HealthCare

Bayer R&D Investor Day 2005

December 8, 2005 | London

Bayer R&D Investor Day 2005

Nexavar - A New Paradigm in Cancer Therapy

Susan L. Kelley

Head of Therapeutic Area Oncology, Global Clinical Development
Bayer HealthCare

Forward Looking Statements

This presentation contains forward-looking statements based on current assumptions and forecasts made by Bayer Group management.

Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in our public reports filed with the Frankfurt Stock Exchange and with the U.S. Securities and Exchange Commission (including our Form 20-F). The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

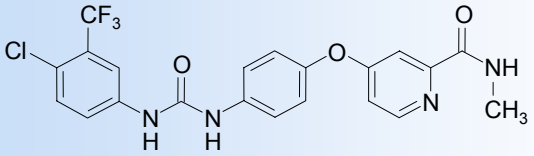
Key Messages

- Nexavar to establish Bayer as an emerging player in targeted cancer therapy
- Nexavar prolongs life in Phase III RCC based on clinical trial interim analysis
- Nexavar‘s encouraging clinical data suggest potential in cancer types beyond RCC: NSCLC as new opportunity
- Nexavar has blockbuster potential

Dual Mechanism: Targeting Tumor Cells Directly as well as the Cancer Blood Vessels

- **Activation of oncogenes** (e.g. Raf), and **malfunction of signal transduction** pathways (e.g. Raf/MEK/ERK pathway) can lead to uncontrolled cell growth and subsequent **development of malignant tumors**
- To survive and grow, solid tumors must acquire **new blood vessels** to provide them with nutrients and oxygen, a process known as angiogenesis
- Targeting **both tumor cell proliferation and angiogenesis** with one therapy may have increased clinical benefits

Nexavar (sorafenib): A Novel, Orally Active, Multi-Kinase Inhibitor



In partnership with Onyx Pharmaceuticals

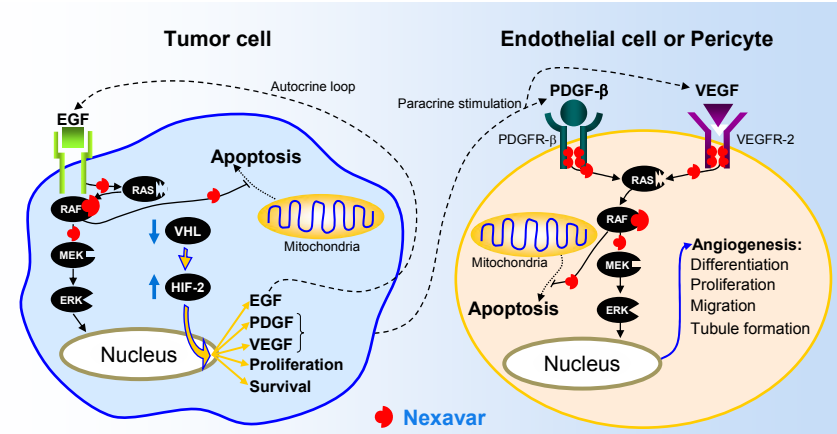
- A novel, oral bi-aryl urea with broad spectrum of anti-tumor activity
- Discovered and developed with Onyx Pharmaceuticals Inc.
- A multi-kinase inhibitor of

  Serine/Threonine: C-Raf (Raf-1) and B-Raf1

  Receptor Tyrosine Kinases: VEGFR-2, VEGFR-3, PDGFR-b, FLT-3 and c-KIT

Wilhelm S, Chien DS. *Curr Pharm Des.* 2002;8:2255–2257.
Wilhelm S, Carter C, Tang L *et al. Cancer Res.* 2004;64:7099–7109.

Nexavar Targets both Tumor-Cell Proliferation and Angiogenesis



Wilhelm S et al. *Clin Cancer Res.* 2004;64:7099-7109.

Nexavar Targets both Anti-angiogenic and Anti-proliferative Effects

	Main anti-angiogenic targets			Main anti-proliferative targets		
Compound	VEGF	VEGFR	PDGFR	EGFR	Raf	mTOR
Avastin®	●					
Nexavar		●	●		●	
Sutent®		●	●			
Tarceva®				●		
AG-013736		●	●			
CCI-779						●

Wilhelm S, et al. *Cancer Res.* 2004;64:7099–109; Mendel DB et al. *Clin Cancer Res.* 2003;9:327-37;
Inai T, et al. *Am J Pathol.* 2004;165:35-52;
Kim KJ, et al. *Nature.* 1993;362:841-4; Polack VA, et al. *J Pharmacol Exp Ther.* 1999;291:739-748;
Licun W, et al. *Cancer Res.* 2005;65:2825-31

Nexavar: Current Clinical Development Status

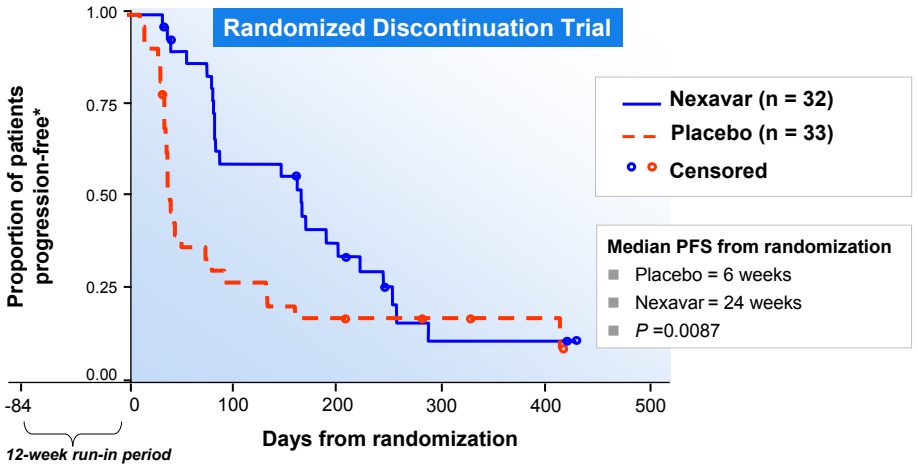
- Under Health Authority (FDA and EMEA) review for advanced renal cell carcinoma (RCC)
- Randomized phase II trial in first line RCC ongoing
- Phase III trial in hepatocellular carcinoma - started March 2005
- Phase III trials in malignant melanoma - started May 2005
- Clinical trials currently ongoing in other tumor types including NSCLC

Renal Cell Carcinoma Epidemiology

- 2005 (US): 36,000 new RCC cases / 12,700 deaths
- Most cases diagnosed after the 4th decade of life
- Almost twice as common in males as in females
- From 1975–1995, steady increase in incidence of 2 – 4% per year
- Current standards of care (interferon and interleukin-2) create significant unmet medical need
- No FDA drug approval in 13 years for RCC

Jemal A et al. *CA Cancer J Clin.* 2005; 55:10-30.
Linehan WM et al. In: *Cancer: Principles & Practice of Oncology.* 7th ed.; 2005:1139-1168.

Phase II RCC: Significant Improvement in Progression-Free Survival



*From randomization

Ratain MJ et al. Paper presented at: ASCO; May 13-17, 2005; Orlando, FL. Abstract 4544.

Largest Randomized Controlled Phase III Trial Conducted to Date in RCC

Eligibility criteria

- Histologically/cytologically confirmed, unresectable and/or metastatic disease
- Failed one prior systemic therapy in last 8 months

(1:1) Randomization n~903

Stratification

- Prognosis
- Region

Nexavar 400 mg bid

Placebo

Major endpoints

- Survival
- Progression Free Survival (PFS)

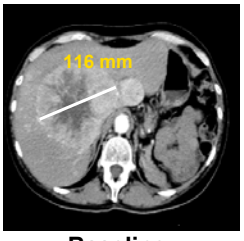
T·A·R·G·E·Ts
Treatment Approaches in Renal cancer Global Evaluation Trial

Phase III RCC: Objective Responses*
Control of Disease Obtained in 84% of Patients

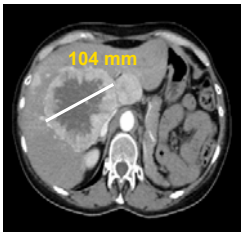
Best Response *RECIST* Criteria	Nexavar (n = 451)	Placebo (n = 452)
Complete response (%)	1 (<1)	0 (0)
Partial response (%)	43 (10)	8 (2)
Stable disease (%)	333 (74)	239 (53)
Progressive disease (%)	56 (12)	167 (37)
Missing (%)	18 (4)	38 (8)

*Investigator assessment; patients randomized at least 6 weeks before data cut-off of May 31, 2005.
Data from Escudier B. ECCO; November 3, 2005; Paris, France.

Phase III RCC: Disease Stabilisation
Indicating Anti-Cancer Activity



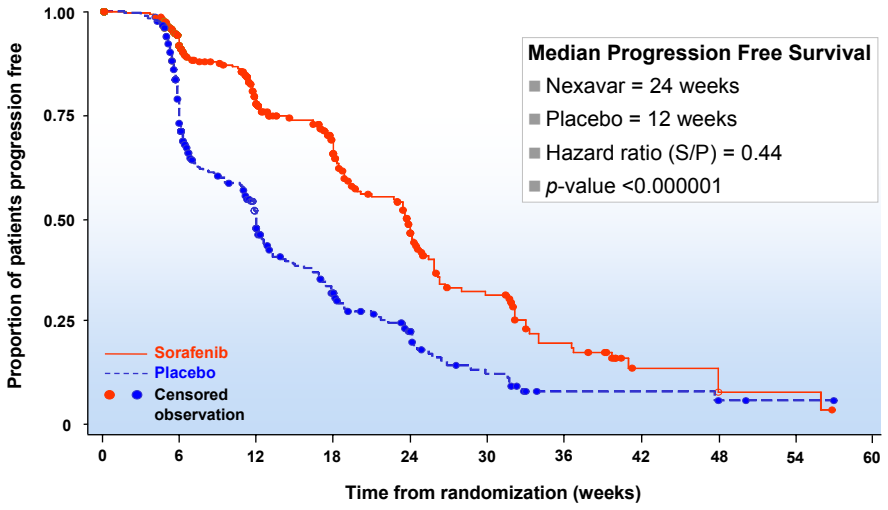
Baseline



Week 6

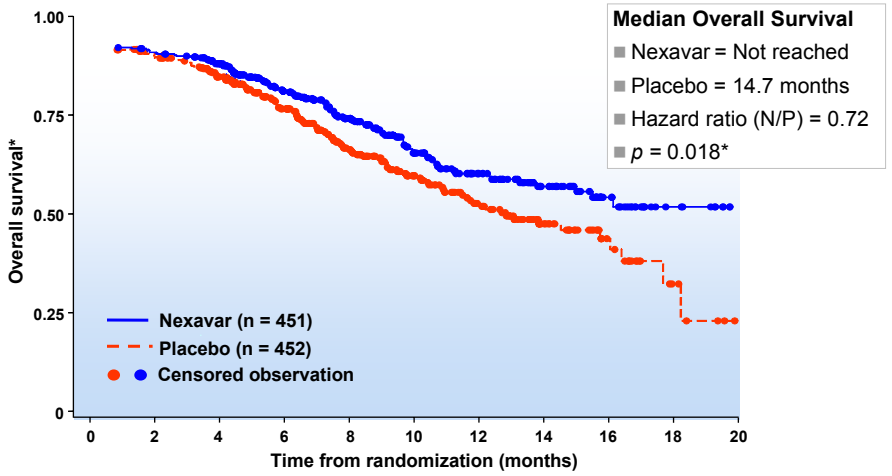
- Classical methods of assessing anti-tumor activity using tumor measurements and WHO or RECIST criteria are not fully adequate for this class of agents
- Nexavar mechanism of action predicts tumor stabilization and delay in recurrence as more meaningful result of treatment
- Anti-proliferative and anti-angiogenic effects of Nexavar are also reflected in tumor changes such as necrosis

Phase III RCC: Highly Significant Doubling of Progression-Free Survival



*Independently assessed

Phase III RCC: Interim Analysis Reveals 39% Improvement in Overall Survival



*Results are from a planned interim analysis as per protocol (220 events) and are considered preliminary.
†Threshold for significance of interim analysis was *P*<.0005.

Data from Escudier B. ECCO; November 3, 2005; Paris, France.

Phase III: Treatment Emergent Adverse Effects Allow for Chronic Administration

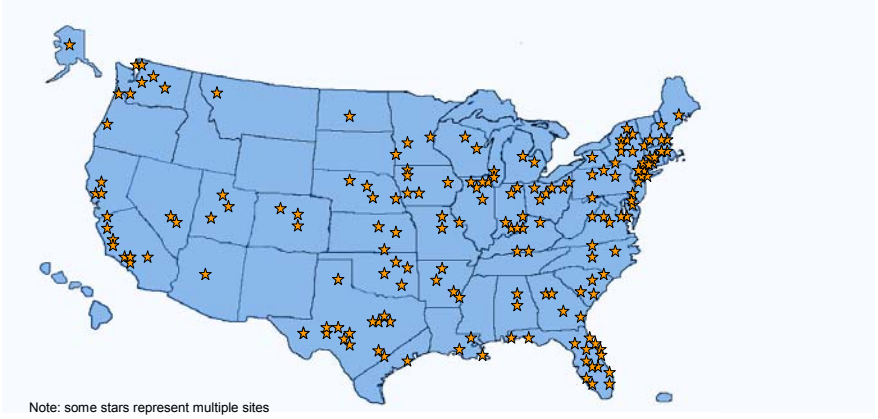
	Grade 3/4		All Grades	
Adverse Events	**Nexavar**	**Placebo**	**Nexavar**	**Placebo**
Hand-foot skin reaction (%)	25 (6)	—	134 (30)	30 (7)
Fatigue (%)	22 (5)	16 (4)	165 (37)	125 (28)
Hypertension (%)	16 (4)	2 (<1)	76 (17)	8 (2)
Dyspnea (%)	16 (4)	11 (2)	65 (14)	52 (12)
Tumor pain (%)	13 (3)	8 (2)	29 (6)	24 (5)
Decreased hemoglobin (%)	12 (3)	20 (4)	34 (8)	33 (7)
Diarrhea (%)	11 (2)	3 (1)	195 (43)	58 (13)
Bone pain (%)	3 (1)	15 (3)	34 (8)	35 (8)

Low rate of drug discontinuation for adverse events: 10% Nexavar vs 8% Placebo
Safety profile supports chronic administration and use in combination regimens

Data from Escudier B. ECCO; November 3, 2005; Paris, France.

Advanced Renal Cell Carcinoma Sorafenib (ARCCS): Extending our Reach to Patients

- Currently approx. 2,000 patients enrolled in first and second-line RCC since June 2005
- ARCCS open at currently approx. 250 US centers



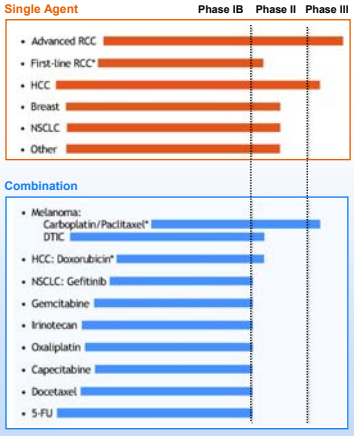
Note: some stars represent multiple sites

RCC: Adjuvant Treatment Offers Possible Long Term Protection from Tumor Recurrence

- Adjuvant therapy of RCC as systemic treatment administered to patients at high risk of recurrence after surgical removal of locally advanced primary tumor
- Nexavar safety profile supports long-term administration
- Phase III studies planned with US and European Cooperative Groups
  - Adjuvant setting for high-risk, locally advanced RCC patients
  - Planned study start 2006, study duration 6-8 years
- US study design (ECOG, US NCI):
  3-arm study including Nexavar, Sutent®, Placebo
- EU study design (MRC, EORTC):
  3-arm study to assess Nexavar
  one year treatment duration vs Nexavar three year treatment duration vs Placebo

Nexavar Clinical Development Beyond RCC

Current Clinical Program Overview



Hepatocellular Carcinoma
(Primary liver cancer)

SHARP

Phase III randomized, placebo-controlled study of sorafenib in patients with advanced hepatocellular carcinoma

Malignant Melanoma (Skin cancer)
Phase III randomized, placebo-controlled study of sorafenib in combination with paclitaxel/carboplatin chemotherapy in subjects with unresectable stage III or stage IV melanoma.

Medical Need for Treatment of Hepatocellular Carcinoma

- Hepatocellular carcinoma (HCC) is the fifth most common malignancy worldwide with about 560,000 cases each year
- The treatment needs of HCC patients are highly unmet, with no approved treatment for unresectable advanced HCC in US / EU
- Strong scientific rationale for the development of Nexavar in HCC
  - HCC tumors are highly vascularized and VEGF has been shown to augment HCC development and angiogenesis

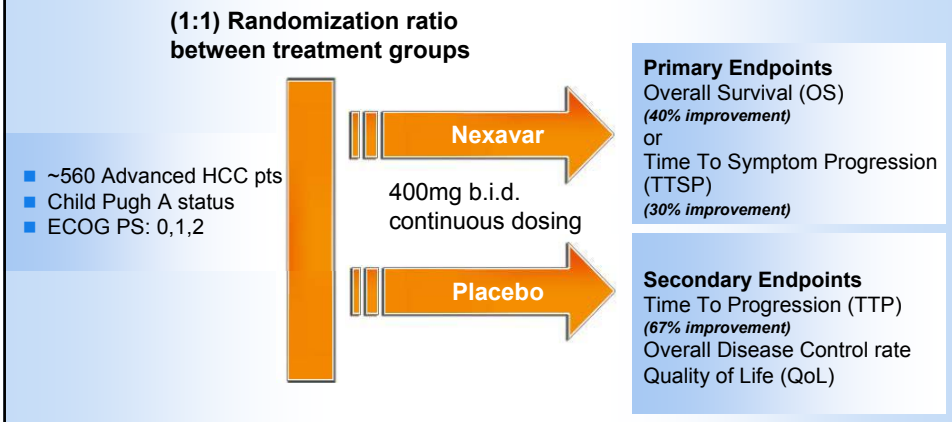
HCC: Rationale for Start of Phase III Program

- Phase II trial evaluating Nexavar 400 mg bid in 137 patients with advanced HCC
- Stable disease as best response in 55% of patients
- Time to progression median 5.7 months in patients with good hepatic function
- Median overall survival 9.2 months
- 7% rate of Nexavar discontinuation for adverse events

Duration of disease stabilization encouraging and warrants evaluation in controlled, randomized trial

Presented at the EORTC-NCI-AACR meeting, Geneva, September 2004.

Randomized Placebo-controlled Phase III Study in Patients With Advanced HCC



Data Safety Monitoring Board to advise on planned analysis of TTP during 1H'06

Melanoma: Clinical Evidence of Additive Activity with Paclitaxel / Carboplatin Combination

- Melanoma accounts for about two percent of all malignancies with an incidence of about 130,000 new cases per year worldwide
- Preliminary phase I/II experience with paclitaxel/carboplatin/Nexavar
  - Majority of patients are progression-free at 6 months (investigator assessment)
- Two phase III randomized controlled trials using paclitaxel / carboplatin +/- Nexavar
  - PRISM: Company-sponsored study
  - ECOG: US cooperative group study
- Phase II trial evaluating dacarbazine (DTIC) +/- Nexavar ongoing

*First 35 evaluable patients, presented at 40th Annual ASCO, June 2004

Epidemiology of Non Small Cell Lung Cancer (NSCLC)

- One third of all cancer deaths
- More deaths each year than prostate, colon and breast cancer combined
- Incidence (global) > 70 new cases /100,000 population
  In USA > 160,000 new cases / year and ~ 156,000 deaths / year
- Therapy
  - Stage I – IIIa: Surgery/ Radiation
  - Stage IIIb – IV: Palliation/ Chemotherapy

Nexavar Demonstrated Clinical Activity in NSCLC Phase I/II Studies

Encouraging preliminary data support phase III development

- 59% disease stabilization rate in 52 patients treated with single agent Nexavar, who had received 1-2 prior treatment regimens

  G. Blumenschein, Molecular Targets and Cancer Therapeutics Meeting, Philadelphia, November 17, 2005

- Encouraging disease stabilization and response rates in 14 patients treated with paclitaxel, carboplatin and Nexavar in a phase I combination study

  Preliminary data Bayer study 100375

Treatment of NSCLC Adds Significantly to the Value of Nexavar

- First-line treatment of advanced NSCLC using Nexavar in combination with standard chemotherapy agents
- Projected first phase III study start 1H'06 - North America and Europe
- Phase I-II program to assess possible additive benefit of combining Nexavar and bevacizumab (Avastin®)
- Extension of Nexavar to NSCLC will have significant impact on commercial potential

RCC, HCC, and melanoma combined potential: € 500 million
Addition of NSCLC increases total Nexavar potential: > € 1 billion

Prepared for US Launch

US oncology organisation in place

- Experienced sales and marketing organization hired
- Joint field team with Onyx Pharmaceuticals of approx. 100 oncology professionals
- Medical scientific liaison managers with 15+ years of oncology experience

Relationships with key market-influencing stakeholders established

- Forged strong relationship with Kidney Cancer Association
- Network of advocacy groups

Expanded access program for Nexavar running

- Advanced Renal Cell Carcinoma Sorafenib (ARCCS): Providing Nexavar to patients in need prior to approval

Key Messages

- Nexavar to establish Bayer as an emerging player in targeted cancer therapy
- Nexavar prolongs life in Phase III RCC based on clinical trial interim analysis
- Nexavar's encouraging clinical data suggest potential in cancer types beyond RCC: NSCLC as new opportunity
- Nexavar has blockbuster potential

Bayer Oncology - Committed to Deliver on Milestones 2006

1H'06

- Nexavar : US launch
- Begin phase III development in NSCLC – start first phase III study
- Initiate clinical studies in adjuvant treatment of RCC through collaboration with cooperative groups in US

2H'06

- Results of clinical trial in first-line treatment of metastatic RCC
- Nexavar: EU launch
- Initiate clinical studies in adjuvant treatment of RCC through collaboration with cooperative groups in EU

Science For A Better Life

HealthCare

Bayer R&D Investor Day 2005

December 8, 2005 | London