



# Bayer HealthCare



Bayer HealthCare Investor Day 2007

## Growth Through Our Portfolio of Marketed Products (1)

### Gunnar Riemann

Business Units Oncology, Specialized Therapeutics,  
Cardiology/Hematology  
Member of the Board  
Bayer Schering Pharma

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## 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.

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## Key Messages



- We are profiling Betaseron as most efficient first-line treatment for MS and are fueling growth through new clinical data
- We are shaping prophylactic treatment standards with Kogenate and are continuing to grow the franchise
- We are maximizing the value of our oncology assets and are aggressively exploiting the pan-tumor potential of Nexavar

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## The MS Market is Forecast to Continue its Growth Driven by High Unmet Medical Need



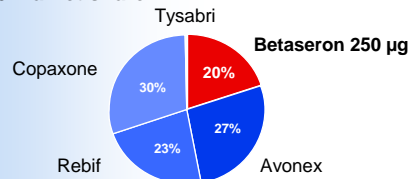
- MS – an attractive specialty market
  - Few products and competitors
  - Active and loyal patient population
  - Difficult clinical development
- Continued strong market growth expected (CAGR 7-9%)
- Competitive landscape focused on life cycle management mid-term
- New products expected to enter the market long-term, benefit/risk profiles still to be determined

### Global MS market

In €bn



### 2006 market share



**The MS market is expected to grow through novel treatment paradigms, combination therapy and indication expansion**

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# Betaseron – Steady and Strong Growth Despite Entry of Competitors into the Market



## Betaseron 250 µg:

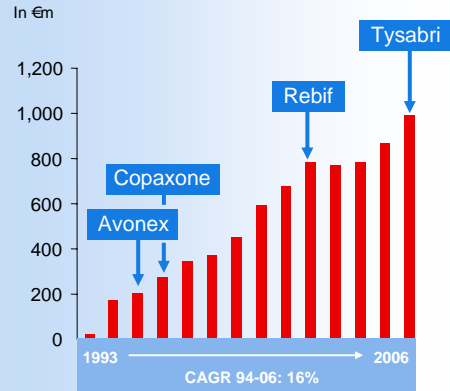
- Significant revenue growth over the past few years but loss of market share due to new entrants
- Good sales performance in 2006

## Betaseron 500 µg

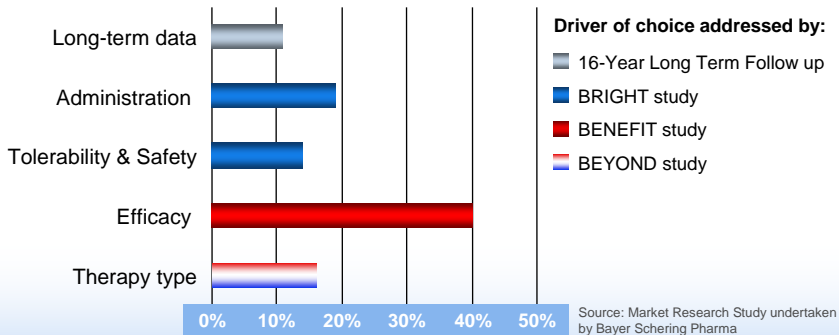
- First regulatory filings expected for Q4'07
- Target profile: superior efficacy with similar safety and tolerability vs. Betaseron 250 µg and Copaxone

## Increased focus on growing the brand

## Betaseron/Betaferon sales and U.S. launches

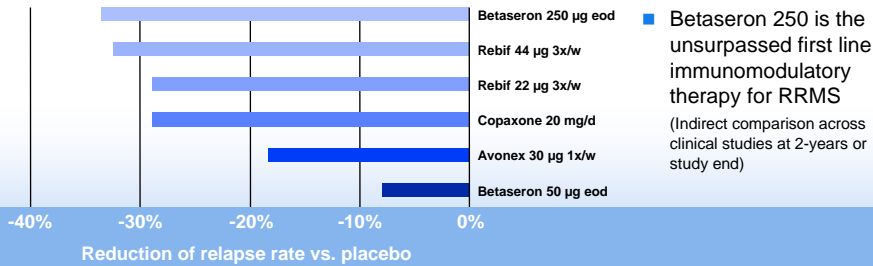


# In the MS Market Efficacy is by Far the Most Important Driver of Choice Among Physicians



**Betaseron clinical program (BENEFIT, BEYOND) expected to establish the position of Betaseron as most efficacious first-line product**

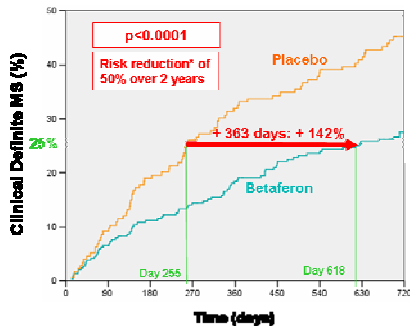
## Last Decade of Betaseron Use Proved this Drug to be Safe and Highly Efficacious



- Betaseron has a more favorable tolerability profile than Rebif in terms of the frequency and severity of injection site pain (BRIGHT Study, 454 patients, 2006)
- Direct comparative data support greater efficacy of Betaseron versus Avonex (INCOMIN trial)
- Unique 16-year follow-up study with the highest patient identification rate in MS proofed long-term safety and tolerability and demonstrated lasting efficacy

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## New Data on Betaseron Demonstrate Clear Benefits from Early-Use Treatment Paradigm



\* adjusted basis

- BENEFIT, a double blind, placebo controlled study including 468 patients to assess the impact of early vs. standard treatment of MS within a 24 month timeframe
- Early treatment with Betaseron delayed the time to a 2nd clinical event by one year compared to placebo
- Risk to develop clinical definitive MS reduced by 50 percent on an adjusted basis
- Label expansion in place in all major markets

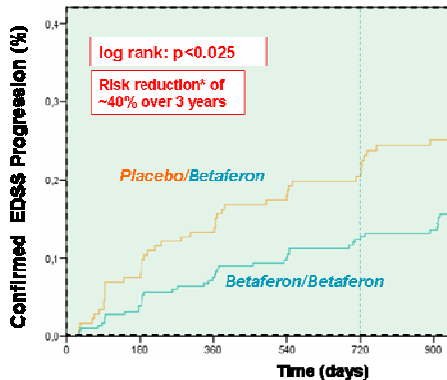
**Betaseron is the only high dose / high frequency beta-interferon approved for use in patients with the earliest signs of MS**

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## Unique Efficacy Data for MS Treatment: Betaseron has the Potential to Reduce Risk of Permanent Disability by 40%



### BENEFIT follow-up study: Time to confirmed EDSS progression



\* adjusted basis  
EDSS: Expanded Disability Status Scale

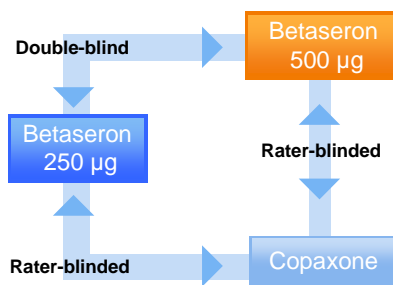
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- All patients in the BENEFIT follow-up study received Betaseron
- Objective was to assess the impact of early vs. standard treatment on the long-term course of the disease
- Patients treated immediately with Betaseron demonstrated superior cognitive functions and quality of life
- Immediate treatment of early MS patients with Betaseron reduced risk of permanent disability by 40% over 3 years
- Betaseron is the only interferon used in MS that demonstrated such new and unprecedented quality of efficacy

## BEYOND is Aiming to Strengthen the Brand by Proving Betaseron 500 to be the Most Efficacious 1st-line Therapy



- Largest multiple sclerosis study ever conducted compares Betaseron 500 µg vs. 250 µg and Copaxone
- Objective is to demonstrate superiority of Betaseron 500 over Betaseron 250 and Copaxone



- 2,244 patients, 198 centers, 26 countries
- Results of an earlier interferon dose escalation study (IDEAS) showed that most patients who tolerated Betaseron 250 µg also tolerated the 500 µg dose
- Study data expected in 2H 2007
- Regulatory filing targeted by the end of 2007

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## Betaseron Strategy Fully Implemented to Deliver Superior Clinical Profile and Long-Term Growth



### Strengthen Betaseron 250 µg (BENEFIT)

- Stabilize and grow
- Maximize early and first-line treatment
  - Delays onset and reduces risk of clinical definite MS
  - Reduces risk of progression
- Gain head-to-head data against Copaxone from BEYOND

### Launch Betaseron 500 µg (BEYOND)

- Focus on growth
- Establish Betaseron as most efficacious first-line therapy
- BEYOND expected to drive increased usage and expand market

### Betaseron franchise well positioned in changing competitive environment

- Improve profitability through agreement with Novartis
- Expand market reach

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## Betaseron Summary and Outlook



- Betaseron – steady and strong growth despite entry of competitors into the market
- New data on Betaseron from BENEFIT study demonstrate clear benefits from early-use treatment paradigm
- BEYOND is aiming to strengthen the brand by proving Betaseron 500 to be the most efficacious first-line therapy
- Regulatory filing of high-dose version targeted by the end of 2007
- Betaseron franchise well positioned in changing competitive environment
- Target to grow with the market at a mid-term CAGR of 7–9 percent



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## Key Messages



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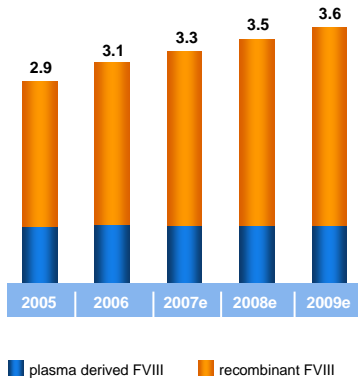
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## Recombinant Factor VIII is Expanding the Hemophilia A Market



### Estimated factor VIII market development

In € billion



- Factor VIII replacement therapy expected to remain the standard of care in hemophilia A
- The overall hemophilia market expected to grow 5% p.a. driven by stronger growing recombinant Factor VIII segment
  - Rec. Factor VIII represents 73% of the global Factor VIII market (2006) and is expected to grow by 7-9%
- Flat to declining share of plasma derived Factor VIII
- Expect no alternative treatment options or follow-on biological to enter the market mid-term

### Bayer Kogenate brand is participating in a growing market segment

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## Hemophilia Market Growth Drivers



### Shift from episodic to prophylactic treatment

- Main factor driving global market growth
- Increasing evidence for improved clinical outcome
- Requires drug infusion several times a week
- Consistent, safe product supply permits higher volumes needed for prophylactic treatment regimen

### Aging patient population

- Weight dependent dosing of factor VIII – older patients typically gain weight

### More convenient application systems

- Improving convenience, compliance and quality of life of the patients

### Substitution of plasma derived factor VIII by recombinant product

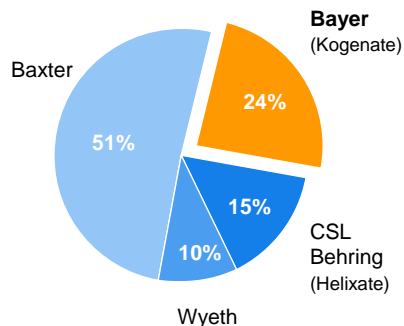
- Some potential in emerging markets (Eastern Europe, Middle East, Asia) – almost complete conversion to recombinant product in the U.S. and Western Europe

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## Our Kogenate Franchise is Well Positioned in the Recombinant Factor VIII Market



### Global rec. Factor VIII market in 2006 €2.3 billion



- The Kogenate brand gained 3 percentage points market share since 2004
- Continuous geographic expansion
- Market participation through own Kogenate brand and through Helixate partnership with CSL
- Helixate contract extension 2010-2017 to maintain and expand market reach
- Proven safety and efficacy based on more than 18 years of clinical experience and over 7 billion IUs infused
- Hemophilia market growth drivers are being addressed

2006 reported sales for Kogenate of €787m include approx. 30 percent active ingredient sales to CSL Behring

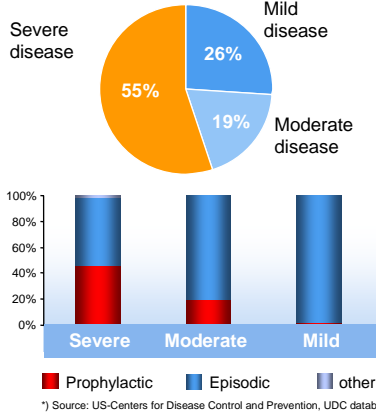
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# Episodic Treatment Still Dominating Among Hemophilia A Patients in the U.S.



## Degree of hemophilia and treatment type\*



\*) Source: US-Centers for Disease Control and Prevention, UDC database

- The majority of U.S. hemophilia patients is still on episodic treatment
- Across all U.S.-patients groups, only 29% are using prophylactic treatment regimens
- Prophylaxis penetration above 50 percent in Western Europe
- Increasing evidence of medical benefit for prophylactic treatment (Joint Outcome Study)
- Our R&D approaches to minimize frequency of administration should increase the share of prophylactic treatment significantly

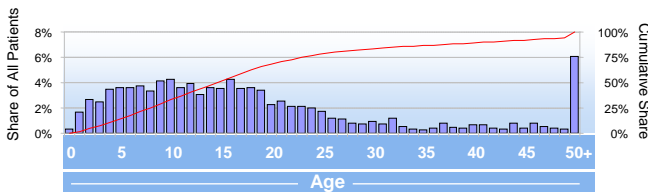
## Prophylaxis is the key growth opportunity in the factor VIII market

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# Healthy Aging Population: Patient Age and Weight Distribution in the U.S. Market

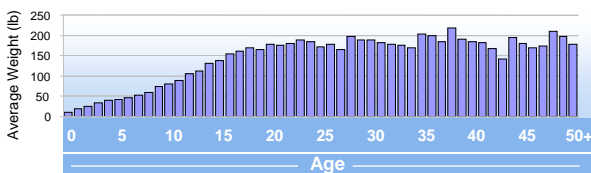


## Hemophilia A Patient Age Distribution (2006)



- Average age of hemophiliacs is lower than that of the general population
- FVIII dosing based on weight: hemophiliacs will require more FVIII as their weight increases with age
- Aging population will drive FVIII consumption by approx. 3% annually

## Average Weight of Hemophilia A Patients by Age (2006)

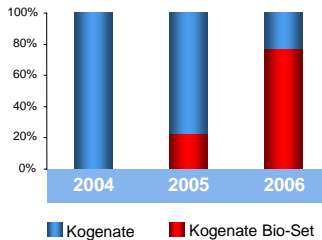


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## Bio-Set - Best Application System in the Market Breaks Barriers for Compliance and Prophylaxis



### Bio-Set penetration of brand sales



- Innovative, first to market, self-contained, simple, needle-less reconstitution system
- Launched in all major markets
- Bio-Set ranked as most preferred reconstitution device vs. competition\*
  - Safety from needle sticks (90%)
  - Easy to use (78%)
  - Speed of preparation (78%)
  - Storage convenience (81%)
- Bio-Set reconstitution system has already achieved 80% share of Kogenate brand sales

\*Bayer commissioned market research study with prescribers and patients against BaxJect and conventional needles

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## Kogenate Summary and Outlook



- Kogenate outperformed the hemophilia market in the last 5 years, posting attractive double digit growth rates against a market that grew 7–9 percent
- Kogenate is targeting continued growth through exploitation of all life cycle management opportunities
- Bayer is leading the race for the next generation, less frequent dosing product: the only company with a long-acting product in clinical trials
- Bayer is increasing investment to drive growth, increase share and expand its portfolio into related areas
- Attractive growth potential going forward – targeting mid-term CAGR of 8–10 percent



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## Key Messages








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## Our Basis for a Growing Presence in Oncology

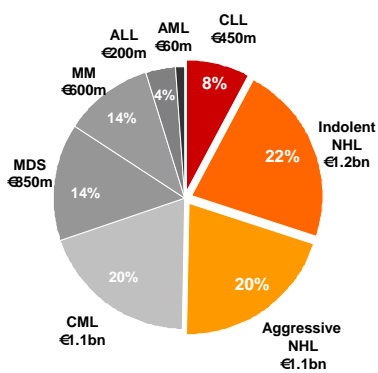


Product	Approved indication	2006 sales (in € m)	% y-o-y
 <b>Nexavar</b> (Sorafenib)	Metastatic Renal Cell Cancer	130	•
 <b>Fludara</b> (Fludarabine)	Chronic Lymphocytic Leukemia	120	14
 <b>Campath</b> (Alemtuzumab)	Chronic Lymphocytic Leukemia (3 <sup>rd</sup> -line)	76	10
 <b>Leukine</b> (Sargramostim)	Blood cell growth stimulator in hematological cancers	68	15
 <b>Zevalin</b> (Ibritumomab Tiuxetan)	Non-Hodgkin's Lymphoma (2 <sup>nd</sup> -line)	14	115

Portfolio of innovative and established cancer drugs in place

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## We Have a Foothold in Hemato-Oncology and are Exploiting Growth Opportunities to Realize Full Commercial Potential



CLL: Chronic lymphocytic leukemia; NHL: Non-hodgkin's lymphoma; CML: Chronic myelogenous leukemia; MDS: Myelodysplastic syndromes; MM: Multiple myeloma; ALL: Acute lymphocytic leukemia; AML: Acute myelogenous leukemia

Source: BSP Internal Analysis

- Hemato-oncology is a €6 billion market (2006)
- Expected market growth: 10-12% p.a.
- New indications and novel products are main growth drivers
- Existing portfolio expanded into additional indications:
  - Campath: 1st- and 2nd-line treatment of CLL
  - Fludara: oral formulation for CLL therapy
  - Zevalin: 1st-line treatment of indolent NHL (FIT-trial)
  - Zevalin: 1st-line treatment of aggressive NHL (ZEAL-trial)

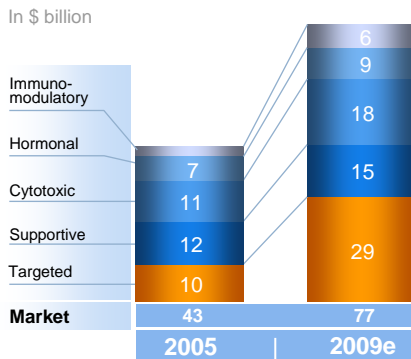
Liquid tumor portfolio is actively pursued – exploiting all options to realize the full commercial potential

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## Oncology Market Growth Driven by Unmet Medical Need and Demographic Trends



### Worldwide oncology sales by market segment



Source: Evaluate 2005

- Targeted therapy segment with twice the growth potential of oncology market:
  - Market growth: 16% CAGR 05-09e
  - Targeted therapies: 30% CAGR 05-09e
- Novel targeted therapies addressing only modest number of tumor types
- Expansion into multiple tumor types with high unmet medical need, new therapies and demographics is driving growth

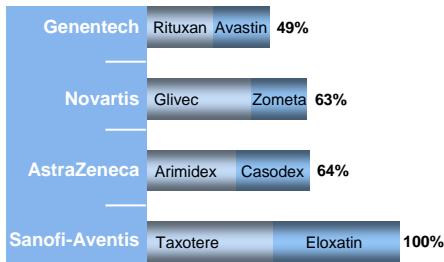
Targeted therapies are driving the paradigm shift in cancer therapy

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## Few Assets Dominate Leading Oncology Portfolios



### 2006 sales share of top 2 products in oncology franchises for major oncology players



Source: Annual Reports 2006 –  
(Genentech sales exclude Roche Sales of \$ 5 Billion)

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- One powerful asset can build a strong oncology franchise
- Top oncology portfolios comprise few major product
- Significant potential for pan-tumor drugs through label expansion into multiple and major tumor types

## Nexavar – A Franchise Building Opportunity



**Nexavar**  
(sorafenib) tablets

- Established global brand in kidney cancer (€130m sales in 1st year after launch)
- Dual mechanism – antiangiogenic & antiproliferative
- Established efficacy in more than one tumor type
- Manageable side-effect profile
- Nexavar has now been approved for treatment of RCC in more than 50 countries and launched in 27 countries
- Submitted for approval in hepatocellular carcinoma (liver cancer)
- >170 clinical studies ongoing

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## Nexavar is an Effective Treatment for Appropriate 1st-line and all 2nd-line RCC Patients



- **Nexavar is appropriate in first-line for some advanced RCC patients.**
  - Physicians have had good first-line experience based on ARCCS data
  - Patients who are unsuitable for other agents or have pre-existing conditions are good candidates for Nexavar
- **Approximately 80% of all first-line patients will progress to second-line therapy.**
- **Nexavar is well positioned to “own” second line.**
  - The largest phase III study in second-line was conducted with Nexavar
  - Tolerability profile makes it ideal for patients switching from first line therapies at the first sign of adverse events or disease progression

ARCCS: Advanced renal cell carcinoma sorafenib expanded access trial in North America

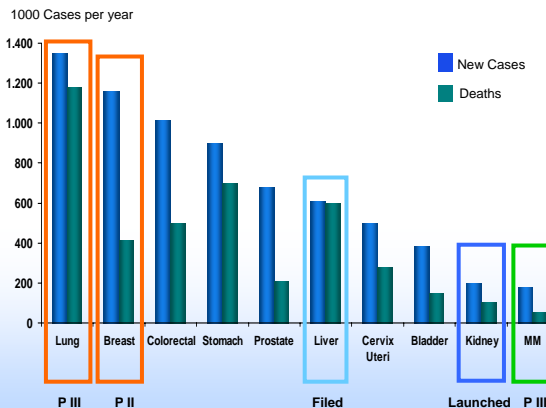
**Nexavar is strong in RCC monotherapy and is expected to have significant further potential in combination therapy**

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## Expanding Nexavar's Reach Into Large Tumor Types



### Proof of concept for pan-tumor activity established



Source: Globocan 2002, ranked by incidence

- Comprehensive development program in place to exploit full commercial potential
- Competitive advantages
  - Manageable side-effect profile
  - Combinability due to non-overlapping toxicity
- Potential to become a standard of care in common tumors

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# Nexavar is Significantly Ahead of Competition in HCC



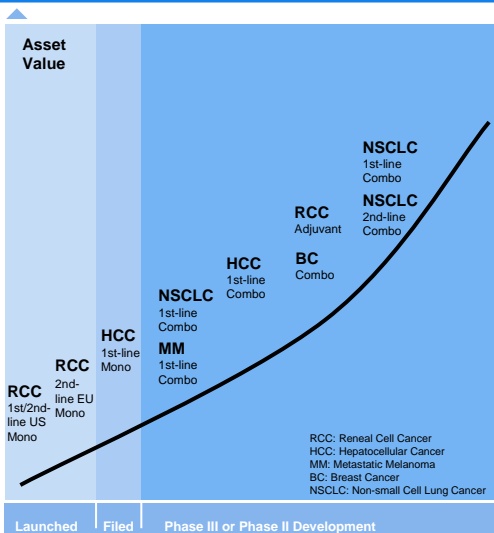
## Targeted cancer therapies in clinical development for treatment of HCC

Launched	No approved agent for unresectable disease in U.S. or EU
Filed	Nexavar
Phase III	-
Phase II	Avastin Tarceva Sutent Other

- No current standard of care in HCC defined; only few chemotherapies demonstrated meaningful activity
- Nexavar's SHARP trial demonstrated 44% improvement in overall survival in HCC
- Submitted in EU, U.S. by end of June – potential market entry in early 2008
- Nexavar has sizeable lead over all other targeted therapies in development for HCC
- Nexavar expected to become the reference standard of care for the first-line treatment of HCC
- Further expansion into other treatment regimens for HCC planned
- Overexpression of Raf in HCC patients favors Nexavar's mode of action

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# Building a Substantial Oncology Franchise on Nexavar's Potential



- We are maximizing the value of Nexavar through:
  - Expanding into major tumor types
  - Exploiting full potential of monotherapy and becoming preferred partner in combination therapy
  - Capturing 1<sup>st</sup> - and 2<sup>nd</sup>-line treatment regimens
  - Expanding into the adjuvant setting
- We are exploiting Nexavar's full potential in attractive markets:

Market	Size 2015e (\$bn)
RCC	1 - 2
HCC	2 - 6
MM	1 - 2
BC	5 - 10
NSCLC	10 - 15

Source: Market / Analyst Reports

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## Oncology Summary and Outlook



- Our oncology franchise has been significantly broadened through the acquisition of Schering
- Nexavar is the cornerstone of Bayer's oncology franchise
- First-to-market targeted therapy in RCC
- Chance to enter the HCC market as standard of care and clearly ahead of competition
- Pan-tumor activity of Nexavar expanding into major tumor types
- Expect to grow our oncology franchise at a CAGR of 17–20 percent mid-term
- We will build our portfolio through internal R&D capabilities and partnerships

