



Science For A Better Life

Innovations at Pharma

Citi Global Healthcare Conference

Dr. Jörg Möller, Head of Global Development

November 03, 2015 - November 05, 2015



This presentation may contain forward-looking statements based on current assumptions and forecasts made by Bayer Group or subgroup 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 Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

Figures for 2012 have been restated due to changes in accounting policies relating to the accounting standards IAS 19R ("Employee Benefits") and IFRS 11 ("Joint Arrangements"). In addition, Bayer changed accounting for the stock-based compensation program.



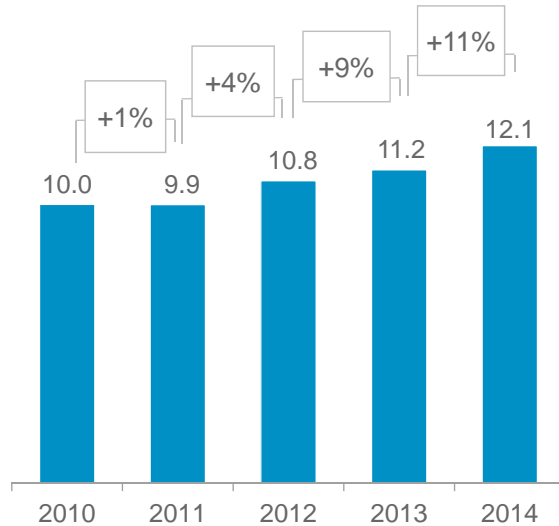
Disclaimer



Fast-Growing Global Pharma Business

Sales

€ billion; Δ% yoy Fx & portfolio adj.



Successful launch of 5 products



Leading novel oral anti-coagulant



Success in treatment of retinal diseases



First-in-class α-pharmaceutical



First marketed sGC modulating agent



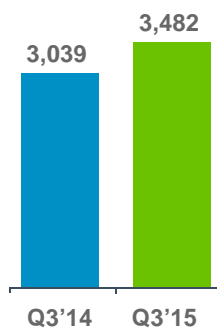
Multi-kinase inhibitor for cancer treatment

Q3 2015: Further Growth Momentum in Pharma



Sales

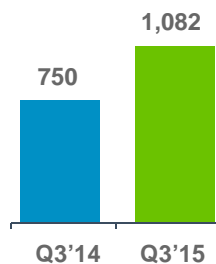
in €million
% currency & portfolio adj.



+12%

Launch Products

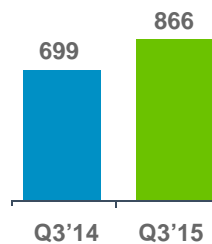
in €million
% currency adj.



+42%

EBIT

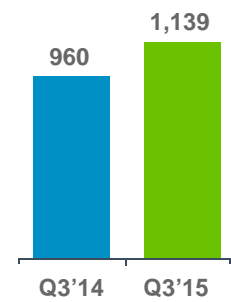
before special items
% yoy



+24%

EBITDA

before special items
% yoy



+19%

Full Year 2015 Pharma Outlook Projects Further Growth and Higher Earnings



Sales Δ % Fx and portfolio adjusted

	2014		2015 Original guidance	2015 Update October
Sales	€12.1bn	▶	Mid-to-high-single-digit % increase ~€13bn (positive FX effect approx. +2%)	High-single-digit % increase ~ €14bn (positive FX effect approx. +5%)
New Product Sales	€2.9bn	▶	Towards €4bn	> €4bn
EBITDA before special items	€3.7bn	▶	Low-teens % increase	Mid-teens % increase

Innovations for Sustainable Growth at Pharma



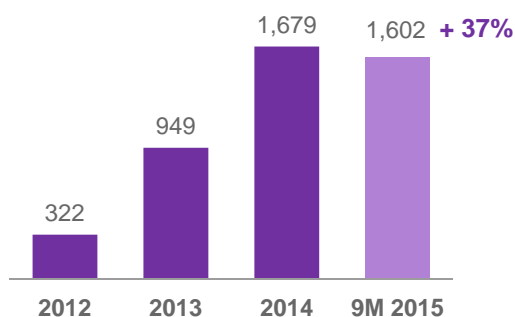
- 1 Exploring multiple opportunities in anti-coagulation
- 2 Expanding treatment options for retinal diseases
- 3 Building a R&D portfolio in oncology
- 4 Developing new therapies for cardio-renal diseases
- 5 Innovation pipeline in hemophilia progressing
- 6 Maintaining global leadership in women's health

Xarelto – Leading Novel Anticoagulant

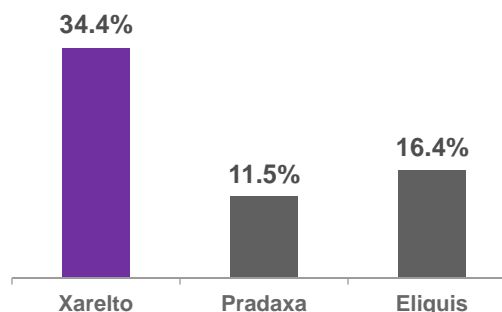


Sales

€million; Δ% Fx adj.



Global Sales Market Share*



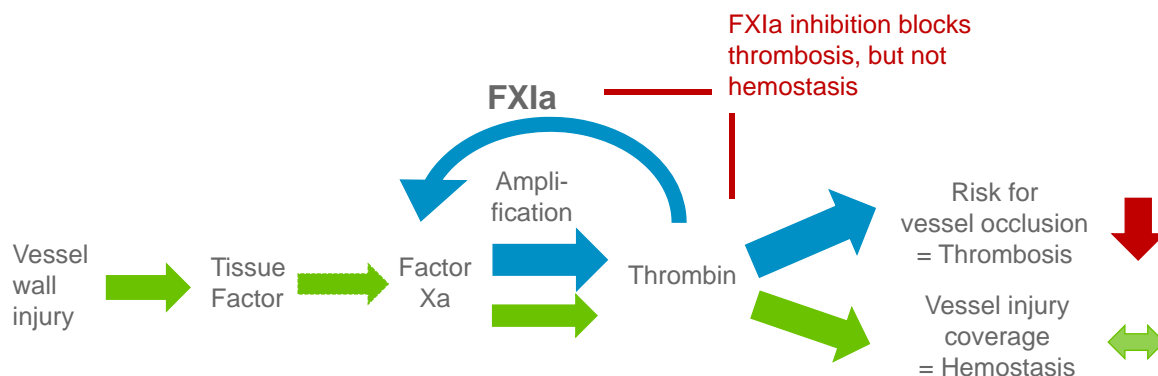
- Continued dynamic growth: gaining 2.2%-age points market share since Dec 2014
- >15 million patients treated to date
- Comprehensive Life-cycle management program underway**
- ✓ **Peak sales potential of ~€3.5bn reiterated**

Investigating New Indications for Xarelto



Major phase III studies*	Indication	# of patients diagnosed**	Primary completion ***
COMMANDER HF	Chronic heart failure and significant coronary artery disease	3-4 million ²	Apr 2017e
COMPASS	Major cardiovascular events in coronary or peripheral artery disease	~35 million ¹	Feb 2018e
NAVIGATE ESUS	Embolic stroke of undetermined source	~2 million ²	Jan 2018e
VOYAGER PAD	Peripheral artery disease	>3 million ²	Jan 2019e

FXIa Inhibition - Exploring a Novel Approach For Anti-thrombotic Therapy



- FXI inhibition may have potential for antithrombotic therapy without increased bleeding risk
- FXI inhibition may offer an additional pathway for treating patients for whom there are currently no suitable therapeutic options available

Investigating New Approaches in Anticoagulation via Anti-FXI Inhibition



ISIS-FXI_{RX} Antisense Drug Candidate

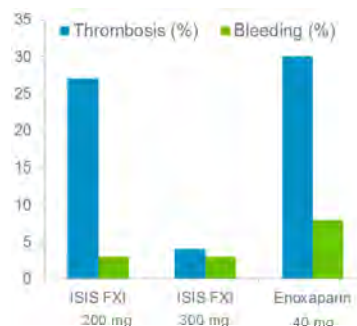
- Antisense oligonucleotide¹ that specifically reduces the biosynthesis of clotting factor XI
- Positive Phase II data²

Fully human IgG Anti-FXIa Antibody

- Preclinical studies showed
 - Strong antithrombotic effect in standard animal models of venous & arterial thrombosis
 - No bleeding in sensitive animal models despite high dosing & combination with antiplatelet therapy
- Phase I initiated

Oral small molecule FXIa Inhibitor

- Preclinical profile confirms anti-coagulation potential with low bleeding risk
- Phase I initiated



1) In-licensed from Isis-Pharmaceuticals

2) Prevention of thrombosis in patients undergoing total knee arthroplasty
Büller et al., NEJM (2015) 372; 232

Innovations for Sustainable Growth at Pharma



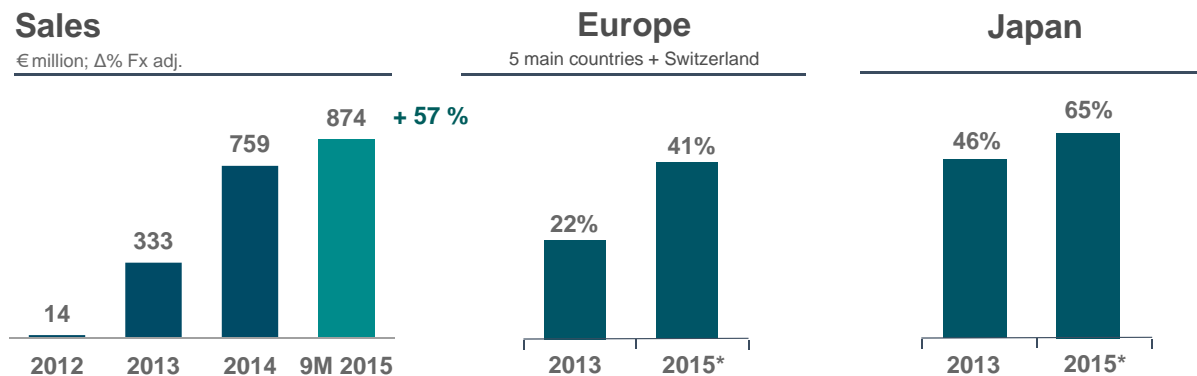
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Eylea – Gaining Share in Key Markets



Sales

€ million; Δ% Fx adj.



- Significant label expansion achieved. New indications approved: DME, mCNV and RVO
- Life-cycle management including combination therapy with PDGFR-β antibody**

✓ **Peak sales potential of ≥ €1.5bn reiterated**

DME: Diabetic macula edema
 mCNV: myopic Choroidal neovascularization
 RVO retinal vein occlusion

Eylea and PDGFR- β Combination Therapy for wet AMD



- **Eylea and a PDGFR- β antibody co-formulation in wet AMD**
 - Program currently in phase II ²
 - PDGF inhibition can potentially augment efficacy of VEGF inhibition in wet AMD¹
- **PDGF is potentially important in the pathogenesis of wet AMD**
 - May induce maturation of pathological neovascularization through pericyte stimulation
 - Was experimentally shown to recruit pro-fibrotic cells in the eye and may therefore have a role in retinal scarring secondary to wet AMD³



¹ Diago et al. Mayo Clin. Proc. 2008; 83, 231-234

² In collaboration with Regeneron

³ Kudelka et al. Exp Rev Ophthalmol. 2013; 8(5):475-484

Innovations for Sustainable Growth at Pharma



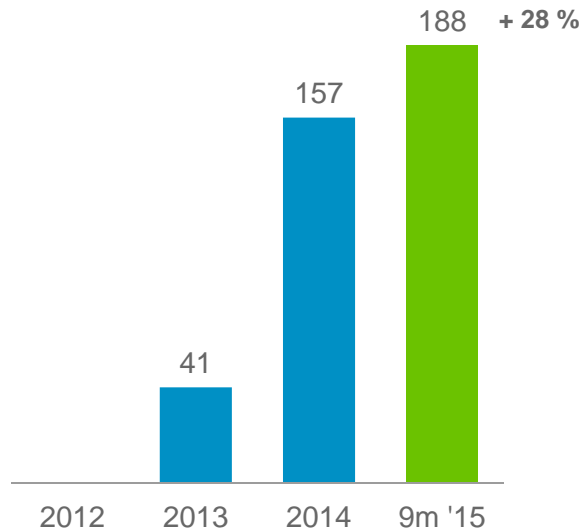
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Xofigo: 1st in Class Alpha-Pharmaceutical



Sales

€ million; Δ% yoy Fx adj.



Achievements

- Roll-out on track
 - Approved in 43 countries*
 - Launched in 34 countries*
- Fully reimbursed in 20 EU countries, including Germany, UK, Spain, Italy
 - Globally, ~13,800 patients have received Xofigo treatment*
- Life-cycle management program targeting label expansions in CRPC and additional cancer indications underway

Addressing Multiple Life-cycle Opportunities for Radium-223 Dichloride (Xofigo)



Life-cycle Opportunities

Addressed Through

Repeat dosing in CRPC



Phase II trial assessing the short and long-term safety of re-treatment

Higher dose in CRPC



Phase II trial with dose higher than the approved 50 kBq/kg

Earlier disease stages of CRPC



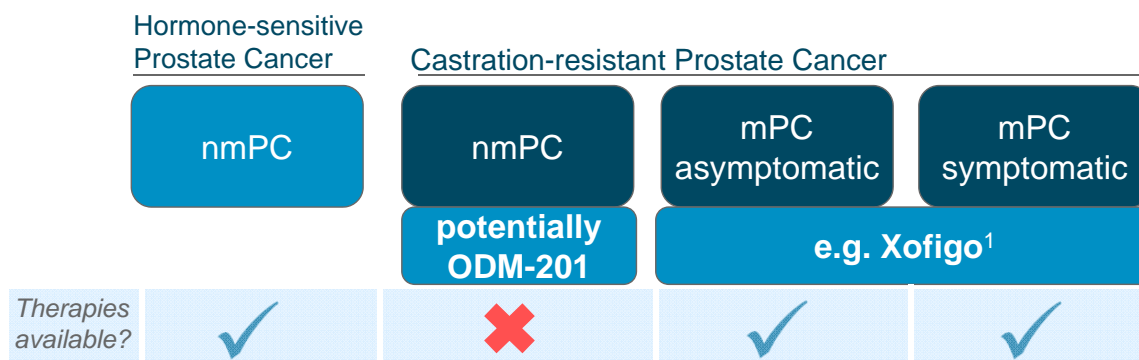
Phase III combination trial with abiraterone
Phase II trial in combination with abiraterone or enzalutamide

Combination studies in CRPC



Phase I and/or II studies in breast cancer, osteosarcoma and potentially in additional cancer types

Expanding CRPC Treatment to Non-metastatic Disease



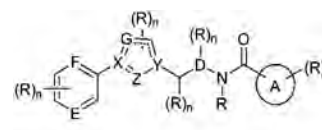
- Most PC patients eventually build up resistance to anti-androgen treatments
- CRPC: more aggressive tumor progression and poor prognosis
- Target populationb ODM-201: non-metastatic CRPC patients, where no therapy is approved
 - Addresses a large prevalent population
 - Long treatment duration (>2 years)

ODM-201 – Targeting the Primary Tumor of CRPC



An AR antagonist in development in non-metastatic CRPC*

- M0 prostate cancer market has no approved therapies
- Unique profile including
 - Promising phase II results
 - No CYP inhibition or induction expected with therapeutic doses; hence low potential for drug-drug interaction
 - Low penetration into the brain¹ vs enzalutamide², and ARN 509² in preclinical studies, which may decrease brain-associated side-effects
- Primary Completion phase III 2018e



1. Rat autoradiography (QWBA confirms brain/plasma ratio of 14C-ODM-201 related radioactivity was 0.04-0.06) indicating negligible penetration to the brain
 2. Refs. Clegg et al, Cancer Research 2012; Forster et al, Prostate 2011

Copanlisib – Clinical Program in NHL Progressing



- PI3K inhibitor targeting non-solid tumors with broad clinical development program with a differentiated profile:
 - ✓ Inhibits both PI3K- α and - δ isoforms
 - ✓ Once weekly dosing
 - ✓ i.v. dosing
- **Phase II** in iNHL ongoing - preliminary results* encouraging:
 - ✓ Significant activity shown
 - ✓ Complete responses observed in several forms of NHL**
- **Phase III** programs on-going:
 - ✓ \geq 3rd line iNHL
 - ✓ \geq 2nd line iNHL
- Clinical program also addresses aggressive NHL (DLBCL)
 - ✓ phase II initiated

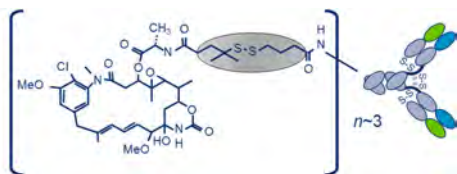
Anetumab Ravnansine – A Novel Antibody-Drug-Conjugate Therapy for Cancer



Mesothelin is overexpressed by a number of solid tumors, including

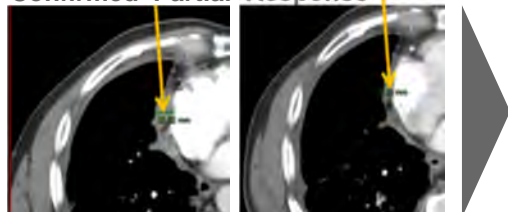
- ⇒ mesotheliomas (100%)
- ⇒ pancreatic cancer (~80-100%) and
- ⇒ ovarian adenocarcinomas (~80%)

Anetumab ravnansine



- Anetumab selectively binds to mesothelin-expressing cancer cells
- Ravnansine - cytotoxic payload targeting tubulin function

Confirmed Partial Response



- Phase I, single-agent, dose-escalation study* with promising results
- Phase II initiated

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Unmet Medical Need – Chronic Heart Failure



Unmet Need

Despite existing therapies and evolving treatment landscape, morbidity and mortality of heart failure remain high

Clinical Burden¹

- 26 million people with HF worldwide
 - 6.5 million in Europe
 - 600,000 new cases per year
 - 5.8 million in US
 - 500,000 new cases per year
- 1 in 5 adults over 40 years of age will develop heart failure in their lifetime
- 1 in 5 patients will die within 1 year of diagnosis



Economic / Societal Burden

- 25 billion in annual health care costs in 2010 (US)
- Average cost of HF-related hospitalization ranges from ~4,000 EUR to >20,000 EUR²

Unmet Medical Need – Diabetic Kidney Disease (DKD)



Unmet Need

- Limited efficacy of SoC (ACEI/ARB) in DKD
- No approved MRAs in kidney disease

Clinical Burden

- ~29 million people with diabetes in the US (9.3% of the population)
- Diabetes causes 44% of new cases of kidney failure
- CV mortality dominates CKD with 45% of deaths¹



Economic / Societal Burden

- Annual treatment cost per patient range from ~2,000 EUR² in earlier disease stages to ~ >75,000² EUR at dialysis
- Diabetes prevalence rising globally

SoC: Standard of Care; ACEI: Angiotensin-converting enzyme (ACE) inhibitors; ARB: Angiotensin receptor blocker; CKD: chronic kidney disease; CV: cardiovascular
1: United States Renal Data System 2012; 2: Bayer estimates

Soluble Guanylate Cyclase Stimulation: Pioneering Novel Therapeutic Options



A novel mode of action...

- An entirely new drug class backed by >20 years of research at Bayer
- soluble Guanylate Cyclase (sGC) is the only known nitric oxide (NO) receptor in the human body
- sGC signaling is a key element of systemic arterial hypertension mediated via cGMP activation
- Proof-of-concept demonstrated (Adempas marketed since 2013)
- Joint development and commercialization with Merck & Co.

... mediating multiple physiological effects

Anti-fibrosis



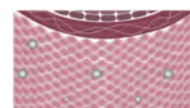
Vasodilation



Anti-proliferation



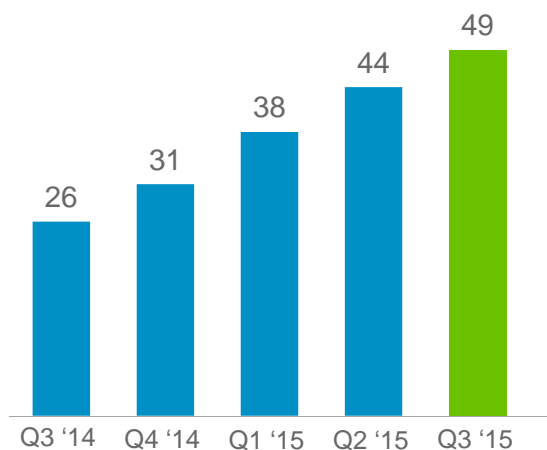
Anti-inflammation



Adempas: First Marketed sGC Modulating Agent



Sales € million



Achievements

- Approved in PAH and CTEPH
- ~5,400 patients treated to date¹
- Life-cycle management underway
 - Systemic sclerosis (SSc)
 - Cystic fibrosis
 - PH associated with idiopathic interstitial pneumonias (PH-IIP)
- Positive phase IIa data in PH-ILD
- Phase IIb program ongoing for SSc and PH-IIP – data 2017e

¹) as of end of Sept 2015; *) as of October '15. PH: Pulmonary hypertension

PAH: Pulmonary arterial hypertension; CTEPH: Chronic thromboembolic pulmonary hypertension
PH-ILD: pulmonary hypertension interstitial lung disease

Vericiguat – Targeting treatment of Heart Failure



A novel sGC stimulator targeting to increase cGMP level

- Potential reduction in morbidity and mortality on top of standard of care in heart failure

New MoA may lead to the restoration of endothelial function

- Holds promise to improve cardiac performance

Presentation of phase IIb data in HFrEF patients at AHA* on November 8th, 2015

*American Heart Association scientific sessions

HFrEF: heart failure with reduced ejection fraction; HFpEF: HF with preserved EF;
sGC, soluble guanylate cyclase; cGMP: cyclic guanosine monophosphate;

The SOCRATES Phase IIb in Worsening Chronic Heart Failure - Study Design



	SOCRATES-REDUCED	SOCRATES-PRESERVED
Design	2 randomized parallel-group, placebo-controlled, double-blind, dose finding phase IIb studies of 4 dose regimens (1.25 – 10 mg) Vericiguat over 12 weeks	
Inclusion criteria	wCHF requiring hospitalization (or IV diuretic for HF) with initiation after clinical stabilization	
	LVEF < 45% (HFrEF)	LVEF ≥ 45% (HFpEF) Left atrial (LA) enlargement
Primary outcome	NT-proBNP at 12 weeks	NT-proBNP / LAV at 12 weeks
Secondary outcomes	Secondary endpoints include clinical outcomes (cardiovascular death; recurrent hospitalization for worsening heart failure etc.)	
Sample size	410 patients in 5 arms	470 patients in 5 arms
Data presentation	AHA Nov. 8, 2015	Planned for 1H 2016

sGC: soluble guanylate cyclase; LVEF: left ventricular ejection fraction; NT-proBNP: N-terminal of the prohormone brain natriuretic peptide; LAV: left atrial volume ; HFpEF: heart failure with preserved ejection fraction; HFrEF: HF reduced EF

Finerenone – Phase II Program Successfully Completed



Heart failure

- **ARTS***: Improved safety and at least similar efficacy in decreasing biomarkers vs. spironolactone
- **ARTS-HF****: Decreased NT-proBNP levels – a marker for cardiac stress – similar to eplerenone. A strong trend to less events with higher doses for the secondary clinical outcome suggesting a potential benefit in reducing mortality and cardiovascular hospitalization

Diabetic kidney disease

- **ARTS-DN⁺**: Finerenone dose-dependently decreased albumin excretion - a marker for kidney function/disease

All doses studied were well tolerated

➔ Phase III program will study Finerenone in CHF and DKD

NT-proBNP: N-terminal pro-B-type natriuretic peptide; CHF: Chronic heart failure; DKD: Diabetic Kidney disease; *Pitt B et al. Eur Heart J 2013;34, 2453-63; ** ARTS-HF was a phase IIb dose-finding study with no confirmatory testing of endpoints presented at ESC congress on Aug 31st 2015; *Bakris GL JAMA 2015;314(9):884-894

Finerenone – Phase III Program Includes Three Event-Driven Outcome Trials



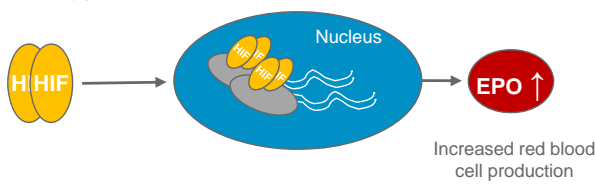
DKD	<p>FIGARO-DKD N~6,400</p> <ul style="list-style-type: none"> • T2DM and DKD • DKD with high risk of developing CV events • Primary endpoint: CV death / non fatal CV events • Position as first-in-class MRA in DKD
	<p>FIDELIO-DKD N~4,800</p> <ul style="list-style-type: none"> • T2DM and DKD • DKD with high risk of progression of CKD and developing CV events • Primary endpoint: Renal death / kidney failure • Position as first-in-class MRA in DKD
CHF	<p>FINESSE-HF N~4,700</p> <ul style="list-style-type: none"> • Chronic HFrEF with T2DM and/or CKD • Patients at high risk of CV mortality and morbidity • Primary endpoint: CV death / CV hospitalization • Target best-in-class MRA profile in HFrEF

CHF: Chronic Heart Failure; CKD: chronic kidney disease; DKD: diabetic kidney disease; MRA: mineralocorticoid receptor antagonist; CV: cardiovascular; HFrEF: heart failure with reduced ejection fraction; T2DM: type 2 diabetes mellitus

Molidustat – An Oral HIF-PH Inhibitor for Treatment of Renal Anemia

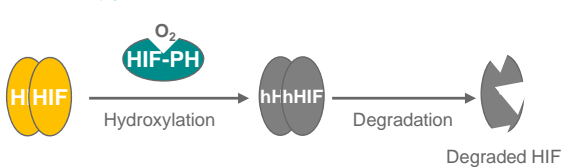


Low oxygen levels



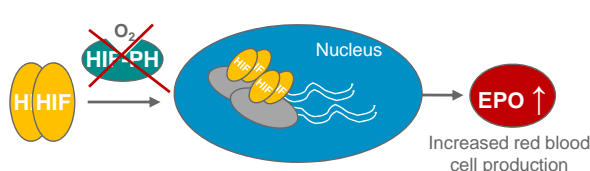
Under hypoxia conditions, HIF is activated and induces the synthesis of erythropoietin (EPO) in the kidneys which stimulates red blood cell formation

Normal oxygen levels



Under normal oxygen conditions, HIF gets hydroxylated by HIF-PH and then degraded

Inhibition

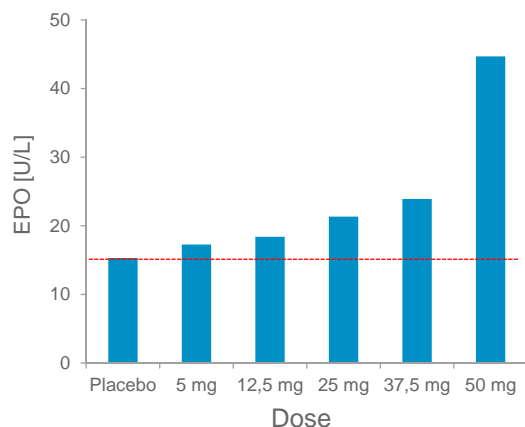


Inhibition of HIF-PH increases the stability of HIF resulting in production of endogenous EPO - potential novel therapeutic approach for the treatment of renal anemia

Molidustat – Proof of Concept Demonstrated



Maximal EPO concentration after single dose administration of Molidustat (phase I)



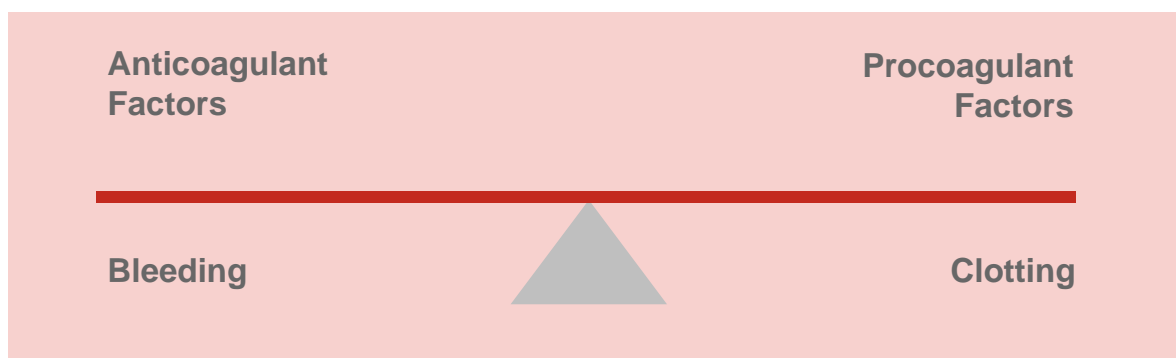
- Molidustat is a novel oral inhibitor of the enzyme HIF-PH
- In development for the treatment of anemia associated with chronic kidney disease
- Phase I in healthy subjects showed:
 - Significant increase of EPO levels after ≥ 12.5 mg
 - Significant increase of reticulocytes for doses ≥ 37.5 mg
 - No prohibitive safety findings
- First data from ongoing phase IIb program expected 1H 2016

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Modulating Hemostatic Balance in Hemophilia



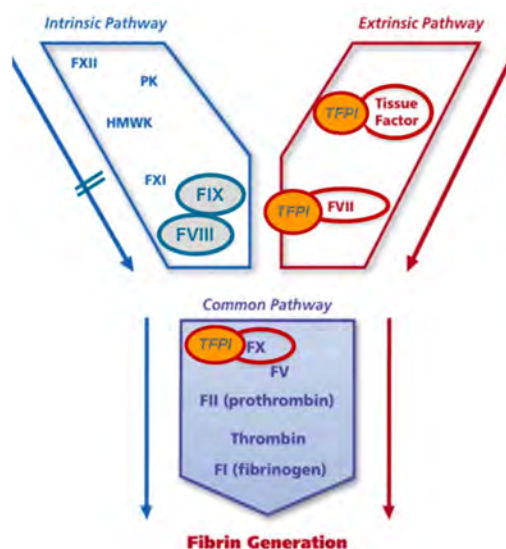
In hemophilia and other bleeding disorders, clotting can be enhanced by

- Increase in procoagulant factors, e.g. factor VIII supplementation
- Decrease in anticoagulant factors, e.g. plasminogen-inhibition, inhibition of TFPI (Tissue Factor Pathway Inhibitor)

TFPI-Inhibition as a Potential Novel Treatment Principle for Hemophilia A/B



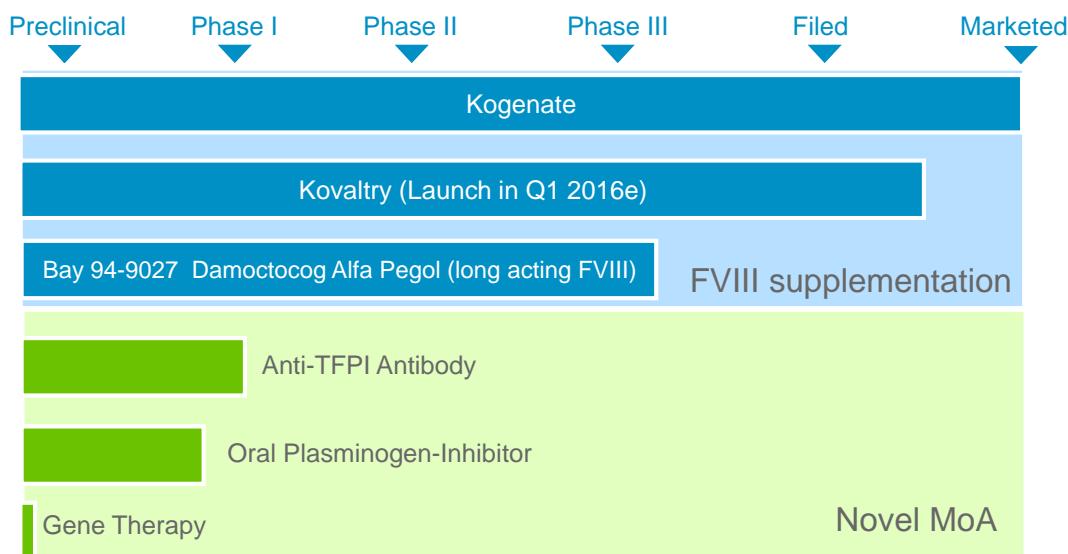
Role of TFPI* in Coagulation



anti-TFPI Facts

- Can reversibly inhibit various clotting factors leading to bleeding
- Inhibition of TFPI potentially offers novel treatment option for Hemophilia A/B patients with or without inhibitors
 - Hemophilia patients depend on extrinsic pathway for clotting. anti-TFPI Ab inhibits TFPI - thereby restoring impaired hemostasis
- BAY1093884 is a fully human monoclonal antibody
- Phase I initiated

Robust Innovation Pipeline in Hemophilia and Bleeding Disorders



Damoctocog Alfa Pegol (BAY 94-9027) Reduction of Infusion Frequency in Prophylaxis



- Site-specific PEGylated B-domain-deleted recombinant factor VIII - Filing planned for mid 2017
- Attachment of PEG extends half-life without reducing FVIII activity

Study Arm	Patients (n) remaining on treatment	Patients with no bleeding	Median ABR
Prophylaxis: infusion 2x/week	n.a.	n.a.	17.4 (reduction to 4.1 after dose increase)
Prophylaxis: infusion every 5 days	43/43	44%	1.9
Prophylaxis: infusion every 7 days	32/43	37% (incl. non-completers)	3.9* (incl. non-completers)
On-demand treatment	n.a.	n.a.	23.0

Phase III results

- No inhibitors against FVIII developed during treatment period, hypersensitivity reaction in two patients within the first 2 weeks of treatment

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Leading in Women's Healthcare



**Oral
contraception**

YAZ-family
Beyaz, Safyral, Natazia, Qlaira



**Long-acting
contraception**

Mirena-family, the leading long-acting
reversible contraception devices



**Gynecological
therapies**

Visanne, a new option for treatment of
endometriosis

Uterine Fibroids - The Most Common Benign Tumors in Women of Reproductive Age



- 5-10% of fertile women suffer from symptoms (peak in late reproductive years)
- Benign, progesterone and estrogen tumors of the myometrium
- Common symptoms: heavy menstrual bleeding, pelvic pain and reproductive dysfunction
- Current therapies include surgical procedures, ulipristal (sPRM) or short-term use of GnRH analogs



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sPRM- selective progesterone receptor modulator
GnRH - gonadotropin-releasing hormone

Vilaprisan – Developed For Treatment of Uterine Fibroids



Targeting best in class drug for treatment of uterine fibroids:

- Novel oral, highly potent and selective progesterone receptor modulator
- Exhibits marked efficacy in an innovative humanized fibroid disease model¹
- Phase IIa data (N=67) showed proof of concept including:
 - Reduction of bleeding
 - Reversal of amenorrhea after treatment cessation
 - No prohibitive safety findings

ASTEROID

ASSESS SAFETY AND EFFICACY OF VILAPRISAN
IN WOMEN WITH UTERINE FIBROIDS

Arm 1 (n=300): **Dose finding study** (placebo controlled)

Arm 2 (n=138): **Vilaprisan vs. ulipristal vs. placebo**

First phase IIb data* H1 2016e

Innovations For Sustainable Growth at Pharma



- Investing in Xarelto and next-gen anti-coagulation therapies
- Exploring combination therapy for Eylea
- Exploiting multiple pathways in oncology research
- Developing new therapies in cardio-renal diseases
- Maintaining leadership in women's health

Expected Newsflow from Pharma Pipeline



Compound	Intended Indication	Status	Expected Completion
Vericiguat sGC stimulator	Wors. chronic heart failure	Phase IIb; reduced ejection fraction	mid 2015e
Vericiguat sGC stimulator	Wors. chronic heart failure	Phase IIb; preserved ejection fraction	end 2015e
Copanlisib PI3 kinase inhibitor	Non-Hodgkin's lymphoma	Phase II	1H 2016e
Roniciclib CDK-Inhibitor	Small cell lung cancer	Phase II	1H 2016e
Regorafenib Multikinase inhibitor	HCC (2 nd line)	Phase III	1H 2016e
Molidustat HIF-PH inhibitor	Anemia	Phase II	1H 2016e
Vilaprisan Selective progesterone receptor modulator	Uterine fibroids	Phase IIb	1H 2016e
Rivaroxaban Factor Xa inhibitor	Atrial fibrillation with Percutaneous Coronary Intervention (PIONEER AF-PCI)	Phase III/IV	2H 2016e
ODM-201 Androgen receptor antagonist	Non-metastatic castration-resistant prostate cancer	Phase III	2018e



Date	Event	Publication
Thursday, February 25, 2016	Investor Conference Call	2015 Annual Report
Tuesday, April 26, 2016	Investor Conference Call	First Quarter 2016 Results Stockholders' Newsletter
Friday, April 29, 2016	Annual General Meeting	
Wednesday, July 27, 2016	Investor Conference Call	Second Quarter 2016 Results Stockholders' Newsletter
Wednesday, October 26, 2016	Investor Conference Call	Third Quarter 2016 Results Stockholders' Newsletter



Reporting Events



Dr. Alexander Rosar

Head of Investor Relations

Phone: +49-214-30-81013

E-mail: alexander.rosar@bayer.com

Dr. Jürgen Beunink

Phone: +49-214-30-65742

E-mail: juergen.beunink@bayer.com

Judith Nestmann

Phone: +49-214-30-66836

E-mail: judith.nestmann@bayer.com

Peter Dahlhoff

Phone: +49-214-30-33022

E-mail: peter.dahlhoff@bayer.com

Constance Spitzer

Phone: +49-214-30-33021

E-mail: constance.spitzer@bayer.com

Dr. Olaf Weber

Phone: +49-214-30-33567

E-mail: olaf.weber@bayer.com



Contacts