

Investor Handout Bayer Pharmaceuticals
Credit Suisse One-on-One Healthcare Conference
March 2017



### Cautionary Statements Regarding Forward-Looking Information

Certain statements contained in this communication may constitute "forward-looking statements." Actual results could differ materially from those projected or forecast in the forwardlooking statements. The factors that could cause actual results to differ materially include the following: uncertainties as to the timing of the transaction; the possibility that the parties may be unable to achieve expected synergies and operating efficiencies in the merger within the expected time-frames or at all and to successfully integrate Monsanto Company's ("Monsanto") operations into those of Bayer Aktiengesellschaft ("Bayer"); such integration may be more difficult, time-consuming or costly than expected; revenues following the transaction may be lower than expected; operating costs, customer loss and business disruption (including, without limitation, difficulties in maintaining relationships with employees, customers, clients or suppliers) may be greater than expected following the announcement of the transaction; the retention of certain key employees at Monsanto; risks associated with the disruption of management's attention from ongoing business operations due to the transaction; the conditions to the completion of the transaction may not be satisfied, or the regulatory approvals required for the transaction may not be obtained on the terms expected or on the anticipated schedule; the parties' ability to meet expectations regarding the timing, completion and accounting and tax treatments of the merger; the impact of indebtedness incurred by Bayer in connection with the transaction and the potential impact on the rating of indebtedness of Bayer; the effects of the business combination of Bayer and Monsanto, including the combined company's future financial condition, operating results, strategy and plans; other factors detailed in Monsanto's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (the "SEC") for the fiscal year ended August 31, 2016 and Monsanto's other filings with the SEC, which are available at http://www.sec.gov and on Monsanto's website at www.monsanto.com; and other factors discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. Bayer assumes no obligation to update the information in this communication, except as otherwise required by law. Readers are cautioned not to place undue reliance on these forwardlooking statements that speak only as of the date hereof.

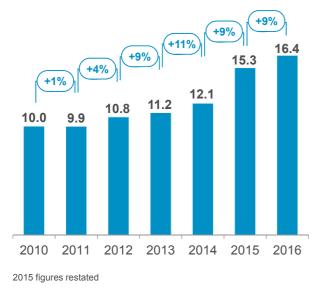




## **Fast-Growing Pharma Business**

#### Sales

€ billion; ∆% 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

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## FY 2016 – Pharmaceuticals Delivers Substantial Increases in Sales and Earnings



#### Sales

in € million; Δ% yoy, Fx & portfolio adj.

### **Key Growth Products**

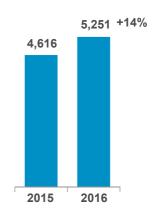
2016 sales in € million, Δ% yoy, Fx adj.

#### **EBITDA**

before special items, in € million; ∆% yoy







# FY 2017 Pharma Guidance - Projecting Profitable Growth



Sales  $\triangle$  Fx & portf. adjusted, adj. EBITDA margin = EBITDA before special items to sales

	2016	2017
Sales		Mid-single-digit % increase to >€17bn
Sales of Key Growth Products*	€5.4bn	> €6bn
EBITDA before special items	€5.3bn	High-single-digit % increase
Adj. EBITDA margin	32.0%	Improve

Assuming end 2016 Fx rates (USD 1.05); Outlook depends on specific planning assumptions as detailed in the Annual Report; \*key growth products include Xarelto, Eylea, Stivarga, Xofigo, Adempas

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## Pharma Mid-Term Aspirations 2018

	2015	Aspiration 2018
Sales	+9.1% to €15.3bn	~6% CAGR (2015-2018)
Adj. EBITDA margin	30.1%	32 - 34% despite dilution through RAD and significant investment in R&D

Sales  $\Delta$  Fx & portf. adjusted, EBITDA before special items Outlook depends on specific planning assumptions outlined in the Interim Report Q2 2016 2015 figures restated; RAD: radiology business – became part of Pharma effective January 1, 2016

# Combined Peak Sales Potential of Key Growth Products Raised to >€10bn



	Old		Current
Xarelto rivaroxaban	~€3.5bn	Continued successful performance and LCM	>€5bn
EYLEA	≥€1.5bn	Continued successful performance	>€2.5bn
Xofigo® radium Ra 223 dichloride injection	≥€1bn	Continued successful performance     Broadened LCM activities	>€1bn
Stivarga®	≥€1bn	Positive phase III in 2 <sup>nd</sup> line HCC     Phase III in adjuvant CRC initiated	≥€1bn
Adempas	≥€0.5bn	Multiple LCM activities including non-PH indications	>€0.5bn

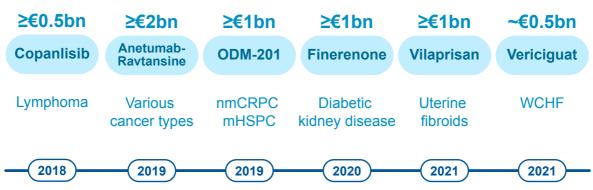
Combined peak sales potential for Xarelto, Stivarga, Eylea, Xofigo and Adempas assuming approvals and launches as planned; LCM: life cycle management; CRC: colorectal cancer; HCC: hepatocellular cancer; PH: pulmonary hypertension

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## Fully Realize Pipeline Potential



### Combined\* Peak Sales Potential ≥€6bn



first expected launches in first countries

<sup>\*</sup> Combined peak sales potential for assets as above assuming approvals and launches as planned; nmCRPC: non-metastatic castration resistant prostate cancer; mHSPC: metastatic hormone-sensitive PC; WCHF: worsening chronic heart failure



## Focused Leadership Strategy for Pharma

### **Build on leading positions in**

- · Cardiology / Thrombosis
- Woman's HealthCare
- Hemophilia

### **Establish focused segment leadership positions in Oncology**

- Realize blockbuster potential for marketed drugs Xofigo and Stivarga
- Focus and reinforce Oncology R&D

### Fully realize pipeline potential

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## Leading Cardiovascular Portfolio



#### **Thrombosis**

- Xarelto performance excellent peak sales estimate raised to >€5bn
- · Continue to invest in Xarelto LCM and launch preparations of LCM indications
- Pursue FXI/FXIa inhibition approach

## Heart Failure

- Ph3 program of Vericiguat (HFrEF) in collaboration with Merck & Co. Inc.
- Pursue development of Neladenoson (Partial A1agonist) in HFrEF and HFpEF in parallel
- · Continue to advance chymase inhibitor and dual vasopressin receptor antagonist to PoC

#### **Kidney**

- Fully support Finerenone in DKD to build a leadership position in nephrology
- · Develop Molidustat in Japan only
- · Advance early pipeline projects to establish franchise

#### Mature Brands

- · Adalat a cornerstone in CV disease treatment
- · Glucobay continued growth expected in Emerging Markets, especially China
- Aspirin Cardio continued growth expected

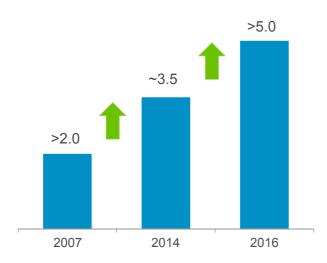
LCM: life cycle management; HFrEF: heart failure with reduced ejection fraction; HFpEF: HF with preserved EF; PoC: proof of concept; DKD: diabetic kidney disease; CV: cardiovascular

## Xarelto – Peak Sales Potential Estimates Raised - Again





€ billion



1: according to IMS; 2: calculation based on IMS Health MIDAS database

- Continued excellent performance Xarelto now a TOP 10 global Pharma brand1
- >26 million patients treated since launch<sup>2</sup>
- Further growth potential driven by:
  - Under-served patient populations in launched indications
  - Demographics
  - · Shift from warfarin
  - New indications targeting patients currently not treated with anticoagulants

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## Xarelto Life Cycle Management Program Addressing The Full Range of Unmet Need

















**Patients without Atrial Fibrillation** 



Patients with acute CAD/PAD

VOYOGER PAD

Patients with chronic CAD/PAD

OMPASS # MMANDER HE



Arterial **Thromboembolism** 



Patients with venous thromboembolism

EINSTEIN & EINSTEIN CHOICE EINSTEIN JUNIOR



Patients in need for VTE prevention









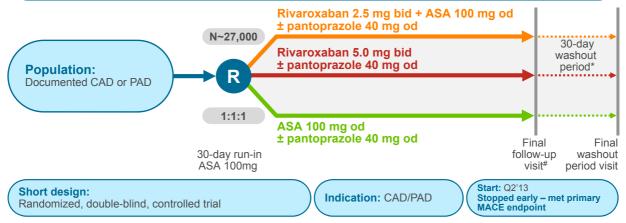
CAD: coronary artery disease; PAD: peripheral artery disease; VTE: venous thromboembolism

## COMPASS CAD/PAD Study



Study title: A Randomized Controlled Trial of Rivaroxaban for the Prevention of Major Cardiovascular Events in Patients With Coronary or Peripheral Artery Disease (COMPASS – Cardiovascular OutcoMes for People Using Anticoagulation StrategieS)

**Objective:** Efficacy and safety of Rivaroxaban, low-dose Rivaroxaban plus ASA or ASA alone for reducing risk of MI, stroke or cardiovascular death in CAD or PAD



- Patients treated according to local standard of care; # ≤30 days of the required pre-specified number of events having occurred
- MACE: major adverse cardiac events;

www.clinicaltrials.gov/show/NCT01776424

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# COMPASS Study Details



#### **Primary efficacy endpoint**

 Composite of MI, stroke or cardiovascular death

#### Key inclusion criteria#

- CAD or PAD plus ≥1 of:
  - Age ≥65 years
  - Age <65 years plus atherosclerosis in ≥2 vascular beds or ≥2 additional risk factors

#### **Primary safety endpoint**

· Modified ISTH major bleeding

### Key exclusion criteria<sup>‡</sup>

- Stroke ≤1 month or any haemorrhagic or lacunar stroke
- Severe HF with known ejection fraction <30% or NYHA class III or IV symptoms</li>
- eGFR <15 ml/min</li>
- Concomitant use of other anticoagulants
- Chronic treatment with non-ASA antiplatelet therapy

<sup>#</sup> including but not limited to; <sup>‡</sup> any other exclusion criteria in conjunction with the local product information and any other contraindication listed in the local labeling for Rivaroxaban or the comparator have to be considered; www.clinicaltrials.gov/show/NCT01776424

# COMPASS Phase III Stopped Early on Success\*



- Phase III COMPASS evaluating rivaroxaban for the prevention of major adverse cardiac events (MACE) in patients with coronary artery disease (CAD) or peripheral artery disease (PAD) showed overwhelming efficacy and met its primary endpoint ahead of time
- Following a planned interim analysis, the DMC recommended to stop the trial early as the primary MACE endpoint has reached its prespecified criteria for superiority
- Full data planned to be presented at an upcoming scientific conference during 2017

\*press release Feb 8, 2017 DMC: independent Data Monitoring Committee

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# Finerenone – Opportunity to Lead in Diabetic Kidney Disease



#### **Finerenone**

- Finerenone is a novel non-steroidal MRA with a differentiated profile
- Steroidal MR antagonists are not approved for kidney diseases
- A Finerenone phase IIb (ARTS-DN) study in Diabetic Nephropathy was successfully completed

#### **Diabetic Kidney Disease**

- Market for chronic kidney disease estimated at ~\$14bn in 2024
- Resulting complications from Diabetes accounting for 35% of CKD
- ~40% of new cases of end-stage renal disease (ESRD) are due to Diabetes Mellitus (DM)
- Patients with Type II DM and CKD are at high risk of cardiovascular (CV) death
- → Significant need for innovative therapies
- → Phase III program in DKD progressing as planned

DKD: diabetic kidney disease; CKD chronic kidney disease; MRA: mineralocorticoid receptor antagonist

# Vericiguat – Potential First-in-Class Treatment for Chronic Heart Failure



# Novel approach targeting the critical cGMP cardiovascular pathway that is impaired in CHF patients

- A lack of sGC stimulation leads to the reduced activity of the "nitric oxidesGC-cGMP" pathway, causing coronary dysfunction and progressive myocardial damage
- By directly stimulating the critical enzyme sGC, Vericiguat restores this pathway and in turn may improve heart and vascular function
- Phase III (VICTORIA) trial assesses a potential reduction in mortality and morbidity on top of standard of care in HFrEF patients
- VICTORIA trial ongoing<sup>1</sup>

1: study sponsor: Merck Sharp & Dohme Corp; cGMP: cyclic guanosine monophosphate; sGC: soluble guanylate cyclase; CHF: chronic heart failure; HFrEF: heart failure with reduced ejection fraction

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# Establish Focused Leadership Positions in Oncology



**Xofigo** 

- Target "agent of choice" status clear survival benefit for patients with bone metastases in prostate cancer demonstrated
- Expand in additional cancer types beyond prostate cancer

Stivarga

- Build position in hepatocellular carcinoma (HCC)
- Strengthen position in colorectal cancer through LCM in adjuvant setting

Nexavar

• Reinforce leadership in liver cancer through capitalizing on optimal treatment continuum / sequence for Nexavar & Stivarga in HCC

Focus Oncology R&D

- Differentiation for leadership in selected areas (Thorium platform; ADC's)
- · Focus on differentiated programs

Execute launch pipeline

- Stivarga HCC 2L → launch 2017e
- Copanlisib iNHL → launch 2018e
- Anetumab R. mesothelioma → launch 2019e
- Xofigo additional indications/uses
   → first launch 2019e
- ODM-201 in nmCRPC
   → launch 2019e

nmCRPC: non-metastatic castration resistant prostate cancer; LCM: life cycle management; ADC: antibody-drug conjugate; iNHL: indolent Non-Hodgkin's lymphoma

## Expanding Xofigo's Position in Castration-Resistant Prostate Cancer Treatment



#### Metastatic castration-resistant prostate cancer

Asymptomatic bone metastases

Symptomatic bone metastases

Potential new disease area for combination therapy

Xofigo (radium Ra 223 dichloride injection)

Novel antihormonal agents (eg. Zytiga® [abiraterone])

#### Chemotherapy

- Combination therapy with abiraterone, an inhibitor of testosterone synthesis
- Expansion to earlier disease stages enhances accessible patient population
- A delay of skeletal-related events is of major clinical importance

For details on approved indications see respective product labels; Zytiga® is a trademark of Johnson & Johnson

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# ODM-201 – A Novel, New-Generation Nonsteroidal AR Antagonist



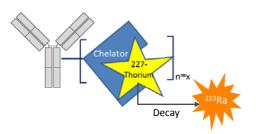
- ODM-201 is a potent and full AR antagonist
- Promising efficacy profile demonstrated in previous studies
  - · Inhibits growth of prostate cancers in preclinical studies
  - · Significantly decreases PSA levels in patients with progressive CRPC
  - Sustained PSA reduction was observed at higher dose levels
- ODM-201 antagonizes mutant ARs linked to resistance to other AR antagonists (ie, bicalutamide, enzalutamide)
- Phase III program ongoing addressing
  - i. hormone sensitive metastatic prostate cancer
  - ii. non-metastatic CRPC

AR: androgen receptor; CRPC: castration-resistant prostate cancer; PSA: prostate-specific antigen

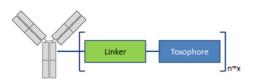
## R&D Differentiates Through Targeted Alpha-Pharmaceuticals and Novel Toxophor ADCs



### Targeted Thorium Conjugates (TTCs)



### Antibody Drug Conjugates (ADCs)

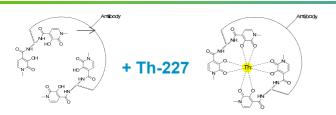


- Thorium-platform unique to Bayer
- Thorium-platform offers to deliver alpha emitters to every tumor
- Thorium-platform offers synergies with Xofigo with respect to manufacturing and supply chain
- Advanced and broad ADC program established
- Synergies between Thorium and ADC platforms with respect to antigens, antibodies, linker technologies, etc.

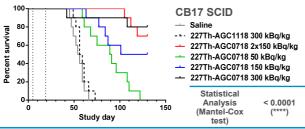
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# Targeted Thorium Conjugates – Expanding the Alpha-Pharmaceuticals Platform





#### Preclinical disseminated AML tumor model



Animals treated 5 days after inoculation of HL60 (AML)

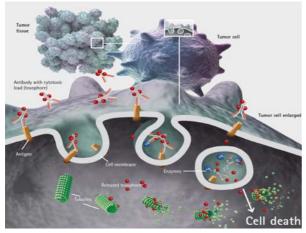
For all surviving animals **no tumors** were found on dissection

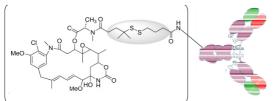
AML: acute myeloid leukemia

- Alpha particle emitter high energy, heavy charged particle
  - Half-life 18.7 days suitable for tumor delivery by mAbs
- Significant efficacy demonstrated in preclinical model
- Fast proof of concept targeted Phase I for α-CD22 Th-227 conjugate progressing
- Next steps initiated to explore Thorium platform in solid tumors



## Anetumab Ravtansine Program Advancing





#### Mode of action:

 ADC targeting tumor-associated antigen mesothelin, and delivering toxophore DM4, which acts on proliferating cells (tubulin inhibitor)

# Potential spectrum of indications determined by mesothelin expression pattern:

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

#### **Clinical program:**

- Phase I\* with promising results including duration of treatment of > 1,000 days
- Registrational phase II in metastatic pleural mesothelioma ongoing

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## **Expected Pipeline Newsflow 2017**



Life Cycle Management Programs			
Asset	Newsflow	Timing	
Rivaroxaban	COMPASS Phase III data	Presentation planned at an upcoming conference	
Rivaroxaban	EINSTEIN CHOICE Phase III data	Presentation at ACC March 2017e	
Rivaroxaban	GEMINI Phase II data	Presentation at ACC March 2017e	
Regorafenib	Launch 2L HCC*	During 2017e*	
Radium-223	Phase III combi. with abiraterone	Primary completion end 2017e	

2L HCC: second line hepatocellular carcinoma; \*subject to regulatory approval

<sup>\*</sup> Blumenschein et al. ASCO 2016; ADC: antibody drug conjugate



## **Expected Pipeline Newsflow 2017**

Mid-/Late Stage Pipeline Programs			
Asset	Indication	Newsflow	Timing
Copanlisib	Non-Hodgkin's Lymphoma	CHRONOS-1 Phase II data	Presentation planned at an upcoming conference
Vilaprisan	Uterine Fibroids	ASTEROID-2 Phase II data	Presentation panned at an upcoming conference
Damoctocog alfa pegol	Hemophilia A	First filing	mid 2017e
Amikacin Inhale	Lung Infection	Phase III	Primary completion 1H 2017e
Molidustat	Renal Anemia	Phase III initiation (Japan)	During 2017e
Vilaprisan	Uterine Fibroids	Phase III initiation	During 2017e

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## Summary



- Projecting future growth for Pharma
- Peak sales estimates for key growth products increased to
   > €10bn
- Pipeline holds promise with a peak sales potential\* of selected assets of
   ≥ €6hn
- · Build on existing leading positions in key therapeutic areas
- Expand successful cardiovascular business
- · Focus Oncology portfolio and build leading segment positions

<sup>\*</sup> Combined peak sales potential for Copanlisib, Anetumab Ravtansine, Finerenone, Vericiguat, Vilaprisan and ODM-201 assuming approvals and launches as planned



Date	Event	Publication
Wednesday, March 15, 2017	Meet Management in London	Investor Conference
Thursday, April 27, 2017	Investor Conference Call	Q1 2017 Interim Report
Friday, April 28, 2017	Annual Stockholders' Meeting	
Thursday, July 27, 2017	Investor Conference Call	Q2 2017 Interim Report
Thursday, October 26, 2017	Investor Conference Call	Q3 2017 Interim Report
Wednesday, February 28, 2018	Investor Conference Call	2017 Annual Report
Thursday, May 03, 2018	Investor Conference Call	Q1 2018 Interim Report
Friday, May 25, 2018	Annual Stockholders' Meeting	



**Reporting Events** 



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