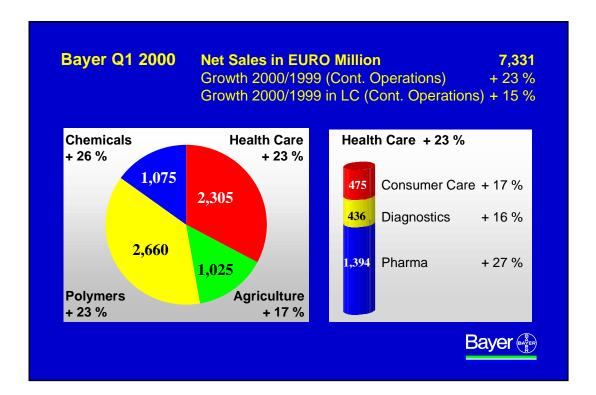
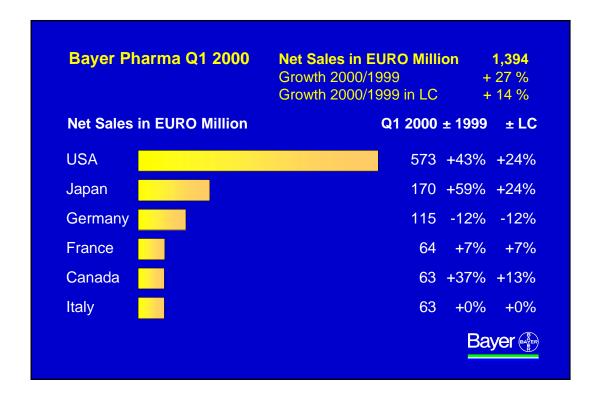
# Bayer Pharma 2000: Performance, Targets, Outlook

Dr. David Ebsworth President Bayer Pharma

Goldman Sachs Health Care Conference Laguna Niguel, June 13, 2000







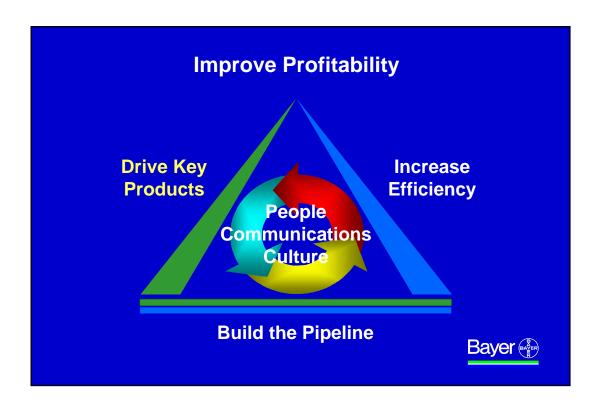


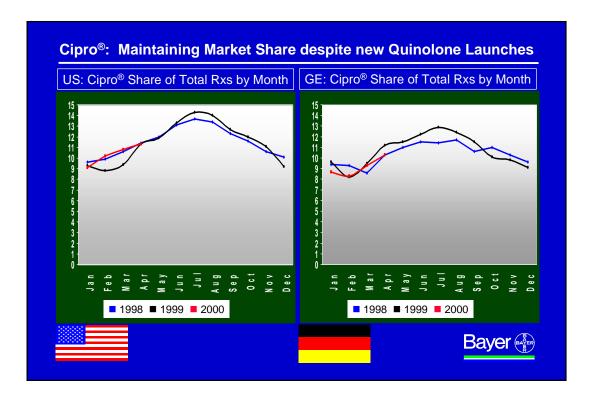
## **Major Achievements 2000**

- Growth (+ 27 %) above market (+ 23 %)
- Cipro<sup>®</sup> : Continuing strong growth (+ 29 %)
- Adalat<sup>®</sup> : Growing (+ 36 %) and enforcing legal position
- Baycol®: On track for doubling 1999 sales (+ 118 %)
- Avelox<sup>TM</sup> : Sound performance in competitive markets (23 launches)
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- New management team

Growth figures: Q1 2000 vs Q1 1999









The ideal respiratory antibiotic providing reliable efficacy now and in the future

Once Daily Dosing 5 Day Therapy in Acute Exacerbation of Chronic Bronchitis Penetrates Tissues Quickly



# **Avelox<sup>™</sup>: Key Product Characteristics**

# Developed in 1,087 days (IND-Approval): 33% less than industry standard

#### **Clinical and Bacteriological Response**

Responses	Clinical	Bacteriological
■ Acute Exacerbation of Chronic Bronchitis	89 %	92 %
■ Community Acquired Pneumonia	94 %	91 %
■ Acute Sinusitis	92 %	96 %

## Safety and Tolerability Profile

- No phototoxicity, no dosage adjustment for renal impairment or mild hepatic insufficiency
- Low CNS side effects (dizziness < 3 %) and low discontinuation rates (3.3 %) in clinical trials



# Avelox™: Successful Launches in Key Markets

■ Germany: Single brand launch achieves highest market penetration of any antibiotic in market history

■ Spain: Three brands launched with partners, together

with partners achieved 16 % of quinolone market

in third month

■ US: Solid start but below Gatifloxacin, resources

increase in Q2 2000

Worldwide: Submitted in 76 countries, approved in 35 countries, launched in 26 countries



# Avelox™: Safety

# Avelox<sup>™</sup> (Moxifloxacin)

- Clinical experience in Phase III: 2,650 patients with ECG
- Moxiflocaxin has been shown to prolong the QT interval of the electrocardiogram in some patients. The drug should be avoided in patients with...

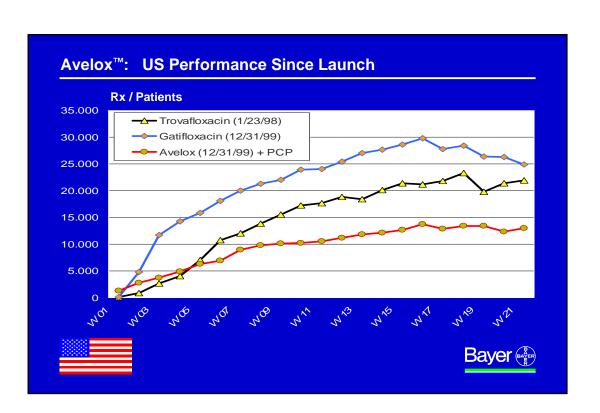


WITH OVER 1.2 MILLION EXPOSURES AVELOX™ CONTINUES TO HAVE AN EXCELLENT SAFETY PROFILE

## **Gatifloxacin**

- Clinical experience in Phase III:patients with ECG
- Gatifloxacin may have the potential to prolong the QT interval of the electrocardiogram in some patients. Due to the lack of clinical experience, gatifloxacin should be avoided in patients with...





# **Avelox™ Life Cycle Management: Challenges**

## **Full Development and Exploitation of Product Potential**

#### By

Adding Resources to Marketing & Sales in the US

Shifting Sales Force capacity to Avelox<sup>™</sup> Co-Promotion arrangement with Alza Corporation Additional P & I resources

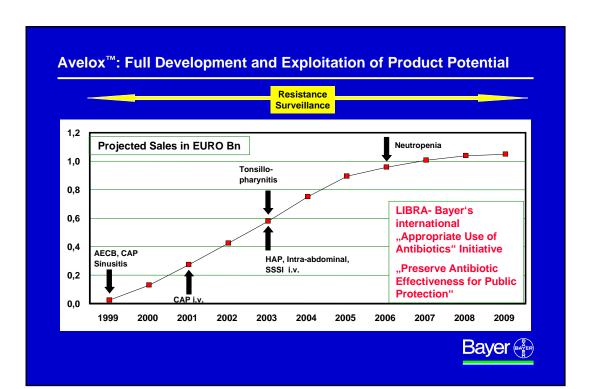
Further increase in share of voice under consideration

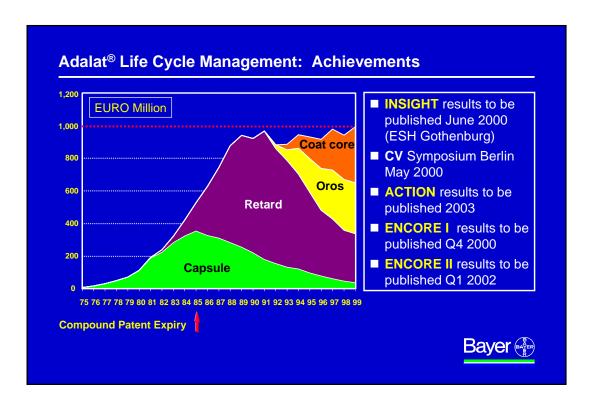
■ Accelerating Roll-Out in Europe, Canada, and Overseas

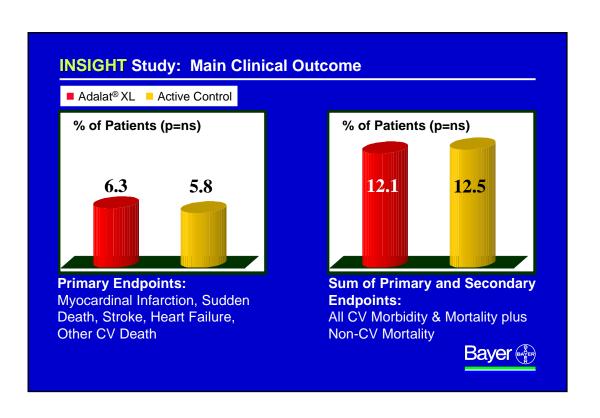
Launches in 40 countries by end of 2000 planned Launched already in 26 countries

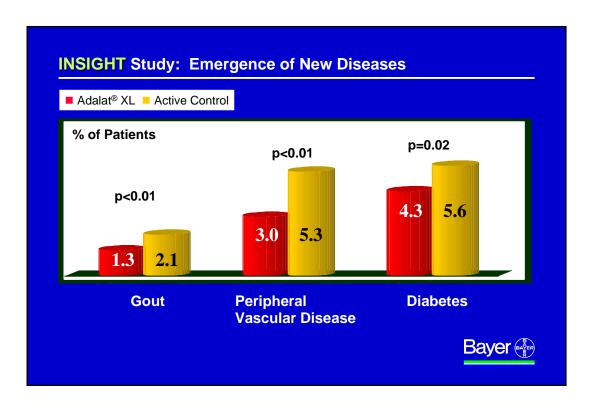
■ Developing Further Indications and IV Formulation

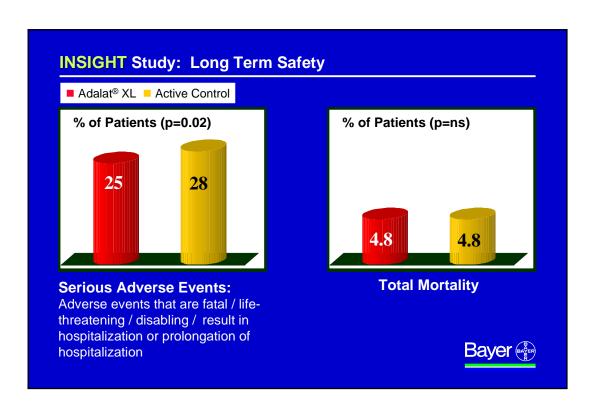












# **INSIGHT** Study: Conclusions

ADALAT® reduces cardiovascular risk by 50 % in hypertensive patients with additional risk factors

ADALAT® *matches* the cardiovascular protection of the best products in the market place

ADALAT® is effective in preventing cardiovascular or cerebrovascular complications

ADALAT® is an appropriate *first line therapy* in hypertension

Study results will contribute significantly to protecting our ADALAT® franchise in the EU and Japan



## Adalat®: The Challenge of Patent Enforcement in US and Canada

Teva has launched a generic version of 30mg Adalat® CC in the US. To date, impact is limited to that strength

#### Litigation is ongoing

- Bayer brought patent infringement suits in the United States against generic pharmaceutical companies to enforce its nifedipine formulation patent
- Suits were triggered by Mylan, Elan, Biovail, LEK and Martec each filing separate Abbreviated New Drug Applications seeking FDA approval of generic versions of Bayer's Adalat® CC and/or Pfizer's Procardia XL products
- Another suit was brought on May 8, 2000 against Teva, Biovail and Elan Pharma and Elan Corp. based on Teva's commercial sale of Elan's 30mg generic to Adalat® CC







US: SmithKline Beecham

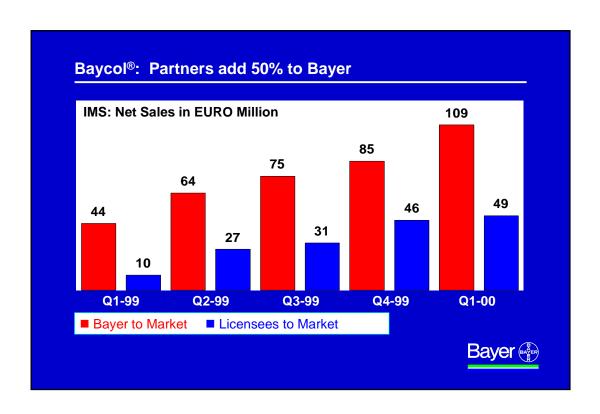


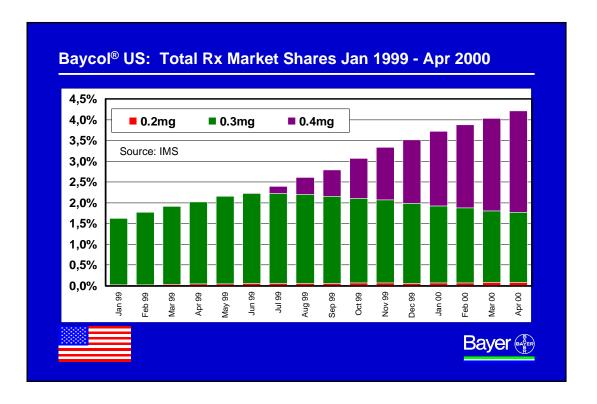
**EU: Fournier** 



Japan: Takeda







# Baycol® Life Cycle Management: Opportunities

## **Full Development and Exploitation of Product Potential**

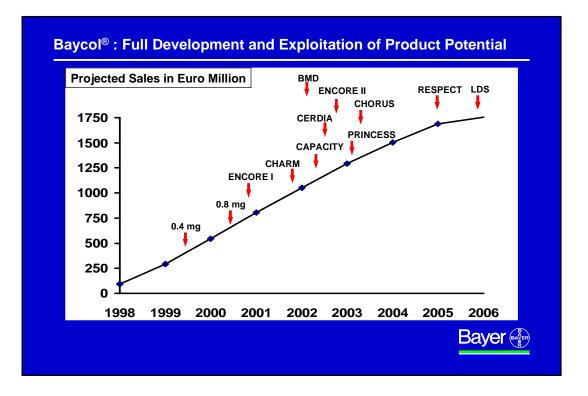
#### By

- **Higher dosages:** Clinical equivalence to competitive products with 0.4mg and 0.8mg
- Differentiation:

Going beyond LDL-C reduction: Investigating use in endothelial function, prevention of arteriosclerosis, plaque stabilization, osteoporosis

**Intervention studies:** Prevention of stroke in the elderly, myocardial infarction in diabetics, mortality in end stage renal disease, recurrent myocardial infarction

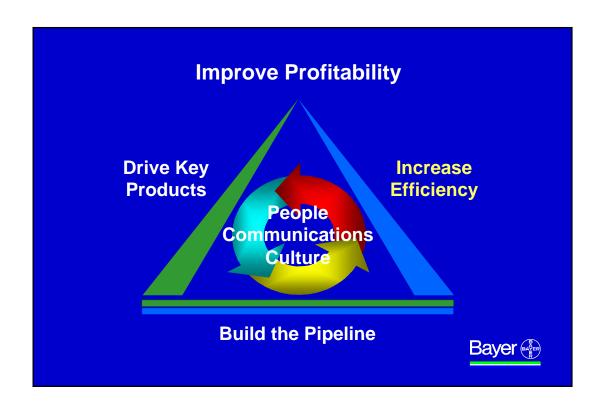


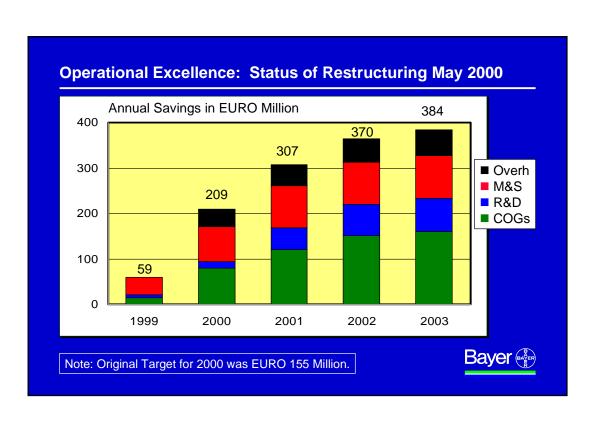


# Kogenate®: Registration on Track, Investment Ongoing

- Kogenate® FS approval expected for Q3 2000 in US and EU
- Solving production problems on track
- \$ 600 million R&D + Techical Operations invested in recombinant technology significantly enhancing the safety of hemophilia products
- Over the next 5 years scheduled investment > \$ 500 million
   (Second Kogenate® FS production suite, new filling & freeze drying facility, Kogenate® 3, gene therapy)







# **Operational Excellence: Major Projects**

# ■ Research to Development Transition (R2DT)

Optimizing pre-clinical development Early Go / No Go - decisions

## ■ Re-Directing Medical

Optimizing skills, resources, and structures Sourcing

## ■ Marketing & Sales Excellence

Optimizing skills, resources, and structures

# Operations

Worldwide manufacturing network
Reduction of product portfolio through product divestiture and cessation of commercialization



## Re-Directing Medical: Skills, Resources, Structures, Sourcing

#### **Objective**

Optimization of global Bayer Medical Organization and cost savings

#### **Focus**

Design, analysis, interpretation and communication of clinical programs

Efficiency of clinical trial operations

Drug safety capabilities

## **Deliverables: Efficiency Improvement and Cost Savings through**

Newly designed global processes

Definition of respective skills and capabilities

Development of optimal structure



# **Re-Directing Medical: Benefits**



Cost Savings and Productivity Improvement

EURO 60 million annually



**Time** 

Critical time reduction of 6 months in product development



Quality

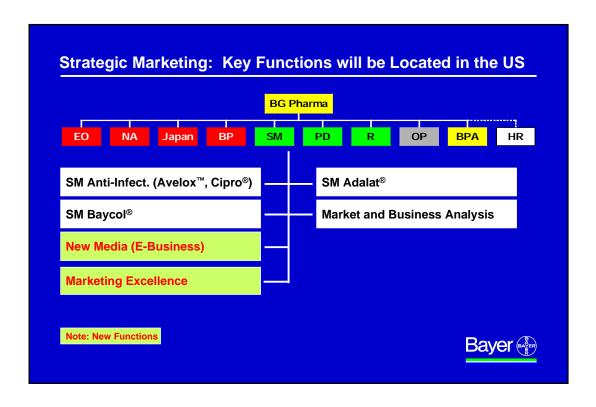
Substantial quality improvements

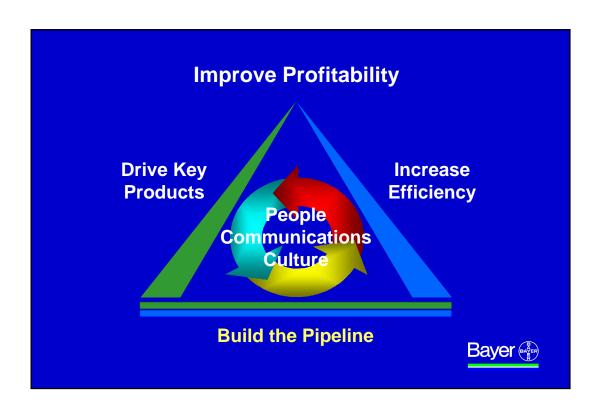
**Flexibility** 

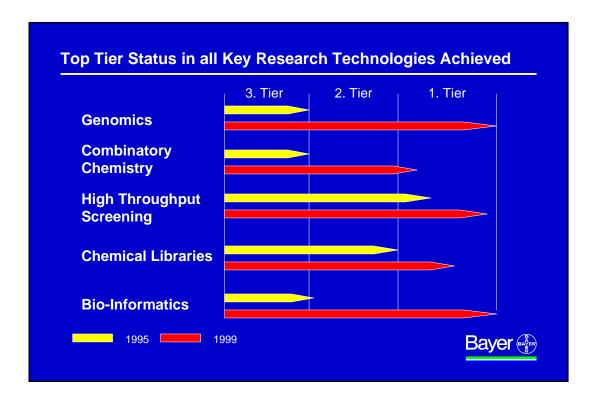
Increased flexibility by increased outsourcing







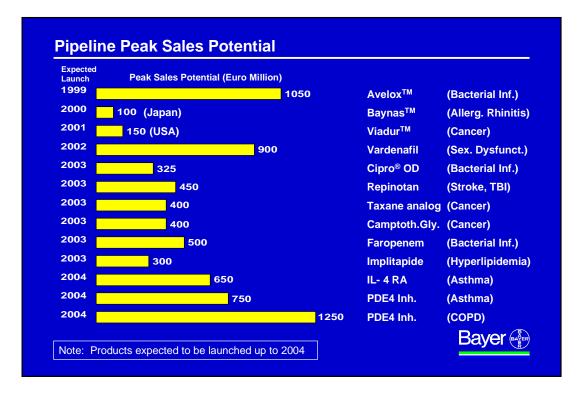




## NPV of Product Portfolio 2000/1999: + 15 %

- Projected Line Extensions of Marketed Products
  - Baycol® 0.8mg, Cipro® OD and pediatric use, Avelox™ IV
- Development Projects Moving into later Stages
  - Vardenafil (PDE V Inhibitor), PDE IV Inhibitor
- In-Licensing of Faropenem from Suntory
- 10 New Development Candidates





# Viadur™ In-Licensed from Alza Corporation (California)

- Leuprolide (LHRH-Agonist)-filled, miniature titanium implant
- Placed under the skin delivering palliative therapy to the patient for a period of one full year
- Provides an alternative to more frequent injections
- First and only product to provide continuous, 12-month testosterone suppression with a single treatment
- Unique treatment, first approved formulation with ALZA DUROS™ implant technology
- NDA approval: March 2000, available to patients by early next year
- Bayer will have commercial rights to Viadur <sup>TM</sup> in the US through 2015



## Innovation, Partnering, Focus US: The Cancer Portfolio

#### **■** Innovation

Directed at treatment, prevention and diagnosis of major solid tumors Co-Operation with Bayer Diagnostics, which after the integration of Chiron is well poised to establish a leadership position in oncology Internal research focus is on angiogenesis inhibition, oncogenes and cell cycling, hormonal intervention, 1/3 of Millennium genomic targets

# ■ Partnering to Speed Up Establishing the Oncology Franchise and to Build on Urology Expertise

In-Licensing Viadur<sup>™</sup> from Alza Corporation In-Licensing IDN 5109 from Indena

#### ■ Focus US

Viadur<sup>TM</sup> in-licensed for the US will contribute to building the organization



# **Cancer Portfolio**

## **Five Development Programs**

Project	Status	Launch anticipated for
■ Viadur <sup>™</sup>	Approved	2001
■ Camptothecin Glycoconjugate	PH I	2003
■ Taxane analogue (IDN 5109)	Preclinical	2003
■ IL-2 SA	Preclinical	2004
■ RAF Kinase Inhibitor	Preclinical	2006

Through internal and external programs, we expect to enter the cancer market in 2001 with sales potential of over EURO 1 billion by 2007- 2009

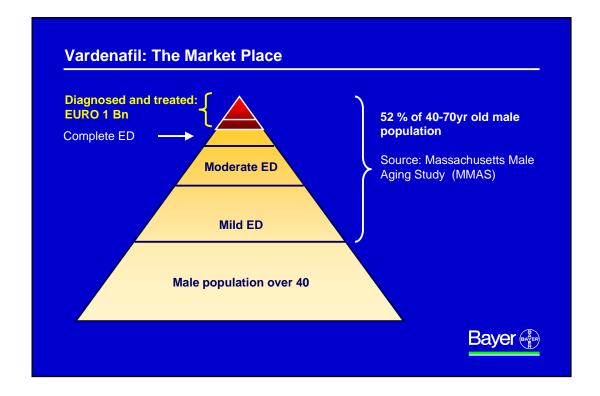


# Innovation, Focus US: Vardenafil

# Vardenafil: A Potent PDE 5 Inhibitor to Treat Sexual Dysfunction

- Selective phosphodiesterase-5-inhibitor
- Impressive activity demonstrated in animal experiments
- Preclinical data showed improved isoenzyme selectivity over other PDE V inihibitors
- Phase II: significant improvements vs placebo, well tolerated
- Phase III started
- Launch anticipated for November 2002
- Focus US: Vardenafil will contribute significantly to building the US organization





## Innovation: Targeting Angina as Major Element of CV Portfolio

## Four Highly Innovative Cardiovascular Compounds under Development

- Angina and hypertension: Guanylate Cyclase Stimulator (GCS)
- Angina and Congestive Heart Failure: Cyclic Guanosine Monophosphate Enhancer (cGMP)
- CHD including unstable **Angina** and Myocardinal Infarction: Ischemia-Selective Adenosine Enhancer
- Lipid-lowering compound: MTP inhibitor



## Innovation: Targeting areas with the highest medical needs

# Interleukin-4 RA for Severe Asthmatics

Innovative principle for asthmatic patients

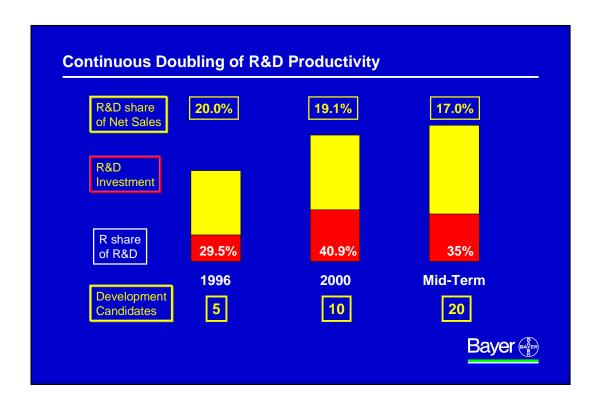
- Elimination of oral steroid use
- Decrease of asthma exacerbation
- Decrease of hospitalizations
- Phase I/II started in Aug 1999, launch anticipated for 2004

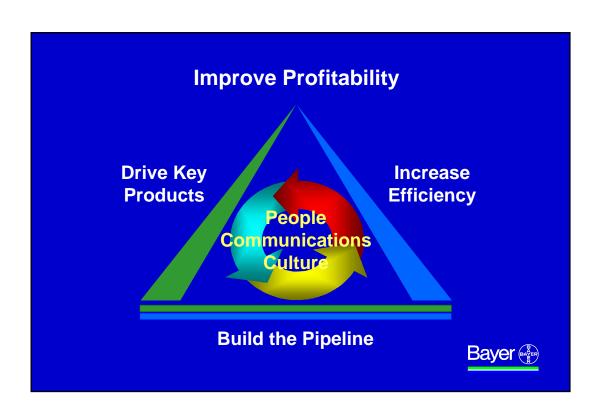
#### **CAP Inhibitor for Cystic Fibrosis**

Novel therapeutic approach to improve lung function

- Low marketing and sales investment
- Excellent return on investment predicted
- Orphan drug status
- Preclinical development started in Dec 1999, launch anticipated for 2004







# **New Management:**



David Ebsworth

President

Born 1954, Kaduna, Nigeria PhD Industrial Relations Joined Bayer in 1983 (Pharma)

Various Posts in PH Marketing, Business Operations, and General Management in Germany, Canada, US, and Worldwide

Previously President, Pharma Division North America, Bayer Corp., West Haven



# **New Management in North America and Japan**



Wolfgang Plischke
North America

Born 1951, Stuttgart, Germany PhD Biological Sciences Joined Bayer in 1980 (Diagnostics) Various Posts in PH Marketing and Sales in Germany and Worldwide Previously Head of PH Region Japan





Born 1954, London, England PhD Biological Sciences Joined Bayer in 1979 (Diagnostics) Various Posts in DS Marketing and Sales in UK, US, and Worldwide Previously Head of DS Region Japan



# **New Management in Strategic Marketing and Finance**



Derek Williams
Strategic Marketing





Born 1958, Bishop Auckland, UK
Business Administration
Joined Bayer in 1983 (Pharma) J
Various Posts in PH Marketing and
Sales in UK, NL, Canada, and Worldwide
Previously GM HealthCare Division,
Bayer Inc., Canada

Born 1963, Hameln, Germany
PhD Law
Joined Bayer in 1994 (Corporate Legal)
Various Posts in Corporate Legal and
in Bayer China Group
Previously GM Bayer (China) Ltd.



## **Major Achievements 2000**

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Growth figures: Q1 2000 vs Q1 1999



# **Summary and Outlook**

## **■ Driving Key Products**

Promising life cycle management plans for all key products
Adalat®: Ongoing enforcement of legal position in US and Canada,
INSIGHT study results will support Adalat® franchise in EU and Japan
Increasing share of voice initiated

## ■ Increasing Efficiency

Ongoing focusing on core products and countries Major projects to achieve operational excellence Restructuring to improve profitability

#### **■** Building the Pipeline

Competitive Research platform established
Alliances deliver (first development project from Millennium)

Value of portfolio increased



