HealthCare

Bayer R&D Investor Day 2005

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BAY 59-7939:
A Novel, Oral, Direct Factor Xa Inhibitor

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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.

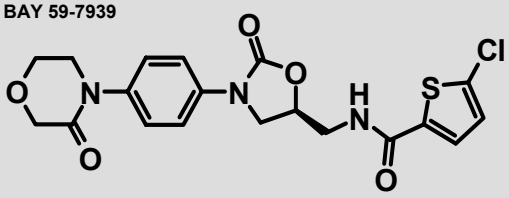
Key Messages

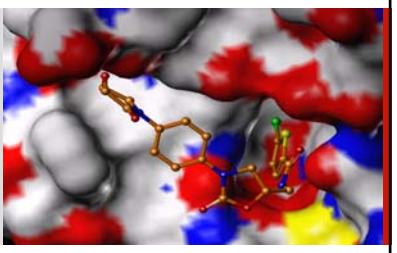
- Driving a potential paradigm shift in treatment of thromboembolic disorders
- Attractive market growth potential
- Maximizing the value of a significant pipeline asset through partnership with Johnson & Johnson
- Initiation of phase III studies in prevention of VTE with once-daily dosing
- On track to start phase III in chronic indications in 2006

BAY 59-7939:
A Novel, Oral, Direct Factor Xa Inhibitor

- New chemical class;
  molecule was optimized using structure-based design processes
- Oral with a very high bioavailability
- Direct mechanism of action: no need for cofactors
- Highly selective: very limited effects outside coagulation
- Potent antithrombotic in both venous and arterial studies

BAY 59-7939

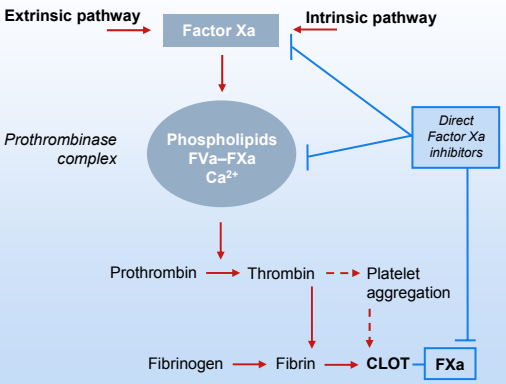




Roehrig *et al.* J.Med.Chem. 2005, 48, 5900-5908

Factor Xa Inhibition Regulates Coagulation Pathway at the Pivotal Point

Oral BAY 59-7939
The coagulation cascade regulator



Advantages of factor Xa inhibition

- Avoids the thrombin burst
- Regulates coagulation (no blocking)
- Leaves primary hemostasis intact
- No rebound after cessation
- Limited effects outside coagulation

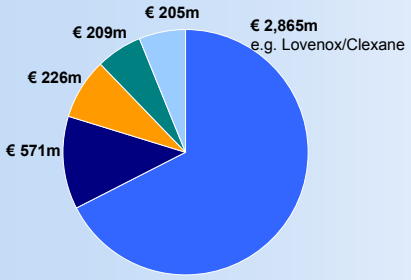
Advantages of direct factor Xa inhibition

- No need for cofactors, independent of antithrombin

Oral Factor Xa Inhibitors Will Compete with Both Oral and Injectable Anticoagulants

Sales world-wide

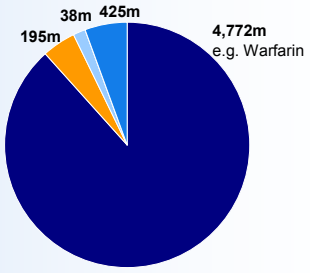
2004: € 4.079 million, growth 5.4%



- Vitamin K antagonists (oral)
- Low molecular weight heparins LMWH (injectable)
- Unfractionated heparins UFH (injectable)
- Direct thrombin inhibitors DTI (injectable)
- Other injectables

Volume world-wide

2004: SU* 5.433 million, growth 8%



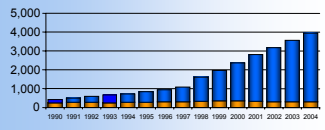
*SU: Standard unit
Source: IMS Health, PADDs, MAT Q4 2004

A New Oral Anticoagulant has the Potential to Redefine the Market

- The anticoagulant market has shown to be receptive for new and improved treatment regimens
  - Expanding the market by growing overall treatment volumes
  - Expanding the market by switching from less efficient treatment regimes to products offering improved clinical outcomes
- A new safe and effective, easy to use oral drug will stimulate
  - More patients to benefit
  - Longer treatment duration
  - Upgrade of the market

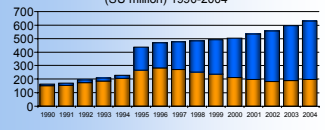
The Anticoagulant Market has shown to be receptive for new and improved treatment regimens

World-wide Heparin sales
(US$ million) 1990-2004



UFH LMWH

World-wide Heparin volume
(SU million) 1990-2004



Source: IMS Health, PADDs, MAT Q4 2004

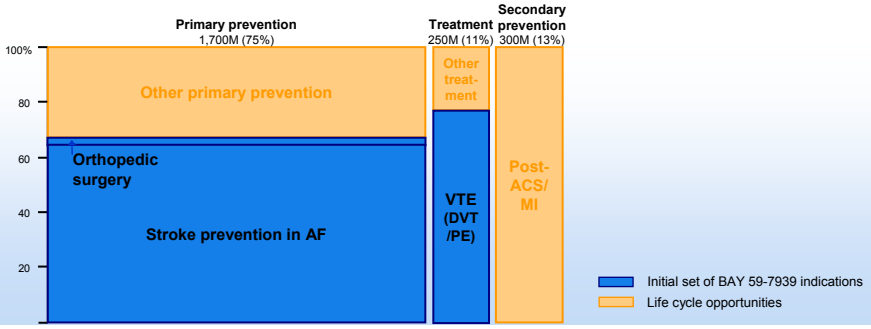
BAY 59-7939: Clinical Potential in Key Market Segments

Primary prevention	Treatment	Secondary prevention
Stroke prevention in: ▪ Atrial fibrillation ▪ Prosthetic heart valve patients	▪ Acute coronary syndrome/Myocardial infarction ▪ Ischemic stroke ▪ Pulmonary artery occlusive disease	▪ Post-Acute coronary syndrome/Myocardial infarction ▪ Ischemic stroke ▪ Pulmonary artery occlusive disease
Prevention of venous thromboembolism ▪ Orthopedic surgery ▪ General surgery ▪ Gynecologic surgery ▪ Non-surgical / medically ill	▪ Deep vein thrombosis/ Pulmonary embolism	▪ Deep vein thrombosis/ Pulmonary embolism

• Arterial indications • Venous indications

The Greatest Need and Opportunities lie in Stroke Prevention in Atrial Fibrillation (AF)

Potential treatment days by indication (major markets)



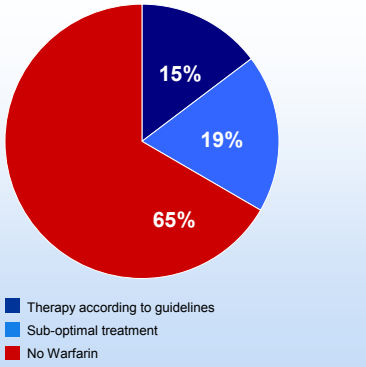
- Major market opportunities in chronic indications
- First indications for BAY 59-7939 focus on major market opportunities and where fastest market entry can be secured
- Additional life cycle indications under consideration

Stroke Prevention in AF: The Limitations of Warfarin Lead to Inadequate Treatment

- **84% of AF patients receive suboptimal treatment for stroke prevention in AF**

Limitations of Warfarin

- Slow onset of action
- Highly variable dose-response relationship
- Narrow therapeutic window
- Drug-drug interactions
- Drug-food interactions
- Dose titration
- Time- and cost-intensive coagulation monitoring and frequent dose adjustments



Samsa et al, Arch Intern Med, 2000

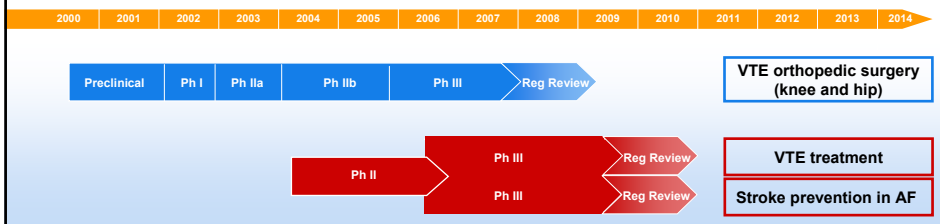
An Ideal Anticoagulant Should Have …

	BAY 59-7939 has:	
Oral administration	Convenient use both in and out of hospital	✔
Predictability	Safe and effective regulation of coagulation from the first dose and throughout therapy	✔
Wide therapeutic window	Broad safety margin at a wide range of effective doses	✔
No dose adjustment	Fixed doses for the majority of patients provide predictable outcomes without the need for dose adjustments	✔
No monitoring	No need for laboratory monitoring saves healthcare costs through fewer hospital / physician visits and patients' time	✔
Low risk of food and drug interactions	Hassle-free use regardless of concomitant use of other medication / diet	✔

… based on current knowledge

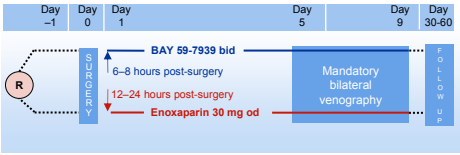
BAY 59-7939: Parallel Clinical Development

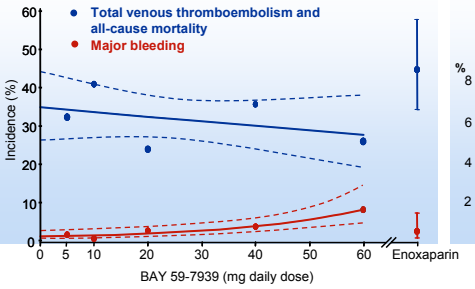
- Primary prevention of VTE after elective orthopedic surgery (hip and knee)
  - Fastest market entry of all indications (shortest treatment duration)
  - An excellent model to evaluate both safety and efficacy
- Treatment of VTE and long-term secondary prevention
  - A simple-to-use oral drug has many potential clinical uses
- Primary prevention of stroke in patients with AF
  - Commercially the largest indication with high unmet medical need

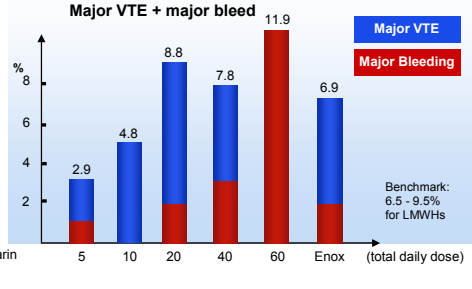


KNEE - BID: Oral BAY 59-7939 Demonstrated Safety and Efficacy Similar to sc Enoxaparin

To evaluate the efficacy and safety over a 12-fold dose range (2.5, 5, 10, 20, and 30 mg) bid of the oral, direct factor Xa inhibitor BAY 59-7939 for the prevention of VTE after total knee replacement, relative to post-operative sc enoxaparin

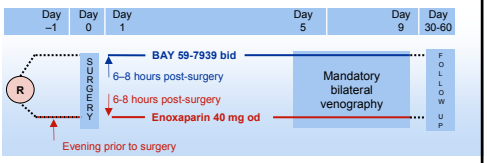


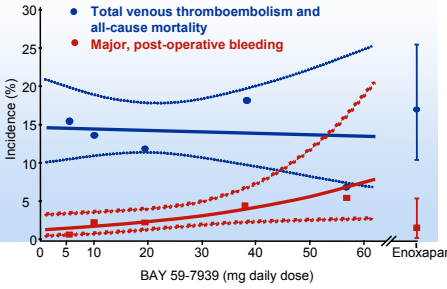


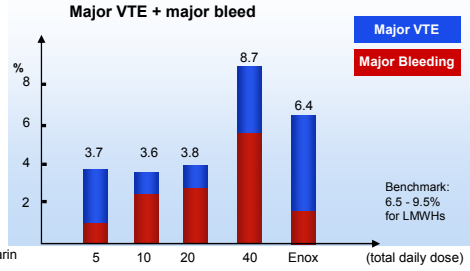


HIP - BID: Oral BAY 59-7939 Demonstrated Safety and Efficacy Similar to sc Enoxaparin

To determine the efficacy and safety over a 12-fold dose range (2.5, 5, 10, 20, and 30 mg) bid of the oral, direct factor Xa inhibitor BAY 59-7939, for prevention of VTE in patients undergoing elective total hip replacement, relative to sc enoxaparin







VTE Prevention BID Dose Finding Studies - Summary

- Oral BAY 59-7939 (bid, daily doses of 5–20 mg) showed similar efficacy and safety to subcutaneous enoxaparin for VTE prevention in patients undergoing total hip[1] or knee[2] replacement
- BAY 59-7939 has a wide therapeutic window
- BAY 59-7939 was well tolerated
- No dose-arm had to be discontinued due to safety concerns or lack of efficacy
- No monitoring or dose-adjustment required for weight or gender with BAY 59-7939 across the 12-fold dose range

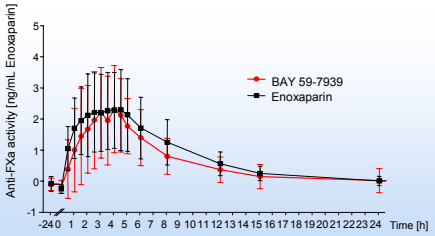
Promising safety and efficacy results

[1] Eriksson et al, J Thromb Haemost, in press
[2] Turpie et al. J Thromb Haemost 2005;3:2479-86

Evidence for a Once-Daily Dosing

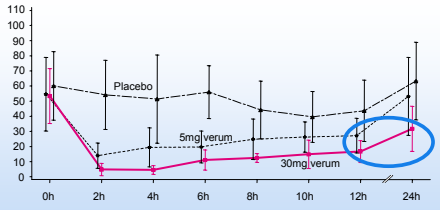
- Pharmacodynamic properties of factor Xa inhibition with BAY 59-7939 similar to enoxaparin, which is usually administered once daily
- Higher doses of BAY 59-7939 (30 mg) produce long-lasting pharmacodynamic effects: thrombin-generation significantly depressed for 24 hours after a single dose
- Early phase II study showed evidence, that efficacy and safety after a 30 mg od dose was well within the range predicted from bid dosing and similar to enoxaparin

Factor Xa inhibition comparable to enoxaparin



Factor Xa inhibition
40 mg enoxaparin versus 10 mg BAY 59-7939

Thrombin-generation inhibition lasts for >24 h after 30 mg



Thrombin-generation inhibition

Once-Daily Dosing: Study Objective and Design

- To determine the efficacy and safety of oral BAY 59-7939 over an 8-fold dose range, for prevention of VTE in patients undergoing elective primary total hip replacement, relative to subcutaneous enoxaparin
- 873 patients randomized, 713 on BAY 59-7939 and 160 on enoxaparin

Once-daily hip surgery: Europe

Day –1	Day 0	Day 1		Day 6	Day 10	Day 35–69

R

SURGERY

BAY 59-7939 od
5, 10, 20, 30, 40 mg
6–8 hours post-surgery

6–8 hours post-surgery
Enoxaparin 40 mg od

Evening prior to surgery

Mandatory Bilateral Venography

FOLLOW UP

Once-Daily Dosing: Study Findings

Once-daily BAY 59-7939 effectively reduced the incidence of VTE

- Methodologically sound study with high validity
- A wide – 8-fold – dose range has been tested
- No dose arm discontinued; no concerns regarding safety or lack of efficacy
- All doses were effective and at least similar to enoxaparin
- Significant dose trend for both efficacy and safety
- Favorable safety profile

No fatal bleeding, no bleeding into a critical organ
Treatment emergent serious adverse events similar to enoxaparin
No signal for liver toxicity

Full dataset to be presented at the American Society of Haematology annual meeting (ASH) in Atlanta, Georgia, USA, Monday 12 December 2005, 11:00am

Once-Daily Dosing: Conclusion & Start of Phase III

- Once-daily dosing with BAY 59-7939 for VTE prevention after major orthopedic surgery is safe and effective
- Optimal dose: 10 mg once-daily
- Comparison of all bid and od studies indicated that safety might be further enhanced by choosing once-daily treatment

Phase III in VTE prevention after major orthopedic surgery has been initiated with a 10 mg once-daily dosing

Exploit the Full Potential of BAY 59-7939

- High unmet medical need in a broad spectrum of both venous and arterial indications
- BAY 59-7939 is viewed to be one of the leading new oral anticoagulants in development
- BAY 59-7939 with blockbuster potential
- To fully leverage the potential development needs large clinical studies in all major indications are required

Teaming up with the best partner to realize the full potential of BAY 59-7939

Partnership With Johnson & Johnson to Co-Develop and Market BAY 59-7939

Key elements of co-operation

- US marketing rights to Johnson & Johnson / Ortho-McNeil for cardiology, primary care and hospital segments
- Sharing of the future global development costs of BAY 59-7939
- Upfront and milestone payments total $ 290 million
- Following US launch, Ortho McNeil to pay royalties up to 30 percent, depending on sales thresholds
- Bayer retains co-promotion rights for US specialty market, and sole marketing rights for BAY 59-7939 outside US
- Bayer gains co-promotion rights to market Elmiron® urology drug

Johnson & Johnson is the Ideal Partner to Maximise the Value of BAY 59-7939

Johnson & Johnson is the partner of choice

- Top US pharma and healthcare company
- Sufficient sales power to fully exploit US market
- Proven track record of developing first-in-class cardiovascular therapies, performing large cardio development/registration programs
- Excellent relationship with key opinion leaders in the cardiovascular arena
- Significant experience of commercializing blockbuster products
- Johnson & Johnson has a heritage of successful partnerships
- Johnson & Johnson is committed to expanding cardiovascular franchise with BAY 59-7939 at center of this strategy

BAY 59-7939: Phase III for VTE Prevention Initiated with Once-Daily Dosing

- BAY 59-7939 10 mg once-daily optimal dose for prevention of VTE after hip and knee surgery
- Phase III program with more than 9,000 patients

RECORD 1

HIP replacement

BAY 59-7939 10 mg od
for 5 weeks
vs
enoxaparin
for 5 weeks

RECORD 2

HIP replacement

BAY 59-7939 10 mg od
for 5 weeks
vs
enoxaparin
for 10–14 days followed by
placebo

RECORD 3

KNEE replacement

BAY 59-7939 10 mg od
for 10–14 days
vs
enoxaparin
for 10–14 days

RECORD: **RE**gulation of **C**oagulation in major **O**rthopedic surgery reducing the **R**isk of **D**VT and PE

Phase III Pivotal Program: RECORD Studies Key Features

- All studies:
  Double-blind, double dummy, parallel group design
  First dose of BAY 59-7939: 6–8 hours after surgery
- Broad study population:
  Men and women > 18 years undergoing hip / knee replacement
- Limited exclusion criteria:
  Patients not eligible for enoxaparin treatment, HIV protease inhibitors, pregnancy, intermittent pneumatic compression
- Primary efficacy endpoint: total VTE detected by mandatory bilateral venography
- Main safety endpoint: major bleeding
- Central blinded adjudication for all endpoints including venographies, bleeding events, VTE & death, cardiovascular events
- Safety follow-up: at least 30 days after the last dose

Clinical Program for Stroke Prevention in AF and VTE Treatment

- Phase II dose finding program on track to initiate phase III in 1H'06
  - No indication that monitoring will be required
  - No signal of liver toxicity
- Chronic use in both indications
- Active comparator warfarin
- The decision regarding the dose regimen (od vs. bid) will be data driven with priority given to safety aspects
  - Top line data will be available 1H'06
  - Full data planned to be presented at major scientific congress 2H'06
- Clinical development program in discussion with regulatory authorities
- Based on benchmark data the total sample size is to be expected in the range of greater than 15,000 patients
- Target filing for market authorization: 2009

BAY 59-7939: Status Clinical Development

VTE prevention after major orthopedic surgery

- BAY 59-7939 was safe and effective in phase II studies across a wide dose range
- No monitoring or dose adjustment required; no signal for liver toxicity
- Phase III program initiated: BAY 59-7939 10 mg once daily versus enoxaparin
- On schedule for regulatory filing in late 2007

Stroke prevention in AF and VTE treatment

- No monitoring or dose adjustment required; no signal for liver toxicity
- Phase II dose finding studies planned to be reported at a major congress 2H'06
- Initiate phase III trials in 1H'06

Key Messages

- Driving a potential paradigm shift in treatment of thromboembolic disorders
- Attractive market growth potential
- Maximizing the value of a significant pipeline asset through partnership with Johnson & Johnson
- Initiation of phase III studies in prevention of VTE with once-daily dosing
- On track to start phase III in chronic indications in 2006

Milestones 2006

- Announcement of top-line data of phase II dose finding for chronic indications in 1H'06
- Initiate phase III in DVT treatment in 1H'06
- Initiate phase III in stroke prevention in atrial fibrillation in 1H'06
- Presentation of full data set of phase II dose finding data for chronic indications targeted for 2H'06 at a major congress

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