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# **A Focused Bayer Pharma**

## *Growth Potential & Promising Pipeline*

Exane - Pharma Conference 2004  
Paris, May 11, 2004

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President Pharmaceutical Division



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## **Safe Harbor**

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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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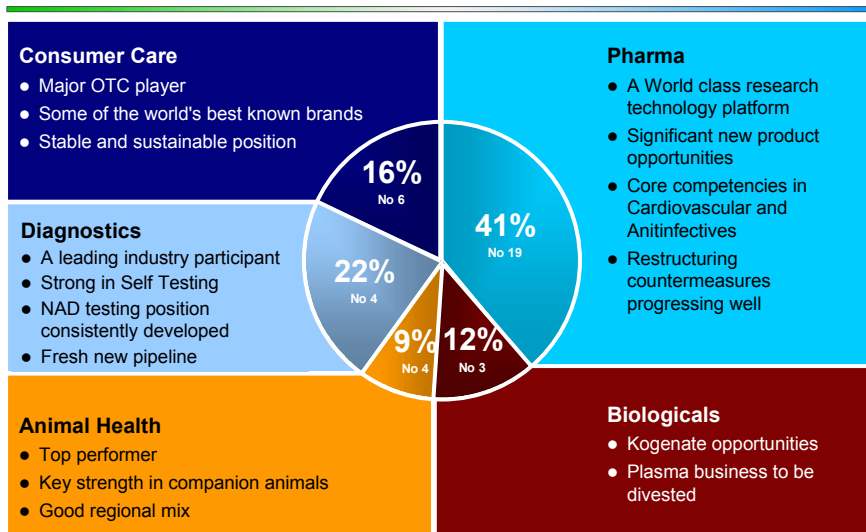
# Agenda

- Bayer HealthCare overview
- Bayer Pharma is on track with its turnaround
- Growth potential in our portfolio
- Bayer Pharma is creating exciting new product opportunities

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## Bayer HealthCare<sup>1)</sup> – Strategic Position



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<sup>1)</sup> Sales breakdown based on 2003 sales of € 8,871m



## Business performance - Q1 / 2004 - Bayer HealthCare & Pharma/Biological Products

|                                     | 2003  | 2004  | Change | Change               |
|-------------------------------------|-------|-------|--------|----------------------|
| [ EUR Million ]                     | Q1    | Q1    | in %   | in loc.curr.<br>in % |
| <b>Bayer HealthCare</b>             |       |       |        |                      |
| Net Sales                           | 2,108 | 2,124 | + 0.8  | + 8.9                |
| EBIT                                | 488   | 277   | - 43.2 |                      |
| EBIT clean                          | 288   | 277   | - 3.8  |                      |
| <b>Pharma / Biological Products</b> |       |       |        |                      |
| Net Sales                           | 1,131 | 1,176 | + 4.0  | + 12.6               |
| thereof Pharma                      | 881   | 906   | + 2.8  | + 12.6               |
| EBIT                                | 203   | 164   | - 19.2 |                      |
| EBIT clean                          | 182   | 164   | - 9.9  |                      |

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## Restructuring measures implemented since 2002 will achieve net savings of at least €650 million

Net savings impact until 2006

### Research and Product Development

approx. €360 million

- Site consolidation: Stoke Court, Kyoto
- Exit CNS and Respiratory research
- Focus Biotech activities in Berkeley

### Technical Operations

approx. €110 million

- Site consolidation: West Haven, Elberfeld, Shiga
- Closure of facilities: Spain, Portugal, France, Korea, Thailand

### Others

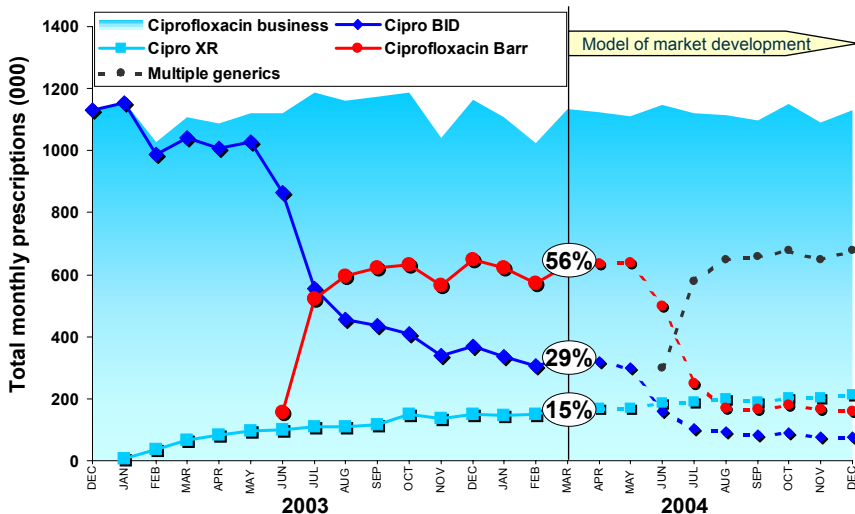
approx. €180 million

- Divestment of Generics business
- Centralization of service functions: procurement, O&I, legal



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## From June 2004 multiple generics for Cipro BID will hit the market - through Cipro XR we will still maintain a sizeable part of the ciprofloxacin business

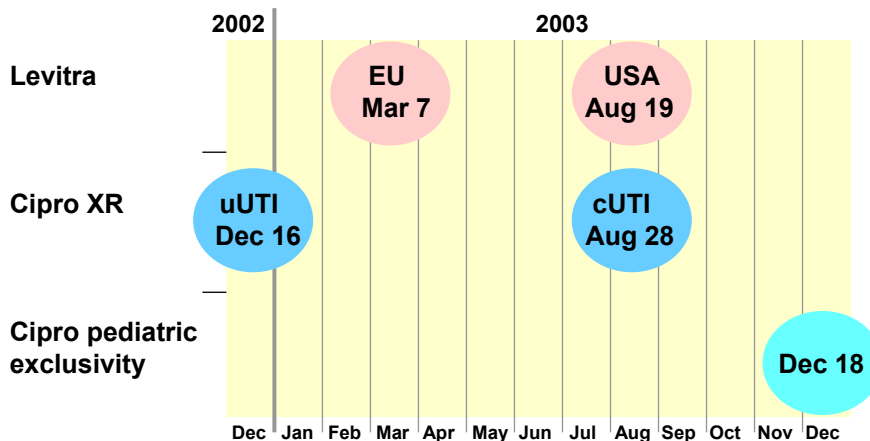


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Source: IMS



## Product approvals in 2003 will enable future growth and increase short term predictability for Pharma



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## Pharma Pipeline is maturing

January 2004

| Project   | Indication     | Status       | Expected Launch >2005 |
|---|----------------|--------------|-----------------------|
| Signal Transduction Inhibitor<br>BAY 43-9006 (Raf Kinase Inhibitor) | Cancer         | Phase III    | ■                     |
| Repinotan (Branosyn)  | Stroke         | Phase IIb    | ■                     |
| Factor Xa Inhibitor   | Cardiovascular | Phase IIb    | ■                     |
| Taxane  | Cancer         | Phase II     | ■                     |
| 11 Projects   |                | Phase I      |                       |
| 18 Projects   |                | Pre-clinical |                       |

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## As mid-sized player we focus our business

*Focus is key strategic driver for Pharma*

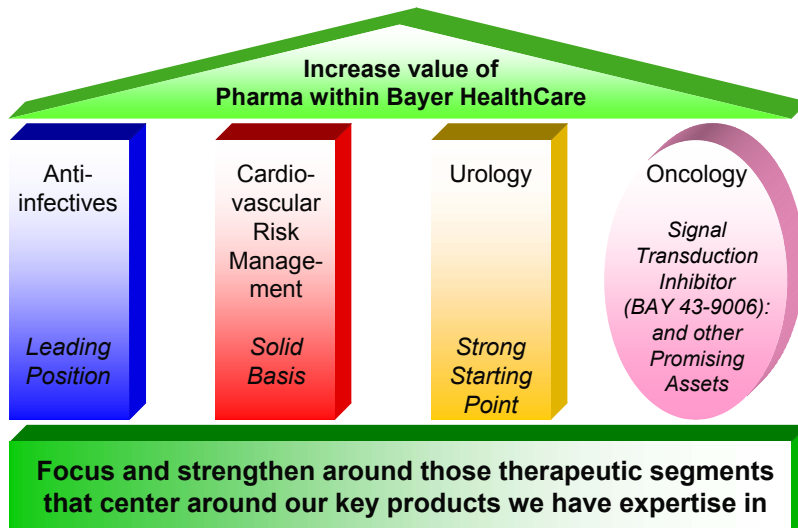
|                 |  |
|-----------------|--|
| Segment Focus   | Focus on segments where leadership can be realistically achieved   |
| Specialty Focus | Within our core segments increase the proportion of specialist-driven businesses with moderate to low marketing costs                              |
| Regional Focus  | Differentiated regional co-operations/alliances, licensing and resource allocation to strengthen and fully maximize the potential of our portfolio |

Align structure, costs and behavior to be competitive to other mid-sized companies

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## Segment focus on selected core areas



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## There is growth momentum in a significant part of our product portfolio

Worldwide sales Q1/2004

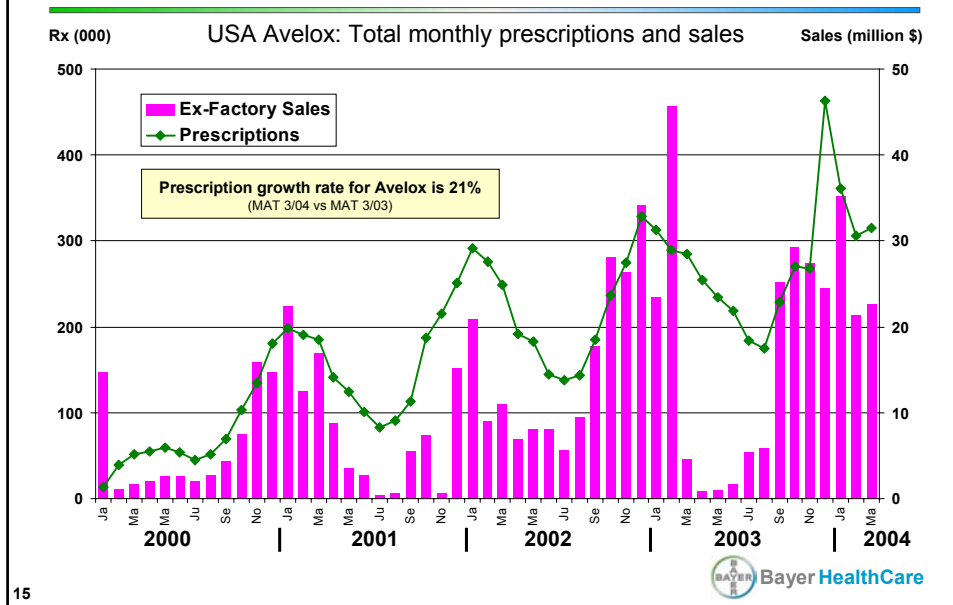
|                 | Sales<br>in € million | Δ % yoy<br>in local currency |
|-----------------|-----------------------|------------------------------|
| Avelox          | 104                   | 6%                           |
| Glucobay        | 73                    | 11%                          |
| Levitra         | 66                    | ●                            |
| Trasylol        | 43                    | 22%                          |
| Aspirin Cardio  | 33                    | 42%                          |
| Adalat CR Japan | 28                    | 23%                          |
| Cipro XR*       | 20                    | - 22%                        |

\* lower sales in 2004 due to launch stocking in 1st quarter 2003

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## Avelox Performance in the US since Launch

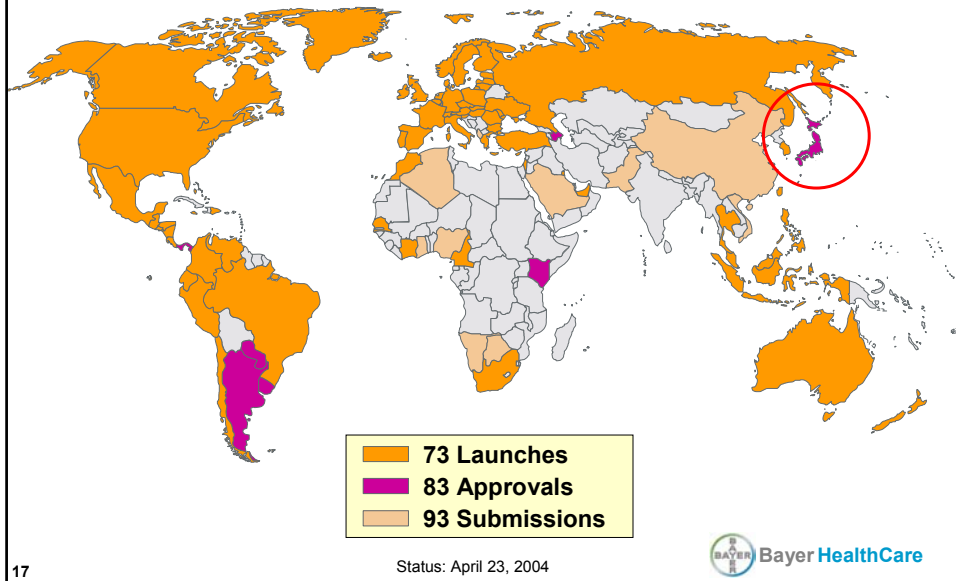


**Avelox is the only RTI antibiotic that has been shown to be superior in all three major RTI indications against standard therapy**

| Indication                                  | Publication                           | Avelox<br>vs standard therapy<br>demonstrated                 |
|---|---------------------------------------|---|
| Acute Exacerbation<br>of Chronic Bronchitis | Chest 2004<br><i>Wilson et al *</i>   | significantly higher<br>clinical cure<br><b>71% vs 63%</b>    |
| Community Acquired<br>Pneumonia             | AAC 2002<br><i>Finch et al</i>        | significantly higher<br>clinical success<br><b>93% vs 85%</b> |
| Acute sinusitis                             | Resp Med 2000<br><i>Siebert et al</i> | significantly higher<br>clinical success<br><b>97% vs 91%</b> |



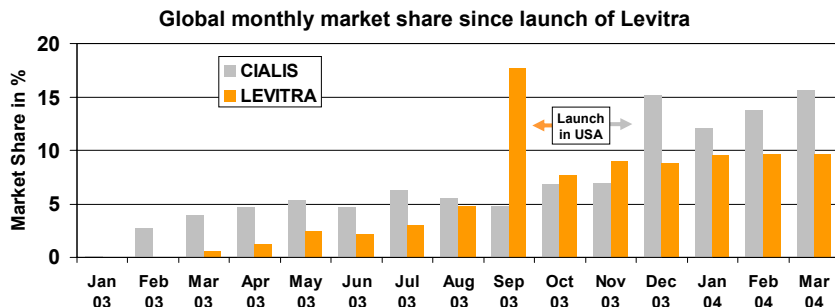
## Levitra: 61 Launches within 1 year - we will enter the Japanese market at the end of June



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## Positive impact of Levitra® on the Pharma business of Bayer HealthCare

- Sales since launch: Euro 200 million (until March 2004)
- Sales in first quarter 2004: Euro 66 million
- One million prescriptions in the US since launch



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Source: IMS/MIDAS (10 main countries)

## New clinical data strongly support quality of Levitra

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- **Improved erections in 83%** of patients while improving depression and self esteem scores <sup>1)</sup>
- **Levitra has the most rapid onset (10 minutes) to date** of any PDE-5 inhibitor on the market <sup>2)</sup>
- **Levitra has been shown to last up to 12 hours** for the treatment of ED <sup>3)</sup>

1. (DRIVER) Efficacy and tolerability of vardenafil in men with mild major depressive disorder and erectile dysfunction: the Depression Related Improvement with Vardenafil for Erectile Response study: Rosen R. et al; European Association of Urology March 24.

2. (ONTIME) Onset of Vardenafil In Men with Erectile Dysfunction study: Montorsi F. et al.; 7<sup>th</sup> Congress of the European Federation of Sexology 12-16 May 2004, Brighton, UK

3. Presented at the World Congress on the Aging Man, Stief et al., Prague, February 2004



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## “... Levitra offers patients what they want!” concluded Professor Montorsi

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- ... **rapid onset was considered important irrespective of age** ... <sup>1)</sup>
- Independent studies find **most men (47%) prefer Levitra** over other PDE5 inhibitors due to ease of getting an erection and consistent efficacy (hardness) <sup>2)</sup>

1. (MALES) Rapid Onset vs. Long Duration of Action: Effect of Age and Comorbidity on Attribute Ranking in The Men's Attitudes to Life Events and Sexuality study; Eardley I. et al., 7<sup>th</sup> Congress of the European Federation of Sexology 12-16 May 2004, Brighton, UK

2. (PREFERENCE) Interim report by Sommer F. et al, Department of Urology, University Medical Centre Cologne, Germany, European Association of Urology March 24



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## **BAY 43-9006 - Signal Transduction Inhibitor: Promising potentially first in class cancer treatment**

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- Dual mechanism of action:
  - Raf Kinase activity - inhibits tumor cell proliferation
  - VEGFR-2 activity - inhibits tumor angiogenesis
- Well tolerated for long-term administration
- 68% of the patients (N=50) with renal cell carcinoma (RCC) had disease control (tumor stabilization or some tumor shrinkage) in preliminary data from a phase II study \*

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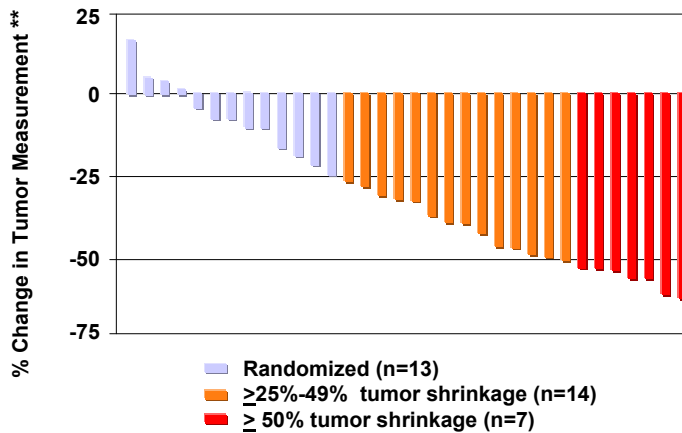
\* By Investigator assessment at 12 weeks,  
as reported at the AACR/NCI/EORTC meeting 11/03



## BAY 43-9006 - Signal Transduction Inhibitor: Phase II interim results in renal cell carcinoma (RCC)

### Tumor Measurements at 12 Weeks

RCC Patients (n=34\*)



\*Includes patients randomized or continued on BAY 43-9006: progressors, AE/other not included

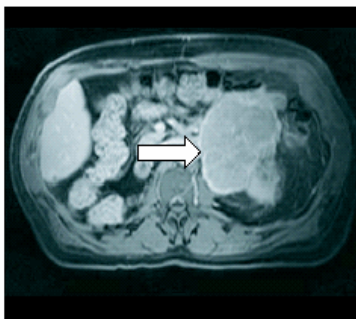
\*\* Investigator assessed (1 patient with 22% tumor shrinkage classified as responder)

As reported at the AACR-NCI-EORTC in 11/03

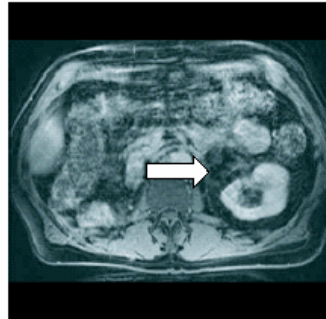


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## BAY 43-9006 - Signal Transduction Inhibitor: Encouraging results in the treatment of renal cell carcinoma (RCC)



Before



After 16 weeks

The left scan shows a patient with kidney cancer that has spread to other internal organs. The tumor mass is identified with the arrow. The right image depicts the same area after treatment with BAY 43-9006. Note the reduction in the tumor size.

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Flaherty KT, et al. Proceedings of the AACR-NCI-EORTC International Conference 2003; 69:A78



## BAY 43-9006 - Signal Transduction Inhibitor: Various phase III and phase II trials ongoing

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- Phase II study in renal cell carcinoma - ongoing
- Phase III study in renal cell carcinoma (RCC)  
- initiated October 2003
- Phase II study in hepatocellular carcinoma - ongoing
- Phase I/II (BAY 43-9006 in combination) in melanoma - ongoing
- Efficacy signals from ongoing phase I and II studies will be evaluated for choosing other potential tumor types to take into phase III

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*As reported at the AACR-NCI-EORTC in 11/03*



## New studies on BAY 43-9006 to be published at ASCO, June 6-8, 2004, New Orleans

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- BAY 43-9006 in **advanced melanoma**
- Phase I/II trial of BAY 43-9006, carboplatin (C) and paclitaxel (P) in **metastatic melanoma**
- Phase II trial of BAY 43-9006 in **metastatic renal cell carcinoma** and other **advanced refractory solid tumors**
- Phase I/II trial of BAY 43-9006 and gemcitabine in **advanced solid tumors** and in **advanced pancreatic cancer**
- Phase I study of BAY 43-9006 in **myelodysplastic syndrome (MDS)** or **acute myeloid leukemia (AML)**
- Phase I trial of BAY 43-9006 in combination with doxorubicin in **refractory solid tumors**
- Phase I trial of BAY 43-9006 in combination with oxaliplatin in **refractory solid tumors**

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## FDA grants “fast track”-status to Bay 43-9006 - Signal Transduction Inhibitor

### Fast Track

- Designed to expedite the drug review for the treatment of patients with serious or life-threatening diseases with an unmet medical need
- Allows to file a NDA on a rolling basis as data becomes available. The FDA reviews the filing as it is received
- Possibility of a priority review, which could decrease the typical review period

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## Major Unmet Medical Need for Anticoagulant Treatment

X = meets medical need

| Medical need    | Current Therapy   |             |
|-----------------|---|-------------|
|                 | Warfarin  | LMW heparin |
| Safety concerns | Narrow therapeutic window<br>(bleeding vs risk of stroke) | X           |
| Monitoring      | Need for regular monitoring                               | X           |
| Convenience     | X (oral)  | Injections  |
| Interactions    | Drug / food interactions                                  | X           |

“One of the greatest unmet medical needs is for an oral anticoagulant that overcomes the interactions, safety concerns and need for monitoring that have limited the use of warfarin”

(Nature, Vol. 2, Jan. 2003 p. 11)

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LMW = low molecular weight



## **BAY59-7939 - Factor Xa inhibitor: Based on encouraging data - phase IIb was initiated end of 2003**

| <b>Medical need</b> | <b>Factor Xa inhibitor characteristics</b>  |
|---------------------|---|
| Safety              | <ul style="list-style-type: none"><li>- well tolerated and safe</li><li>- no evidence for excessive bleeding</li></ul>  |
| Monitoring          | <ul style="list-style-type: none"><li>- no need for routine monitoring</li><li>- predictable pharmacodynamic effects</li><li>- dose-dependent inhibition of Factor Xa</li></ul> |
| Convenience         | <ul style="list-style-type: none"><li>- oral, small easy to swallow tablet</li></ul>  |
| Interactions        | <ul style="list-style-type: none"><li>- reduced risk of drug - drug and food interactions (compared to warfarin)</li></ul>  |

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Source: based on findings of clinical studies



## **Bayer Pharma - strategic direction clarified**

- Focus Bayer Pharma and strengthen portfolio
- Drive growth of Avelox, Levitra and protected portfolio
- Move promising development projects into Phase III and beyond
- Build-up oncology business

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