



# Bayer HealthCare



## Bayer HealthCare Investor Day 2007 Addressing High Medical Needs, Building a Sustainable Pipeline to Ensure Future Growth (1)

Andreas Busch

Head of Global Drug Discovery

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



- Our R&D strategy will leverage our learnings and focus on key assets, fast portfolio decisions and maximization of asset value
- Consolidation of the R&D pipeline completed – quality of R&D portfolio improved
- Exciting pipeline progress achieved – progress made with key assets with the potential to transform the business

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## Our R&D Strategy Addresses Key Factors for Success



### 1 ... more focus:

4 therapeutic research areas with activities from target discovery up to launch

### 2 ... higher productivity:

increase in development candidate output at decreased cost per NME

### 3 ... better quality:

PoC concept and strict progression criteria in research

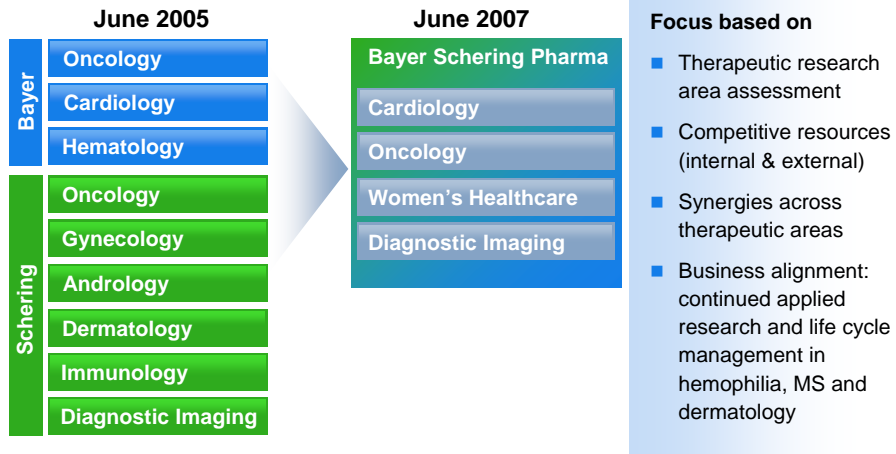
### 4 ... value maximization:

common mechanism approach, prioritization across whole portfolio and flexible resource allocation

PoC: Proof of Concept  
NME: New Molecular Entity

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## Focus on Four Therapeutic Research Areas



### Leveraging our learnings in improving R&D efficiency

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## Fully Integrated R&D Sites Rather than Satellite Approach



	Therapeutic activities	Technology platform
<p><b>Berlin</b></p>	<ul style="list-style-type: none"> <li>Oncology</li> <li>Women's Healthcare</li> <li>Diagnostic Imaging</li> </ul>	<ul style="list-style-type: none"> <li>Lead generation and optimization</li> <li>Preclinical development</li> <li>Phase I in-house unit</li> </ul>
<p><b>Wuppertal</b></p>	<ul style="list-style-type: none"> <li>Cardiology</li> <li>Oncology</li> </ul>	<ul style="list-style-type: none"> <li>Lead generation and optimization</li> <li>Preclinical development</li> <li>Phase I in-house unit</li> </ul>
<p><b>Berkeley</b></p>	<ul style="list-style-type: none"> <li>Applied research and life cycle management in hemophilia, MS and dermatology</li> </ul>	<ul style="list-style-type: none"> <li>Protein sciences</li> </ul>

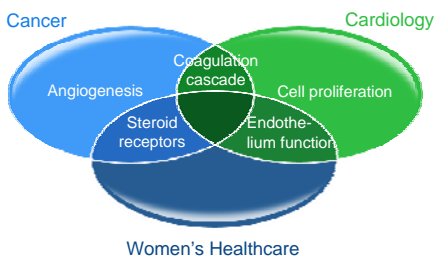
- Co-localization of therapeutic areas and technology platforms according to expertise
- Therapeutic areas compete for technology platforms

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# Leverage Common Mechanism Opportunities Across and Beyond Bayer Core Areas



## Common mechanism background

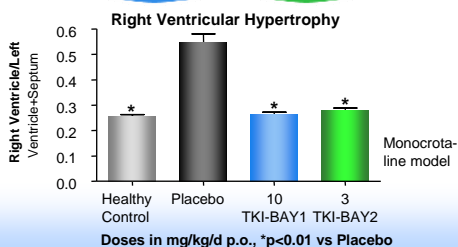


### Leverage of common mechanisms provides:

- Value maximization
- Risk mitigation
- Drug repositioning opportunities

30% of research portfolio represent common mechanisms

## Case study – Tyrosine Kinase Inhibitors (TKIs)



PoC study of TKI in PAH (Univ. of Chicago)

# R&D Strategy Provides a Clear Perspective for our Therapeutic Areas



## Short-term

- NME focus on cardiology, oncology and molecular imaging
- Refocus Women's Healthcare towards gynecological therapies
- Life cycle management and applied research in female fertility control, contrast media, and for hemophilia and multiple sclerosis

## Mid-term

- Additional NME output in gynecological therapies

## Long-term

- Recognized innovation leader in cardiology, gynecological therapies and molecular imaging
- Delivery of significant innovation in oncology

## Consolidation of the Combined R&D Pipeline Completed



	Number of projects			
	Phase 1	Phase 2	Phase 3	Reg.
Combined Bayer/Schering pipeline as presented in June 2006	13	16	21	4
Deprioritizations / Phase-shifts out	9	8	11	4
New projects / Phase-shifts in	10	9	9	9
Pipeline as of June 2007	14	17	19	9

- Consolidated R&D pipeline focusing on quality and sustainability
- Deprioritization of R&D pipeline projects without strategic fit or of low quality
- 3 project launches accomplished: Nexavar RCC, YAZ, Vasovist
- Successful in-licensing of VEGF Trap-Eye and rThrombin

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## R&D Pipeline Decisions



Main deprioritized projects	Indication	Decision
■ PTK / ZK	Cancer	Outlicensing
■ Sargramostim	Crohn's Disease	Termination
■ Asoprisnil	Benign Uterine Tumors	Outlicensing
■ Alfimeprase	PAO / CO	Deprioritization
■ Trasylol	Non-CABG Surgery	Termination
■ MS 275	Cancer	Outlicensing
■ Angiogenesis Inhibitor	Cancer	Outlicensing
■ Dual Acting Peptide	Diabetes	Outlicensing
■ CETP Inhibitor	Dyslipidemia	Outlicensing

- R&D portfolio prioritized across all therapeutic areas to ensure optimal resource allocation
- Decision making process based on technically and commercially evaluation
- Options to outlicense individual assets pursued
- Decision on TOCOSOL-Paclitaxel dependent on Phase III results (expected in Q3 2007)

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# Our R&D Pipeline Provides a Balanced Mix of NME and LCM Opportunities



As of June 2007	Phase I	Phase II	Phase III	Submitted
<ul style="list-style-type: none"> <li>New Molecular Entities (NME)</li> <li>Life Cycle Management (LCM)</li> </ul>	<ul style="list-style-type: none"> <li>HT / HF sGC Stimulator</li> <li>PH in COPD Elastase Inhibitor</li> <li>Pancreatic Cancer L19-Interleukin 2</li> <li>Cancer L19-SIP</li> <li>Cancer L19-TNF</li> <li>Cancer DAST Inhibitor</li> <li>Menopausal Management ERB Agonist</li> <li>Hypogonadism Treatment eF-Ment</li> <li>Gastro IBD Lipoxin</li> <li>DME VEGF Trap-Eye</li> <li>Alzheimer PET Imaging AV1ZK</li> <li>ACS Aspirin I.v.</li> <li>Fast Dissolving Tablet Levitra</li> <li>Lung Infection Cipro Inhale</li> </ul>	<ul style="list-style-type: none"> <li>A/1b / Stable Angina Adenosine A1 Agonist</li> <li>Acute Heart Failure sGC Activator</li> <li>Pulmonary Hypertension sGC Stimulator</li> <li>ACS Rivaroxaban</li> <li>RCC 1st / 3rd line L19-Interleukin 2</li> <li>Breast Cancer ZK-PRA</li> <li>Lung / Ovar / Breast / Prostate Sargolone (ZK-EPO)</li> <li>wet AMD VEGF Trap-Eye</li> <li>Parkinson's Disease Spheramine</li> <li>Liposomal Formulation Kogenate</li> <li>Breast Cancer Nexavar</li> <li>Additional Indications Nexavar</li> <li>Fertility Control FC Patch, Fidencia</li> <li>Fertility Control Valette low</li> <li>Multiple Sclerosis Alemtuzumab</li> <li>MRI (USA, J) Gadovist</li> <li>New Indications Levitra</li> </ul>	<ul style="list-style-type: none"> <li>VTE Prevention Rivaroxaban</li> <li>SPAF Rivaroxaban</li> <li>DVT Treatment Rivaroxaban</li> <li>Melanoma Nexavar</li> <li>NSCLC Nexavar</li> <li>Ind. / agr. NHL, 1st line Zevalin</li> <li>CLL 2nd line Campath</li> <li>Bone Metast. Prevent. (Breast Ca.) Bonafos</li> <li>Dysmenhorrea (J) YAZ</li> <li>Fertility Control YAZ Flex</li> <li>FC / Uterine Bleeding DUB-OC (E2/DNG)</li> <li>Menorrhagia Mirena</li> <li>Menopausal Management Angeliq low-low</li> <li>Endometriosis Visanne</li> <li>Fertility Control Yasmin plus / YAZ plus</li> <li>Fertility Control LCS (ULD LNG)</li> <li>MS Treatment Betaferon high dose (BEYOND)</li> <li>CT Ultravist 370</li> <li>New Indications (US) Avexol</li> </ul>	<ul style="list-style-type: none"> <li>CKD (J) Fosrenol</li> <li>Bleeding control rTrombin</li> <li>HCC Nexavar</li> <li>CLL 1st line Campath</li> <li>VMS Menostar transdermal</li> <li>HRT (J) E2 / LNG</li> <li>MRA Magnevist MRA</li> <li>MRI (US, J) Primovist</li> <li>PID / New Indications (EU) Avexol</li> </ul>

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# An Emerging World-Class Cardiology Pipeline



As of June 2007	Phase I	Phase II	Phase III	Submitted
<ul style="list-style-type: none"> <li>New Molecular Entities (NME)</li> <li>Life Cycle Management (LCM)</li> <li>Early CV pipeline projects</li> </ul>	<ul style="list-style-type: none"> <li>HT / HF</li> <li><b>sGC Stimulator</b></li> <li>PH in COPD</li> <li>Elastase Inhibitor</li> <li>Pancreatic Cancer</li> <li><b>L19-Interleukin 2</b></li> <li>Cancer</li> <li>L19-SIP</li> <li>Cancer</li> <li>L19-TNF</li> <li>Cancer</li> <li><b>DAST Inhibitor</b></li> <li>Menopausal Management</li> <li>ERβ Agonist</li> <li>Hypogonadism Treatment</li> <li>eF-Ment</li> <li>Gastro IBD</li> <li>Lipoxin</li> <li>DME</li> <li><b>VEGF Trap-Eye</b></li> <li>Alzheimer PET Imaging</li> <li><b>AV1ZK</b></li> <li>ACS</li> <li>Aspirin Iv.</li> <li>Fast Dissolving Tablet</li> <li>Levitra</li> <li>Lung Infection</li> <li>Cipro Inhaler</li> </ul>	<ul style="list-style-type: none"> <li>A/tib / Stable Angina</li> <li><b>Adenosine A1 Agonist</b></li> <li>Acute Heart Failure</li> <li><b>sGC Activator</b></li> <li>Pulmonary Hypertension</li> <li><b>sGC Stimulator</b></li> <li>ACS</li> <li><b>Rivaroxaban</b></li> <li>RCC 1st / 3rd line</li> <li><b>L19-Interleukin 2</b></li> <li>Breast Cancer</li> <li><b>ZK-PRA</b></li> <li>Lung / Ovar / Breast / Prostate</li> <li>Sigepilone (<b>ZK-EPO</b>)</li> <li>wet AMD</li> <li><b>VEGF Trap-Eye</b></li> <li>Parkinson's Disease</li> <li><b>Spheramine</b></li> <li>Liposomal Formulation</li> <li>Koginate</li> <li>Breast Cancer</li> <li><b>Nexavar</b></li> <li>Additional Indications</li> <li><b>Nexavar</b></li> <li>Fertility Control</li> <li><b>EC Patch, Efidencia</b></li> <li>Fertility Control</li> <li><b>Valette low</b></li> <li>Multiple Sclerosis</li> <li><b>Alentuzumab</b></li> <li>MRI (USA, J)</li> <li><b>Gadovist</b></li> <li>New Indications</li> <li><b>Levitra</b></li> </ul>	<ul style="list-style-type: none"> <li>VTE Prevention</li> <li><b>Rivaroxaban</b></li> <li>SPAP</li> <li><b>Rivaroxaban</b></li> <li>DVT Treatment</li> <li><b>Rivaroxaban</b></li> <li>Melanoma</li> <li><b>Nexavar</b></li> <li>NSCLC</li> <li><b>Nexavar</b></li> <li>Ind. / agr. NHL, 1st line</li> <li><b>Zevalin</b></li> <li>CLL 2nd line</li> <li><b>Campath</b></li> <li>Bone Metast. Prevent. (Breast Ca.)</li> <li><b>Bonefos</b></li> <li>Dysmenorrhoea (J)</li> <li><b>YAZ</b></li> <li>Fertility Control</li> <li><b>YAZ Flex</b></li> <li>FC / Uterine Bleeding</li> <li><b>DUB-OC (E2/DNG)</b></li> <li>Menorrhagia</li> <li><b>Mirena</b></li> <li>Menopausal Management</li> <li><b>Angeliq low-low</b></li> <li>Endometriosis</li> <li><b>Yasmin</b></li> <li>Fertility Control</li> <li><b>Yasmin plus / YAZ plus</b></li> <li>Fertility Control</li> <li><b>LCS (U/L/LNG)</b></li> <li>MS Treatment</li> <li><b>Betaferon high dose (BEYOND)</b></li> <li>CI</li> <li><b>Ultravist 370</b></li> <li>New Indications (US)</li> <li><b>Avelox</b></li> </ul>	<ul style="list-style-type: none"> <li>CKD (J)</li> <li><b>Fosrenol</b></li> <li>Bleeding control</li> <li><b>rThrombin</b></li> <li>HCC</li> <li><b>Nexavar</b></li> <li>CLL 1st line</li> <li><b>Campath</b></li> <li>VMS</li> <li><b>Menostar transdermal</b></li> <li>HRT (J)</li> <li><b>E2 / LNG</b></li> <li>MRA</li> <li><b>Magnivist MRA</b></li> <li>MRI (US, J)</li> <li><b>Primovist</b></li> <li>PID / New Indications (EU)</li> <li><b>Avelox</b></li> </ul>

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## sGC Activator: Potential for Superior Efficacy in Acute Heart Failure

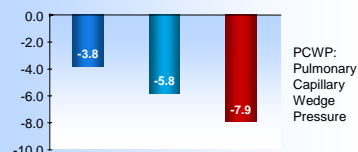


### Background

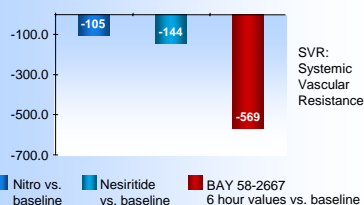
- Direct activator of soluble Guanylate Cyclase (sGC) – project BAY 58-2667
- Lead Indication: Acute decompensated heart failure (ADHF) – could be first in class treatment
- PoC achieved: hemodynamic improvement and relief of symptoms in patients with ADHF demonstrated
- Next milestone: Phase IIb entry planned for 2H 2007
- Potential main differentiator to existing therapies:
  - Effective therapy, promising safety profile
  - Preservation of kidney function
- Peak sales potential € 500-750 million

### Key data

#### PCWP decrease vs. baseline\* (mm Hg)



#### SVR decrease vs. baseline\* (dyn\*s\*cm<sup>-5</sup>)



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\* Slides show historical comparison; not tested neither vs. Nitro nor vs. Nesiritide

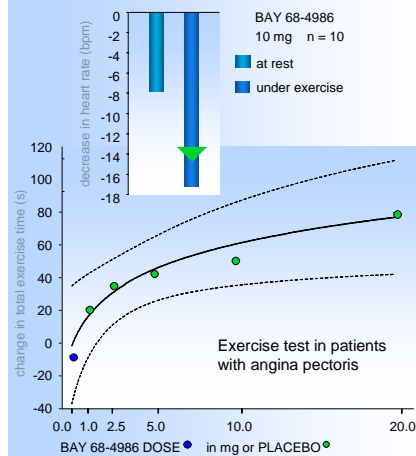
# Adenosine Agonist: Targeting Effective Treatment of Major CV Diseases



## Background

- Selective Agonist for the adenosine A1 receptor – project BAY 68-4986
- Indications: Stable angina pectoris (lead indication), atrial fibrillation
- PoC achieved: Prevention of exercise induced tachycardia in patients with stable angina pectoris
- Differentiation potential: Decreases heart rate without pro-arrhythmic potential nor influence on blood pressure. The higher the heart rate increase the greater the effect – effective when needed!
- Next milestone: Phase IIb planned in 2008
- Peak sales potential €500-750 million

## Key data for stable angina



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# sGC Stimulator: Potential New Treatment Option in Pulmonary Hypertension



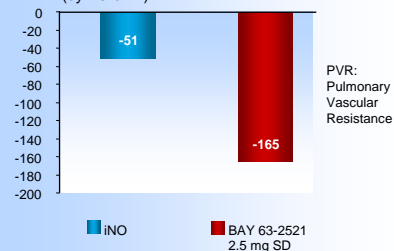
## Background

- Stimulator of soluble Guanylate Cyclase (sGC) – project BAY 63-2521
- Lead Indications: Pulmonary arterial hypertension, chronic thromboembolic pulmonary hypertension, other indications
- PoC achieved: hemodynamic improvement in patients with pulmonary hypertension, anti-remodelling properties
- Differentiation potential: effective therapy with very good safety profile; no deterioration in perfusion mismatch; combination partner of choice for patients on pulmonary hypertension therapy
- Next milestone: Phase III planned for 2008
- Peak sales potential €250-500 million

## Key data

Acute administration in patients with pulmonary arterial hypertension

### PVR decrease vs. baseline (dyn\*s\*cm<sup>-5</sup>)



- Reduction of right atrial pressure
- Pre- and afterload reduction of left and right ventricle

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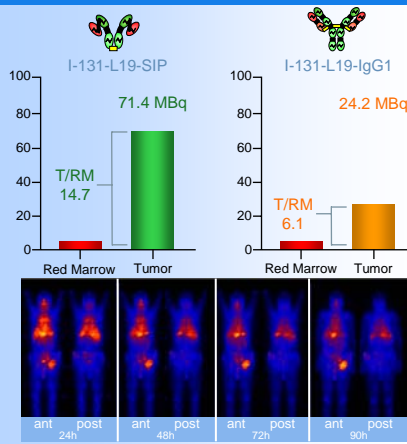
# L19-SIP (Small Immunoprotein): Solid Tumor Imaging and Radio-Immunotherapy



## Background

- L19 antibody, in SIP format and labeled with 131Iodine ("131I-L19-SIP")
- Innovative MoA: tumor-tissue targeted radioactivity (new target ED-B fibronectin)
- Patient selection via dosimetry, followed by radio immunotherapy with the same compound at higher dose as potential entry into personalized cancer medicine
- Developed under an agreement with Phlogen
- Next milestone: results of Phase II PoC study planned for 2008

## Key data



Planar scan of tumor uptake in melanoma patient with metastatic lesions

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# [<sup>18</sup>F]AV1/ZK for Molecular Imaging in Alzheimer's Disease

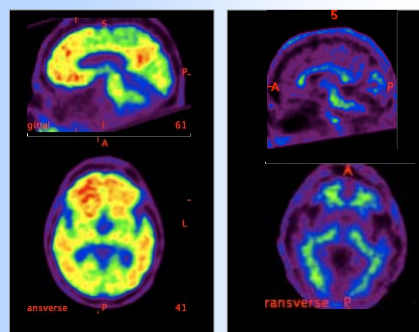


## Background

- Amyloid β is the key pathological hallmark of Alzheimer's Disease (AD)
- [<sup>18</sup>F]AV1/ZK (BAY94-9172) is a Fluorine-18 labeled amyloid β binding stilbene suitable for PET imaging; in-licensed from Avid Radiopharmaceutical
- Images are diagnostic and allow discrimination between AD patients and healthy controls
- AV1/ZK has the potential to become the first commercial PET compound for amyloid imaging
- Next milestones: start of phase II in 2008

## Key data

**First clinical data in man:**  
12 AD & 12 HC (healthy control)



Mild AD patient

Healthy Control  
(aged matched)

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## Early Pipeline Assets with Significant Progress



Preclinical → Phase 1	Phase 1 → Phase 2	PoC achieved in phase transition
sGC Stimulator (Phase 1) Hypertension / Biventricular HF	Adenosine A1 Agonist Stable Angina	ZK-EPO Cancer
Cipro Inhale Lung Infection	Adenosine A1 Agonist Atrial Fibrillation	eF-Ment Hypogonadism
L19-SIP Cancer	sGC Activator Acute Heart Failure	
ERβ Agonist Menopausal Management	sGC Stimulator (Phase 2) Pulmonary Hypertension	
Lipoxin Gastro IBD	L19-IL2 Cancer	
	Levitra New Indication	
	ZK-PRA Breast Cancer	
	Kogenate Liposomal Hemophilia A	

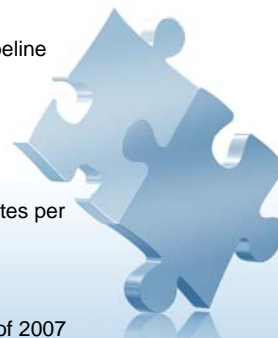
■ Proof-of-Concept (PoC) achieved

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## Summary and Milestones



- Smooth and efficient integration
  - New processes fully established
  - Global drug discovery organization finalized and implemented
- Compelling R&D strategy defined, full implementation in 2007
- We have delivered on our promises, are reporting exciting pipeline progress and developing a world-class CV pipeline
- Pipeline cleaned
- We plan to further increase productivity:
  - Deliver 10 innovative high-quality preclinical drug candidates per year by 2010
  - Transfer 3 NMEs into the clinic by the end of 2007
  - Deliver proof-of-concept results for 4 projects by the end of 2007



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