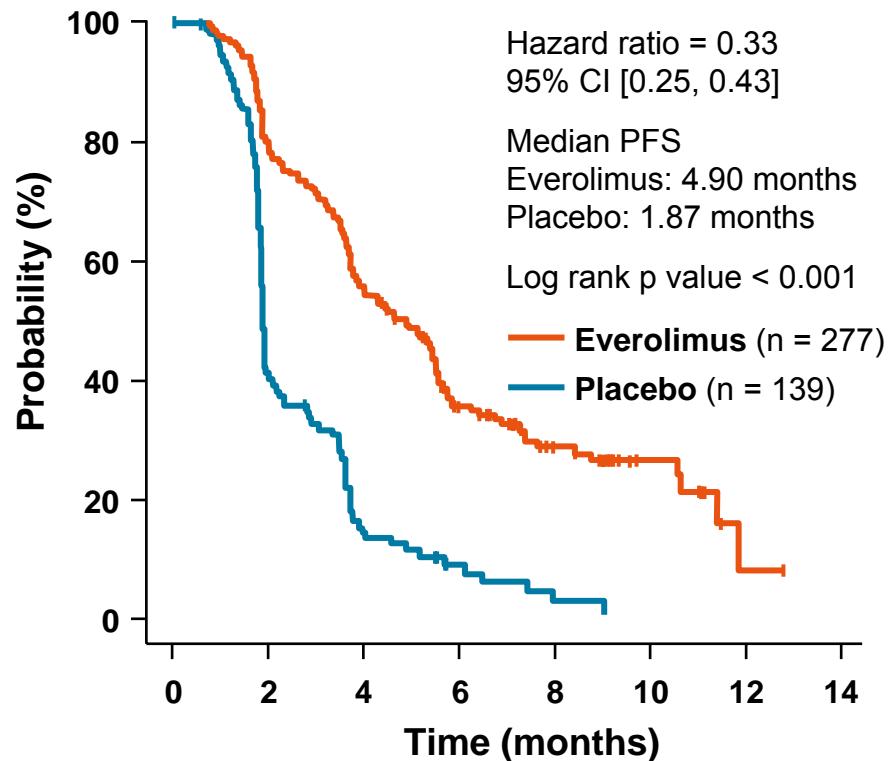


MSKCC = Memorial Sloan-Kettering Cancer Center;

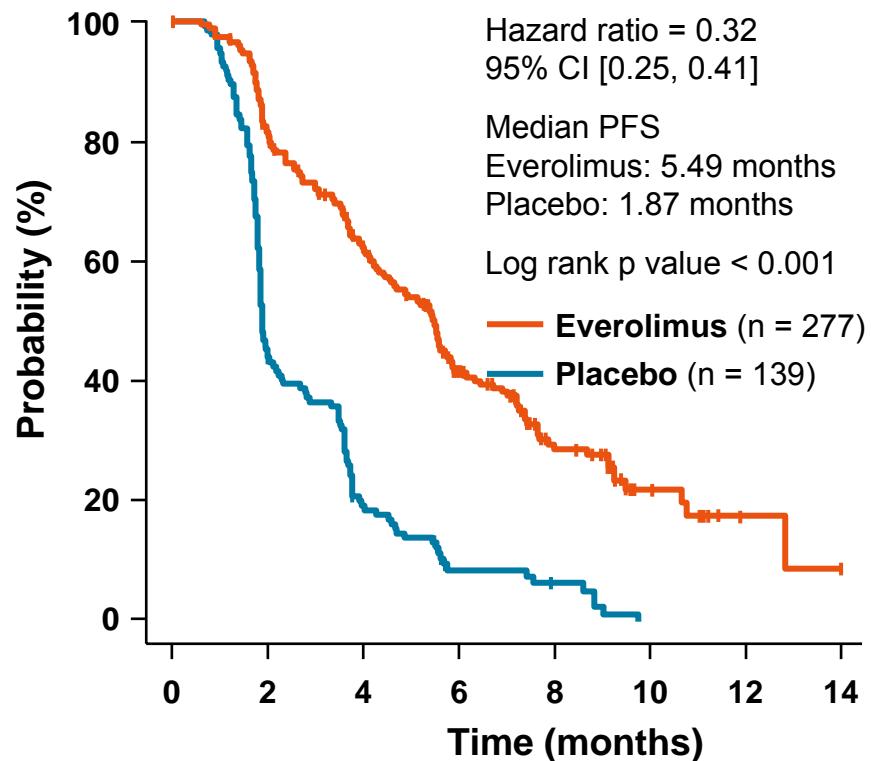
BSC = best supportive care.

# PFS by treatment end of double-blind

Central radiology review<sup>1</sup>



Investigator assessment<sup>2</sup>



Number of patients at risk, n

Everolimus	277	192	115	51	26	10	1	0
Placebo	139	47	15	6	2	0	0	0

Analysis on Feb 2008 data cut-off.

1. Escudier B, et al. Ann Oncol. 2008;19:viii45 [Abstract 720];

2. Kay A, et al. Presented at ASCO-GU 2009 [Abstract 278] by Motzer.

# Novartis Oncology

A strong partner

*Combines the power and resources of a big pharma with the passion and speed of a biotech*

- A global leader in Oncology, with
- Proven commercial excellence

