



Investor Handout Pharmaceuticals



March 2019





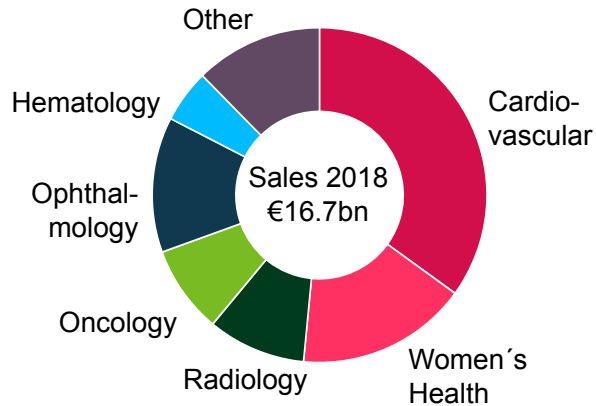
Cautionary Statements Regarding Forward-Looking Information

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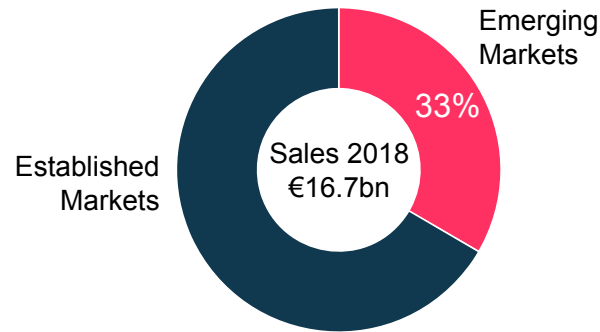


Innovative Medicines in Areas of High Unmet Medical Need

Therapeutic area focus



Emerging markets exposure



Global leadership in important therapeutic areas

- // **No. 1** in Retinal Diseases
- // **No. 1** in Women's Health
- // **No. 1** in Radiology
- // **No. 2** in Cardiovascular
- // **No. 2** in Hematology

Leading Brands

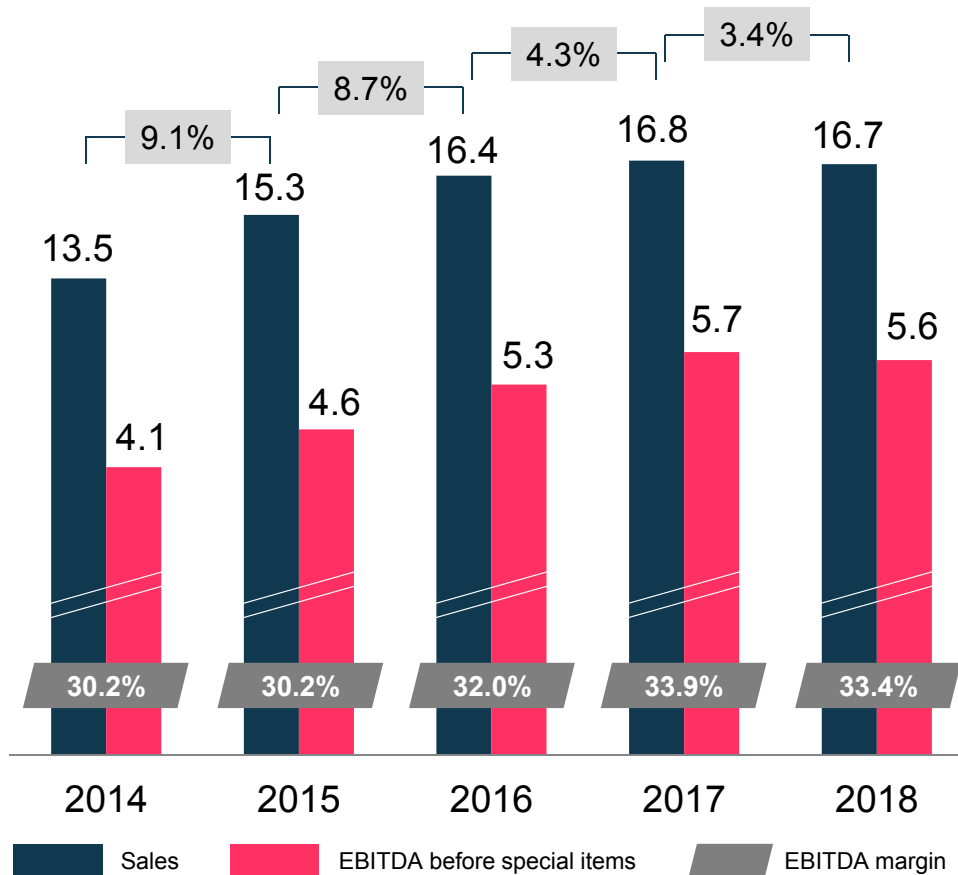


Emerging markets include Latin America, Asia (w/o Japan, Australia, New Zealand), Africa and Middle East incl. Turkey, Eastern Europe



Attractive Sales Growth and Margin Expansion

€bn



// Attractive sales growth

// Successful commercialization of innovative products, with Xarelto and Eylea becoming blockbuster brands

// Disciplined resource allocation

// Further growth in sales and profitability expected:

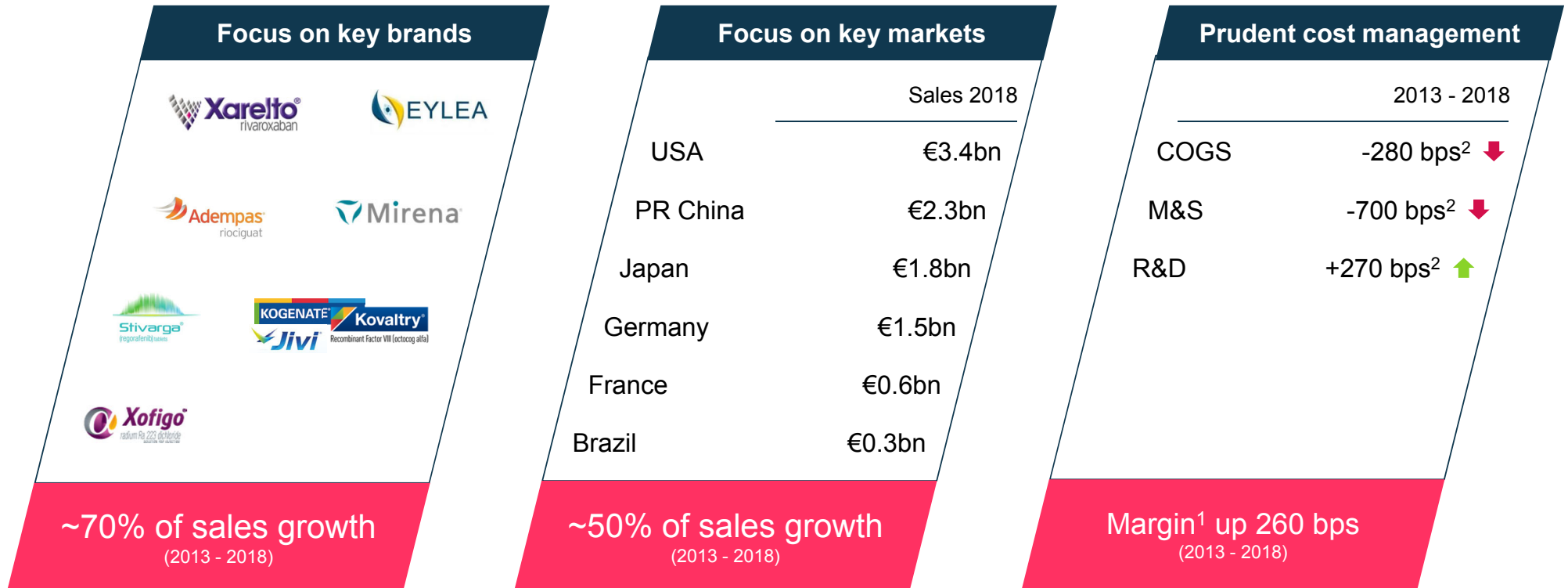
// Sales growth in the range of 4 to 5 percent per annum on average until 2022

// Further margin expansion to more than 35 percent in 2022

Including Radiology; Sales growth currency and portfolio adjusted; EBITDA margin before special items



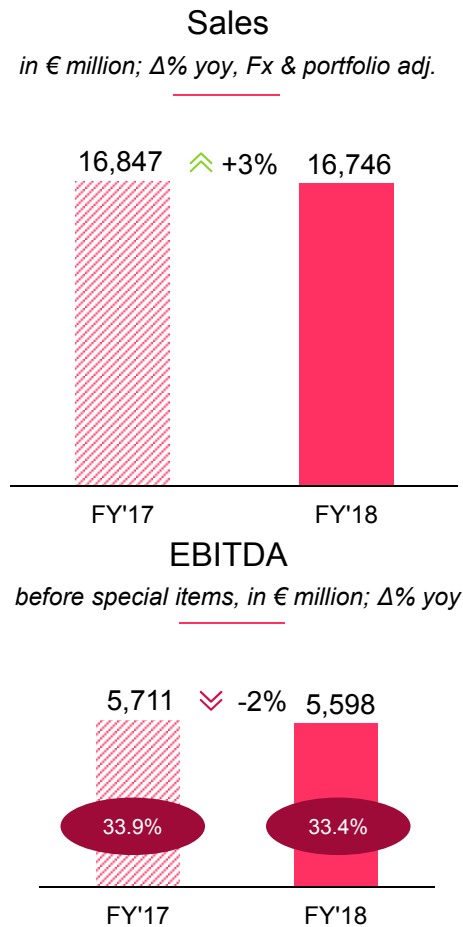
Key Drivers for Growth and Margin Expansion



¹ EBITDA margin before special items; bps: Basis points, ² as percentage of sales; R&D costs adjusted by opt-in payment from J&J of about €190million



FY 2018 – Pharmaceuticals Driven by Xarelto & Eylea



// Volume	+6%	// Currency	-4%
// Price	-2%	// Portfolio	-0%

- // Key growth products grew by 14%, top 15 products by 6%*
- // Xarelto (+13%) & Eylea (+20%) with continued strong growth*

- // New launches / indications for Xarelto (CAD/PAD), Vitrakvi (US), Jivi, Kovaltry (China) and Eylea (China DME & wAMD)
- // Darolutamide with strong efficacy and safety data

// EBITDA heavily impacted by negative Fx effects of €256m

● EBITDA Margin *Δ% yoy, Fx & portfolio adj.



Further Growth in Sales and Profitability

Pharma	2018	Outlook 2019	Target 2022
Sales/Sales growth	€16.7bn	~4%	CAGR 4-5%
EBITDA/EBITDA margin	€5.6bn	~34%	>35%

Key Products	2018	Outlook 2019
Xarelto	€3.6bn	Low teens percentage increase
Eylea	€2.2bn	High-single-digit percentage increase

2019 Outlook at constant currencies; 2022 targets at constant currencies, not including portfolio measures
EBITDA / EBITDA margin based on EBITDA before special items






We Are Confident for Pharma Also Beyond 2022



LoE: Loss of exclusivity








Focused Leadership Strategy to Deliver Mid-term Targets and to Ensure Long-term Success

Focused Leadership		
 Relentless Focus	 Innovation	 Excellence in Execution
<ul style="list-style-type: none">// Stringent focus on key brands and markets incl. China// Achieve category/segment leadership within Oncology and Cardiovascular	<ul style="list-style-type: none">// Supplement organic pipeline with select in-licensing and bolt-on M&A options// Transform innovation model to ensure long-term success beyond LoEs	<ul style="list-style-type: none">// Maintain operational focus// Deliver on mid-term growth and margin aspirations// Execute efficiency measures

LoE: Loss of exclusivity



Cardiovascular and Oncology in Focus for Leadership Aspiration

Cardiovascular	Oncology	Ophthalmology Pulmonology	Women's Health Hematology	Radiology & Others
 <ul style="list-style-type: none"> // Strong heritage and capabilities // Leading player in Thrombosis // Major success with state-of-the-art anticoagulant Xarelto 	 <ul style="list-style-type: none"> // Emerging player in Oncology // Delivered first marketed alpha-therapy, Xofigo // Pioneering precision medicine in cancer with Vitrakvi 	 <ul style="list-style-type: none"> // Eylea being a leader in retinal diseases // First therapeutic sGC modulator with Adempas 	 <ul style="list-style-type: none"> // Comprehensive product portfolio for Women's Health: short- and long-acting reversible contraception, gynecological therapies // Strong profile in Hemophilia 	 <ul style="list-style-type: none"> // Maintain leading industry position for Radiology // Focus on cash flow contribution
Achieve Category / Segment Leadership		Maximize Potential	Maintain Leadership	



Cardiovascular

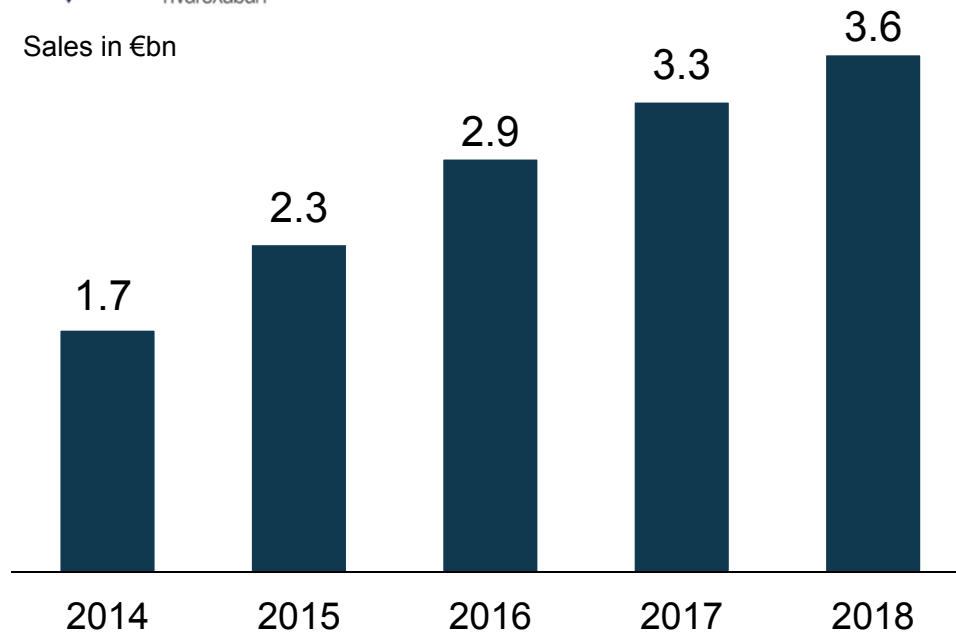




Xarelto – Continued Growth of a Leading Anticoagulant



Sales in €bn



- // Most broadly indicated anticoagulant for use in venous and arterial thromboembolic conditions
- // A leading pharma brand with global sales of €5.2bn in 2018 incl. sales at Johnson & Johnson
- // New CAD/PAD indication launching in EU and the US
- // Peak sales potential: >€5.0bn¹
- // Further growth driven by:
 - // Under-served patient populations
 - // Demographics
 - // Shift from warfarin
 - // New indications targeting patients currently not treated with anticoagulants

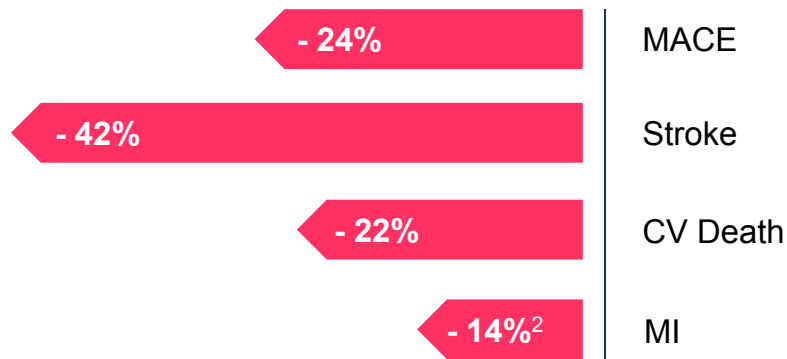
CAD: Coronary artery disease; PAD: Peripheral artery disease
¹ Ex-US sales plus royalty from J&J as reported by Bayer



Xarelto Demonstrates Significant Therapeutic Benefits in CAD/PAD

Potential for Changing the Current Standard of Care

Efficacy (RRR)



// Combination of Xarelto 2.5 mg bid + aspirin 100 mg od compared to aspirin 100 mg od alone (COMPASS)

// Significant reduction in the relative risk for the primary composite of stroke, myocardial infarction and cardiovascular death (MACE)

// 20% improvement in net clinical benefit¹

// Provides a larger relative risk reduction than dual anti-platelet strategies

// Xarelto is the only oral anticoagulant that is approved for the prevention of atherothrombotic events in patients with CAD or PAD

Safety

// Low overall bleeding incidence rates, although major bleeding was increased

// No significant increase in fatal or intracranial bleeding

Eikelboom et al., N Engl J Med 2017; 377: 1319-1330

CAD: Coronary artery disease; PAD: Peripheral artery disease; MACE: Major adverse cardiovascular events; CV: Cardiovascular; MI: Myocardial infarction; RRR: Relative risk reduction

¹ Net clinical benefit was defined as the composite of stroke, cardiovascular death, myocardial infarction, fatal bleeding or symptomatic bleeding in a critical organ; ² Not statistically significant



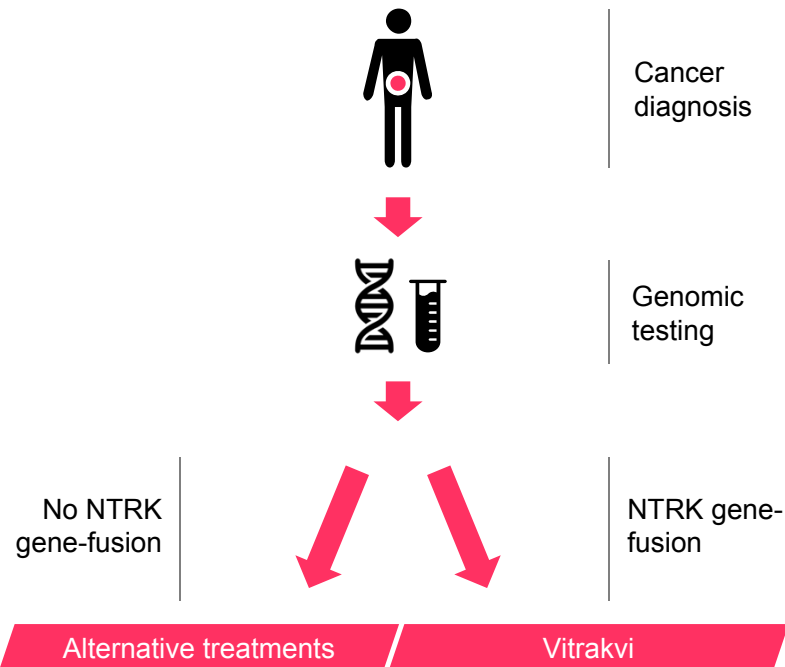
Oncology





Vitakvi Provides Novel Tumor-Agnostic Precision Medicine Cancer Therapy

Precision medicine, identifying the right patient for the right treatment



- // Vitakvi is an oral, small molecule, highly selective inhibitor of tropomyosin receptor kinases (TRKs)
- // NTRK gene fusions can lead to cancer and are facilitating tumor growth as oncogenic drivers
- // Relevant genetic alteration is estimated to occur in about 0.5 - 1.0% of patients with solid tumors
- // FDA approved for the treatment of adult and pediatric patients with solid tumors that have a neurotrophic receptor tyrosine kinase gene fusion
- // Distinguished science, in-licensed from Eli Lilly together with 2nd generation TRK inhibitor LOXO-195
- // Peak sales potential of >€750 million

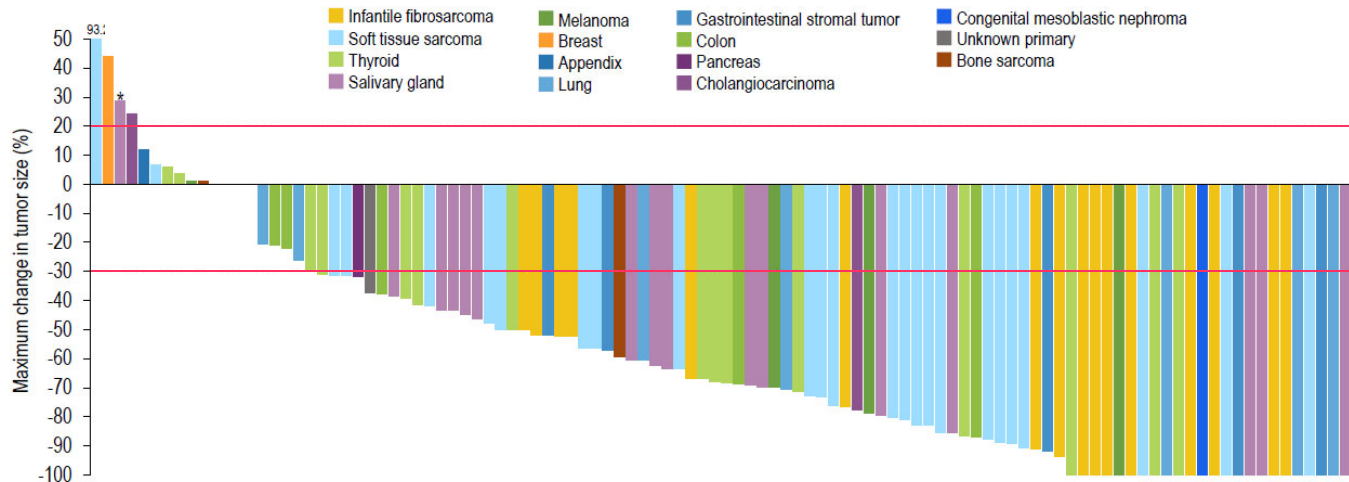
NTRK: Neurotrophic receptor tyrosine kinase
Full labeling information available at http://labeling.bayerhealthcare.com/html/products/pi/vitakvi_PI.pdf



Vitrakvi Demonstrates Impressive Anti-Tumor Activity

Activity in a Wide Range of Tumors Associated with NTRK Gene Fusions

Maximum change in tumor size according to tumor type (RECIST)



Objective response rate

Assessment (N=109)	
Objective response rate (95% CI)	81% (72-88%)
Best response	
// Partial response	63%
// Complete response	17%

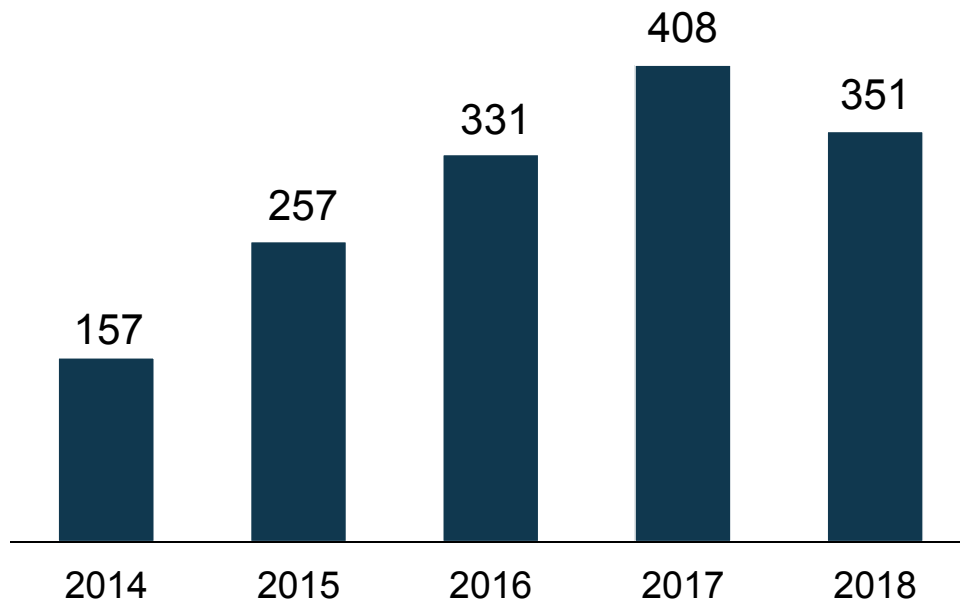
Lassen, U. et al., ESMO 2018
 NTRK: Neurotrophic receptor tyrosine kinase; RECIST: Response evaluation criteria in solid tumors



Xofigo – Important Treatment Option in Prostate Cancer



Sales in €m



// First marketed alpha-pharmaceutical

// Specifically targeting bone metastases

// Approved for the treatment of adults with metastatic castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastases¹

// Over 51,000 patients worldwide treated so far - Xofigo continues to be an important treatment option in prostate cancer

CRPC: castration resistant prostate cancer

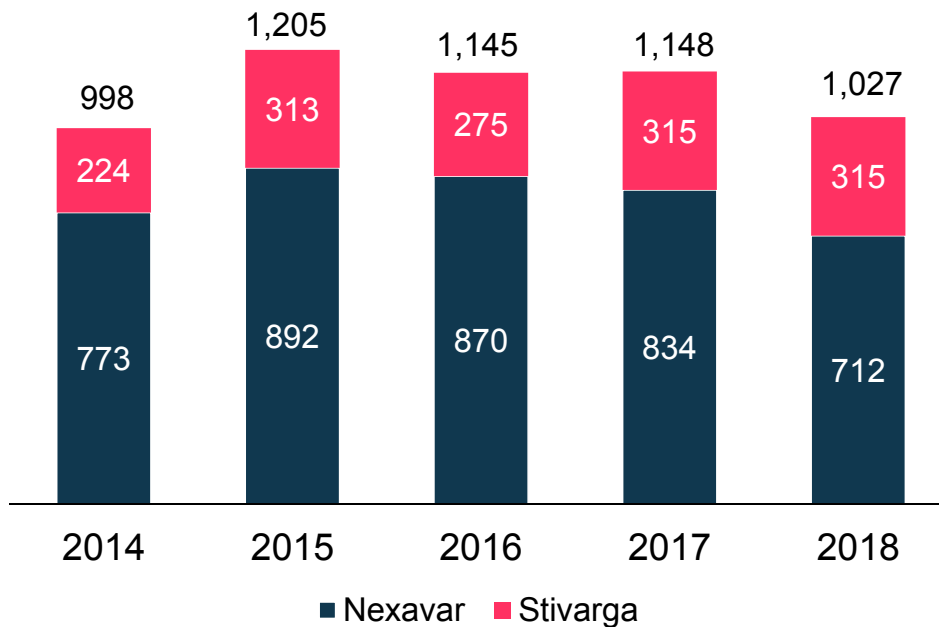
¹Valid for US. In the EU, the product label is as follows: Xofigo is indicated for the treatment of patients who have had two previous treatments for mCRPC (castrate resistant prostate cancer that has spread to the bone) or who cannot receive other treatments.



Nexavar and Stivarga – Defend and Grow Positions in HCC and CRC



Sales in €m



Nexavar

- // Approved for kidney cancer (RCC), liver cancer (HCC) and radioactive iodine refractory differentiated thyroid cancer (DTC)
- // Increasing competitive pressure in the US and in Japan
- // Strong volume growth in China

Stivarga

- // Approved for metastatic colorectal cancer (mCRC), advanced gastrointestinal stromal tumors (GIST) and 2nd line liver cancer (HCC)
- // For HCC, Nexavar as 1st line treatment and Stivarga as 2nd line after progression on Nexavar

DTC: differentiated thyroid cancer; GIST: gastrointestinal stromal tumor; HCC: hepatocellular cancer; mCRC: metastatic colorectal cancer; RCC: renal cell carcinoma



Ophthalmology Pulmonology

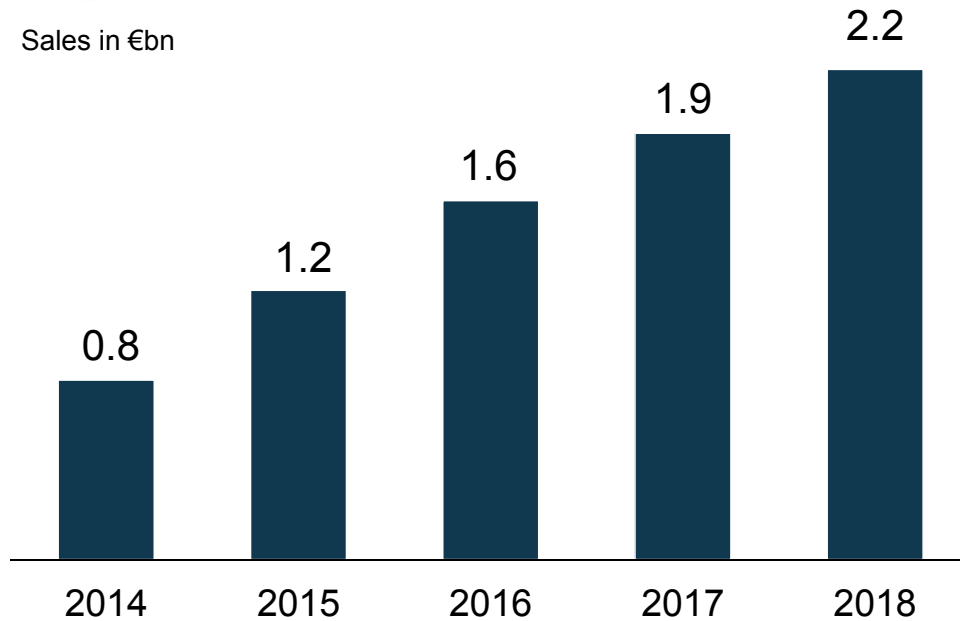




Eylea – A Leader in Retinal Diseases



Sales in €bn



// A leader in retinal diseases with global brand sales of €5.6bn in 2018 incl. sales at Regeneron¹

// Approved for the treatment of 5 retinal diseases: wAMD, DME, BRVO, CRVO, mCNV

// Treat and extend dosing regimen with injection intervals of up to 12 weeks or more for wAMD

// Peak sales potential: >€2.5bn²

// Further growth driven by:

// Continued generation of real-life experience in wAMD across key markets and treatment-naïve patient share gains

// Market expansion in DME

¹ Marketed by Bayer ex-US only; ² As reported by Bayer

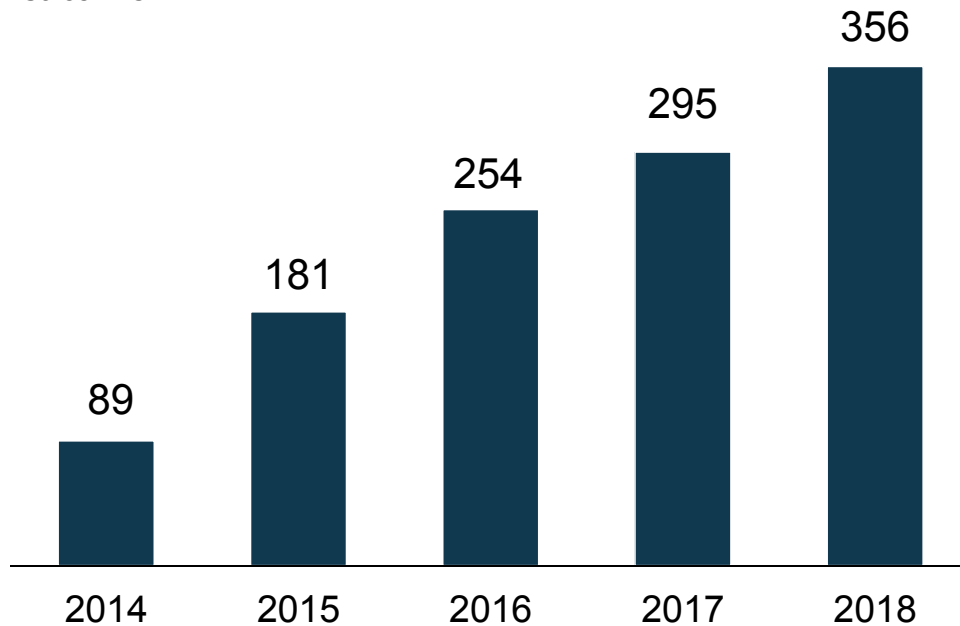
wAMD: Wet age related macular degeneration; DME: Diabetic macular edema; BRVO: Branch retinal vein occlusion; CRVO: Central retinal vein occlusion, mCNV: Myopic choroidal neovascularization



Adempas – Pioneering sGC-modulators with Adempas as First-in-Class Product



Sales in €m



- // Oral soluble guanylate cyclase (sGC) stimulator approved for two forms of pulmonary hypertension: PAH and CTEPH
- // First and only drug receiving marketing authorization for the treatment of CTEPH
- // Agreement with Merck & Co. for joint development and commercialization of sGC-modulators in place
- // >14,000 patients treated to date¹
- // Peak sales potential: >€500m²

¹ As of December 2018; ² As recorded for Bayer
CTEPH: Chronic thromboembolic pulmonary hypertension; PAH: Pulmonary arterial hypertension; sGC: soluble guanylate cyclase



Women's Health Hematology

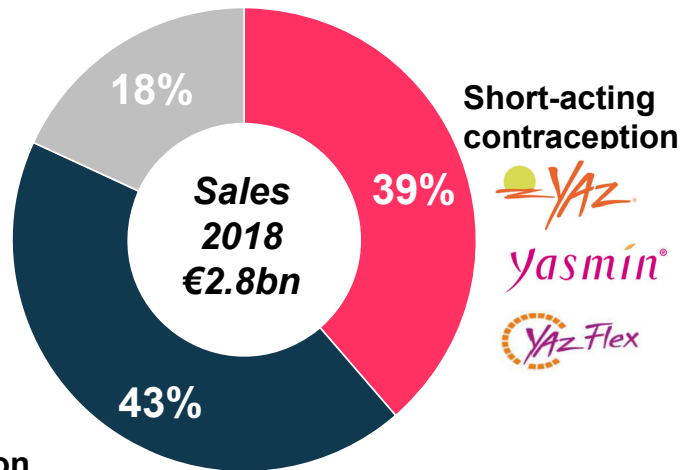




Leader in Women's HealthCare

Comprehensive Product Portfolio in Place

Menopause Management & Gynecological Therapies



Long-acting reversible contraception



Short-acting contraception



Short-acting contraception

- // Leverage potential in developing markets and from life cycle management such as e.g. Yaz Flex

Long-acting reversible contraception

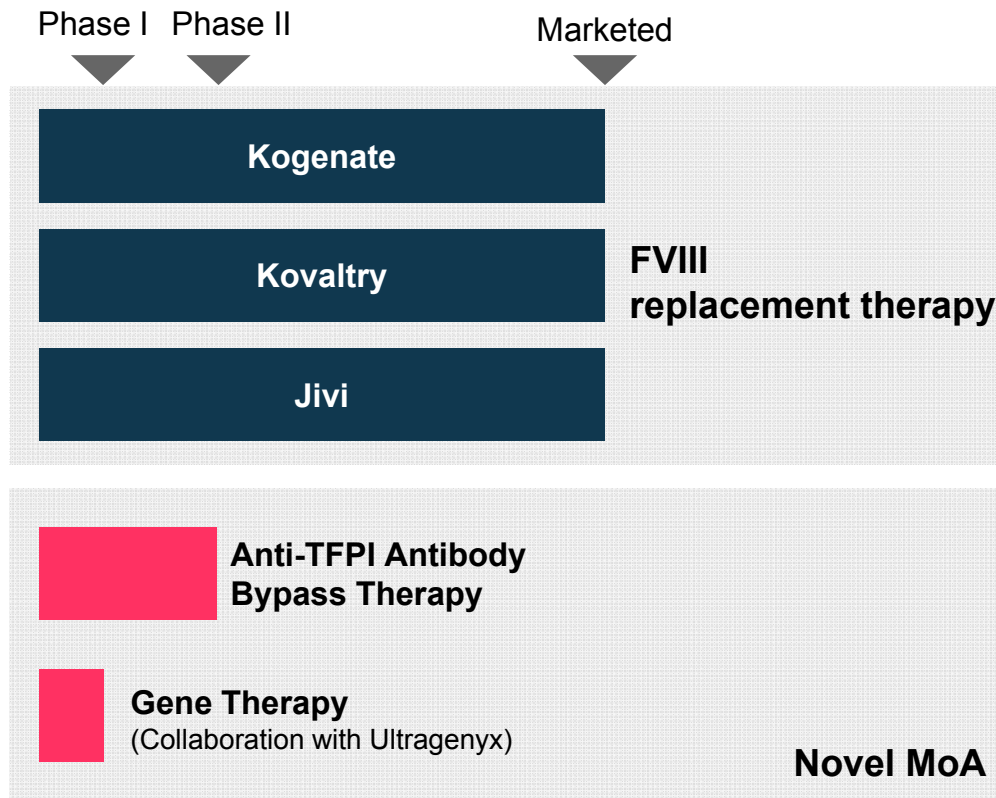
- // Established market leader
- // Mirena - Intrauterine device for reversible long-term contraception (up to 5 years) and treatment of heavy menstrual bleeding
- // Life-Cycle Management:
 - // Jaydess: Small low-dose long-acting (up to 3 years) device
 - // Kyleena: Long-acting (up to 5 years), low-dose, small device

Menopause Management / Gynecological Therapies

- // Continued R&D efforts in areas of high unmet medical need: Endometriosis, Fibroids



Trusted Key Player in Hemophilia



// Number 2 position in Hemophilia with a portfolio of standard half-life (Kogenate, Kovaltry) and extended half-life factor VIII products (Jivi)

// Kovaltry is a full-length rFVIII product allowing for prophylaxis treatment with as few as two applications per week

// Jivi is the only extended half product to demonstrate effective bleed protection with unique prophylaxis regimen

// Robust innovation pipeline:

// Anti-TFPI Antibody Bypass Therapy: Phase II ongoing

// Gene Therapy: Phase 1/2 started end of 2018

MoA: mode of action
TFPI: tissue factor pathway inhibitor



R&D Pipeline





Re-alignment of R&D-activities to Increase Sustainable R&D Productivity

From

- // **Broad set of indications** in Oncology, Cardiovascular Diseases and Gynecological Therapies
- // Focus on **functional and technical expertise**
- // Strong reliance on **small molecules**
- // Majority of **assets sourced internally**
- // Highly **concentrated geographical footprint**
- // **Internally oriented** resource model

To

- // **Focus on select areas** with high unmet medical need in Oncology, Cardiovascular Diseases and Gynecological Therapies
- // Focus on **deep disease understanding**
- // **Broader mechanistic approach** beyond therapeutic area focus
- // Invest in **new technologies and capabilities**
- // Continue to explore potentially **game-changing innovations** through LEAPS
- // Increased portion of R&D **assets to be sourced externally** in the future
- // Evolve footprint with **more co-location in science hubs**
- // Adapt internal cost base to **free up funds for sourcing inorganic opportunities**



Our Pipeline Contains ~50 Projects in Clinical Development

Phase I (27)	
Cancer / TRK Inhibitor (LOXO-195)	
Cancer / Rogaratinib (pan-FGFR Inhibitor)	
Cancer / PTEFb Inhibitor	
Cancer / ATR Inhibitor	
Cancer / DHODH Inhibitor	
Cancer / Copanlisib (PI3K Inhibitor)	
Cancer / Regorafenib* (multi-Kinase Inhibitor)	
Cancer / Anetumab Ravtansine (Mesothelin-ADC)	
Cancer / CD22-Targeted Thorium Conjugate	
Cancer / MSLN-Targeted Thorium Conjugate	
Cancer / PSMA-Targeted Thorium Conjugate	
Cancer / CEACAM6 fb Antibody	
Cancer / ILDR2 fb Antibody	
Heart Failure / Vasopressin Receptor Antagonist	
Chronic Kidney Disease / sGC Activator 1	
Chron. Kidney Disease / Vasopressin V1a Receptor Antag.	
Pulmonary Hypertension / sGC Activator 2	
Anti-coagulation / FXIa Inhibitor	
Endometriosis / P2X3 Antagonist 1	
Endometriosis / P2X3 Antagonist 2	
Endometriosis / P2X4 Antagonist	
Endometriosis / Rheumatoid Arthritis / IRAK4 Inhibitor 1	
Hemophilia / FVIII Gene Therapy	
Acute Respiratory Distress Syndrome / sGC Activator 3	
Acute Respiratory Distress Syndrome / PEG-ADM Inhale	
Obstructive Sleep Apnea / TASK Channel-Blocker 2	
Rheumatoid Arthritis / IRAK4 Inhibitor 2	

Phase II (12)	
Urothelial Cancer / Rogaratinib (pan-FGFR Inhibitor)	
Thrombosis / FXI Antisense (IONIS)	
Thrombosis / anti-FXIa Antibody	
Peripheral Artery Disease / AR-Alpha 2c Receptor Antagonist	
Heart Failure preserved EF / Vericiguat (sGC Stimulator)	
Chronic Kidney Disease / Fulacimstat	
Endometriosis / Vilaprisan (S-PR Modulator)	
Contraception / Combi IUS: LNG (Progestin) + Indomethacin (NSAID)	
Hemophilia / anti-TFPI-Antibody	
Obstructive Sleep Apnea / TASK Channel-Blocker 1	
Persistent Chronic Cough / P2X3 Antagonist 1	
Persistent Chronic Cough / P2X3 Antagonist 2	

Phase III (8)	
Prostate Cancer (mHSPC) / Darolutamide	
Non-Hodgkin Lymphoma / Copanlisib (PI3K Inhibitor)	
Peripheral Artery Disease / Rivaroxaban (FXa Inhibitor)	
Venous Thromboembolism in Children / Rivaroxaban	
Heart Failure reduced EF / Vericiguat (sGC Stimulator)	
Diabetic Kidney Disease / Finerenone (nst MR Antagonist)	
Renal Anemia / Molidustat (HIF-PH Inhibitor)	
Sympt. Uterine Fibroids / Vilaprisan (S-PR Modulator)	

■ Oncology
 ■ Cardiovascular & Kidney Diseases
 ■ Gynecology
 ■ Hemophilia
 ■ Others

As of February 2019



Late-stage Pipeline with Progress in Oncology

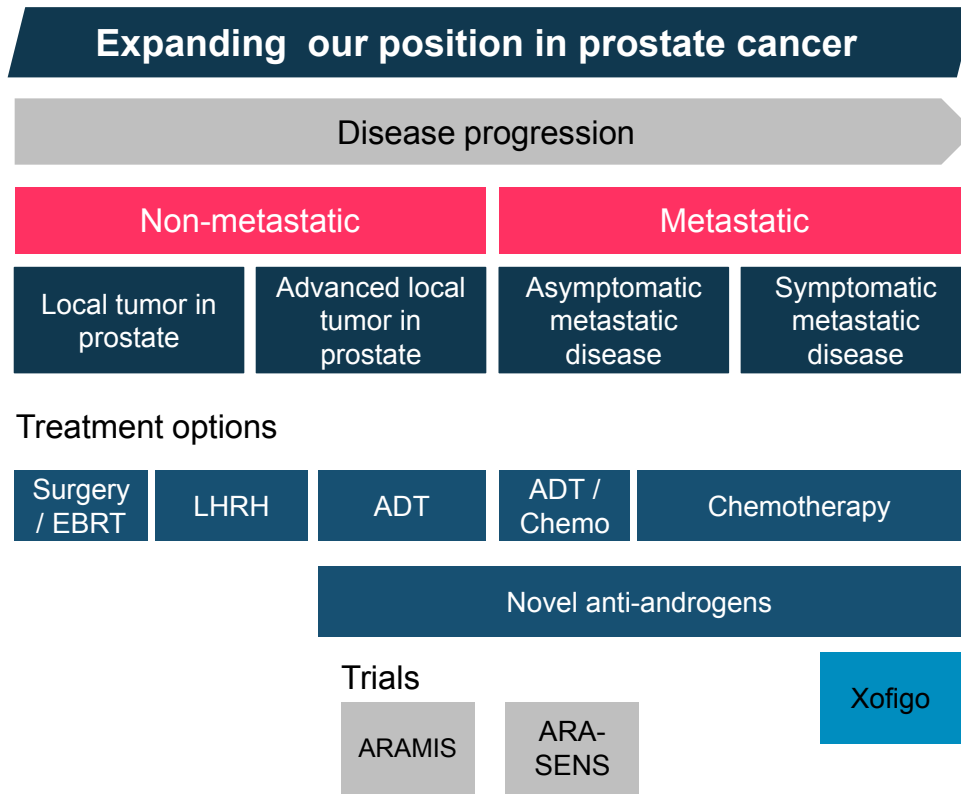
Darolutamide met Primary Endpoint in Phase III-trial and FDA-approval of Vitrakvi

	Vitrakvi	Darolutamide	Copanlisib	Finerenone	Vericiguat
Indication	// TRK-fusion Cancer	// Prostate Cancer	// Lymphoma	// Diabetic Kidney Disease	// Chronic Heart Failure
Status	// FDA approved / in registration	// Phase III (nmCRPC) // Phase III (mHSPC)	// Launched in the US // Phase III	// Phase III	// Phase III (HFrEF) // Phase II (HFpEF)
Commercial Potential	// PSP >€750m	// PSP ≥€1bn	// PSP ≥€0.5bn	// PSP ≥€1bn	// PSP ~€0.5bn
Clinical Completion	// Clinical program ongoing	// Completed (ARAMIS, nmCRPC) // Aug 2022e (ARASENS, mHSPC)	// May 2020e (CHRONOS-3) // Sep 2021e (CHRONOS-4)	// Apr 2020e (FIDELIO-DKD) // June 2021e (FIGARO-DKD)	// Jan 2020e (VICTORIA, HFrEF) // Dec 2019e (VITALY, HFpEF)

NTRK: Neurotrophic receptor tyrosine kinase; nmCRPC: Non-metastatic castration resistant prostate cancer; mHSPC: Metastatic hormone sensitive prostate cancer; HFrEF: Heart failure with reduced ejection fraction; HFpEF: Heart failure with preserved ejection fraction; PSP: Peak sales potential



Darolutamide to Expand Our Position in Prostate Cancer

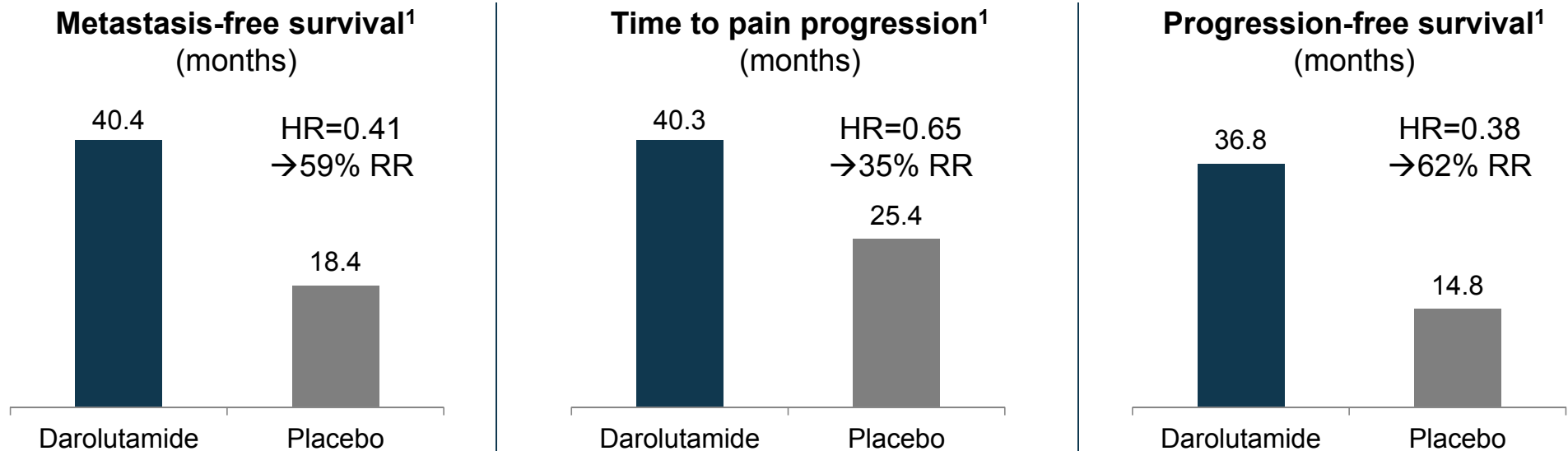


- // Darolutamide is a novel non-steroidal androgen receptor antagonist in development for the treatment of prostate cancer
- // Met primary endpoint of metastasis-free survival in the ARAMIS trial in non-metastatic CRPC
- // Strong safety profile demonstrated in ARAMIS
- // Phase III trial in metastatic HSPC (ARASENS) ongoing
- // Potential for differentiation:
 - // Differentiated chemical structure
 - // High binding affinity
 - // Negligible blood-brain barrier penetration¹

CRPC: Castration resistant prostate cancer; HSPC: Hormone sensitive prostate cancer; EBRT: External beam radiation therapy; LHRH: Luteinizing hormone-releasing hormone; ADT: Androgen deprivation therapy;



Darolutamide Significantly Extended Metastasis-free Survival in Men with Castration Resistant Prostate Cancer



- // Darolutamide showed a positive trend in overall survival (OS), with a 29 percent reduction in the risk of death (HR=0.71, 95% CI 0.50-0.99; P=0.045, median not reached)
- // All other secondary endpoints also demonstrated a benefit in favor of darolutamide (time to cytotoxic chemotherapy, time to first symptomatic skeletal event)

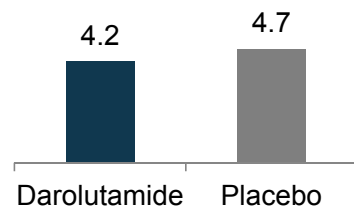
HR: Hazard ratio; RR Risk reduction
¹N Engl J Med; DOI: 10.1056/NEJMoa1815671



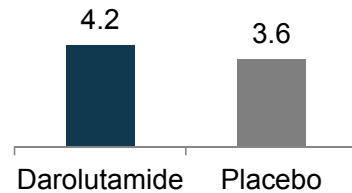
Darolutamide Demonstrated Overall Favorable Safety Profile with Key Adverse Events not Increased Relative to Placebo

Key adverse events of interest (%)¹

Falls incl. accident (%)



Bone fracture (%)

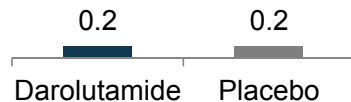


// Incidence of adverse events comparable between darolutamide and placebo arms

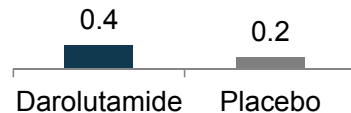
// Overall favorable safety and tolerability profile, allowing patients with nmCRPC, who are mainly asymptomatic, to maintain their quality of life – addressing an unmet need for men at this stage of the disease

// Other key adverse events of interests were:

Seizures (%)



Cognitive disorder (%)



%	Darolutamide	Placebo
Fatigue/asthenic condition	15.8	11.4
Dizziness	4.5	4.0
Memory impairment	0.5	1.3
Hypertension	6.6	5.2
Coronary artery disorders	3.2	2.5
Heart failure	1.9	0.9

¹ N Engl J Med; DOI: 10.1056/NEJMoa1815671



Copanlisib is a Differentiated PI3K-inhibitor for the Treatment of Lymphoma

Key phase II data (CHRONOS-1)¹

Overall response rate in patients with follicular B-cell non-Hodgkin's lymphoma who had relapsed disease following at least two prior treatments:

n=104	Copanlisib
Overall response rate	59%
// Complete response	14%
// Partial response	44%

Copanlisib had a favorable safety profile with a low rate of severe toxicities overall.

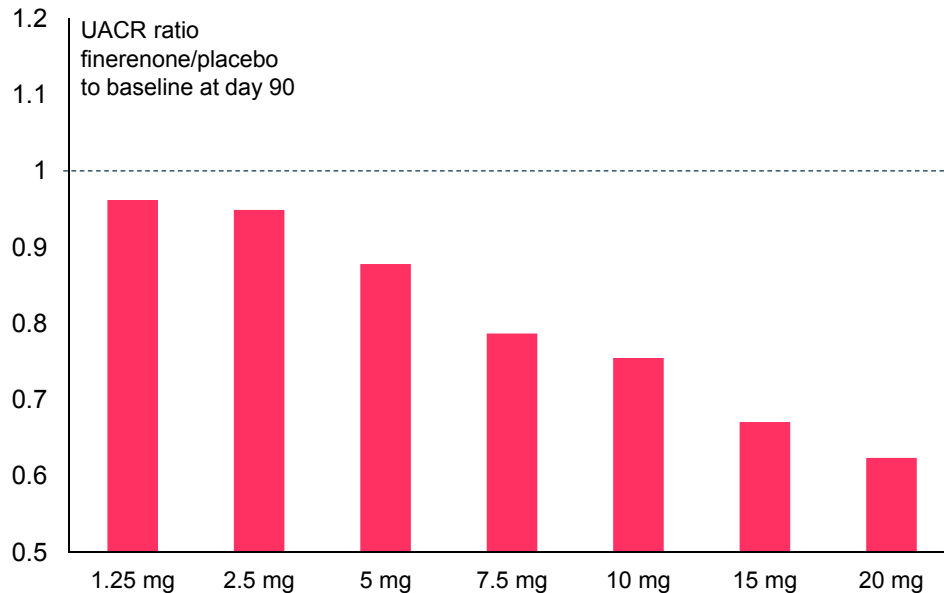
- // Phosphatidylinositol-3-kinase (PI3K) inhibitor blocking cellular signal transduction processes crucial for cancer progression
- // In development for various forms of lymphoma
- // Potential for differentiation:
 - // Inhibits different isoforms of PI3K
 - // Intravenous administration, thus lower propensity for serious gastrointestinal toxicity
 - // Intermittent once weekly dosing
- // Launched in the US in 2017 for the treatment of relapsed follicular lymphoma. Registration granted under accelerated FDA approval based on phase II data

¹ Dryling M. et al.: Blood 2017; 130: 2777



Finerenone May Reduce the Risk of CV-mortality and the Progression of Kidney Disease in Patients with Diabetic Kidney Disease

Key phase II data (ARTS-DN¹)



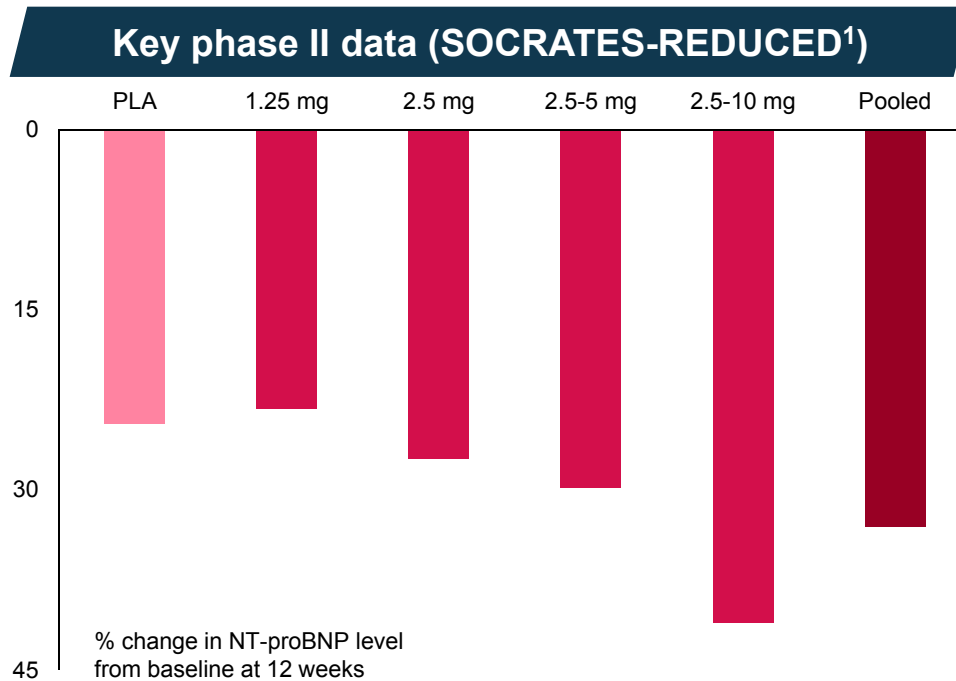
Dose dependent reduction of proteinuria by finerenone when added to RAS blocker therapy in patients with DKD

- // Finerenone is a novel non-steroidal MRA under development with a specifically high selectivity and receptor affinity
- // Addressing high unmet medical need
- // Two phase III trials in diabetic kidney disease underway: FIDELIO DKD (CV study) and FIGARO DKD (renal study)
- // Potential for differentiation:
 - // First-in-class MRA for treatment of DKD
 - // Non-steroidal structure, no interaction with steroid hormone receptors compared to existing MRAs
 - // Low risk of hyperkalemia which prohibits the use of marketed MRAs in DKD

MRA: Mineralocorticoid receptor antagonist; RAS: Renin-angiotensin system; CV: Cardiovascular; DKD: Diabetic kidney disease; UACR: Urinary albumin-creatinine ratio
¹ Bakris, G.L. et al., JAMA 2015; 314:884-894.



Vericiguat is a Potentially New Treatment Option on Top of Standard of Care for Patients with Heart Failure



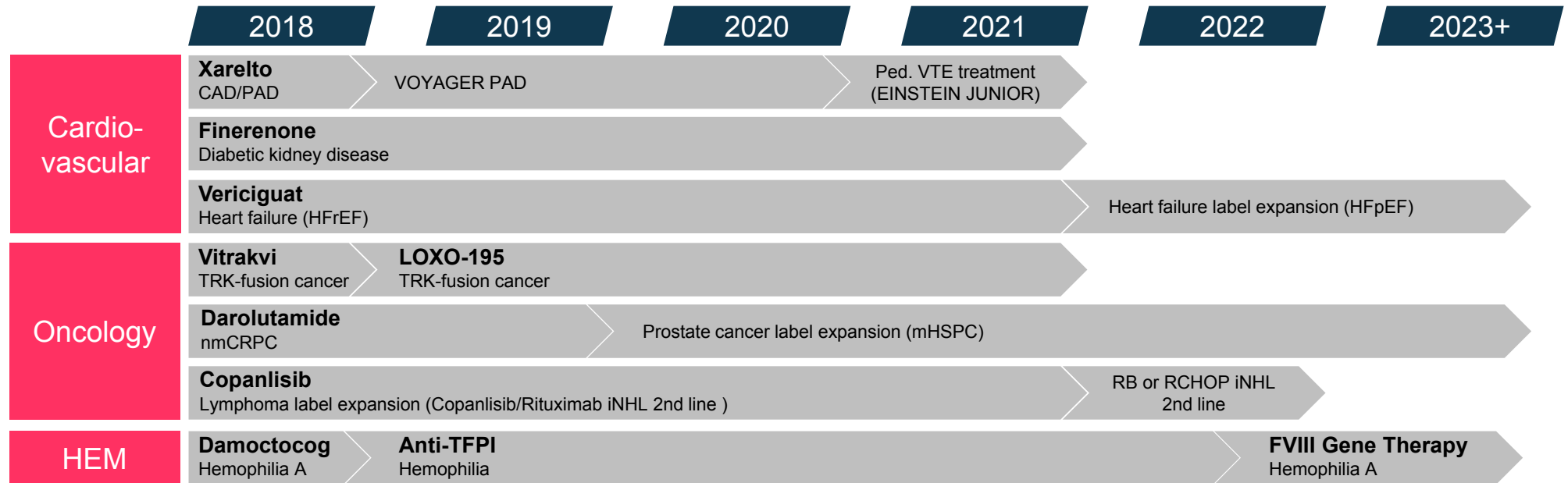
- // First-in-class, direct sGC stimulator addressing the NO-sGC-cGMP pathway, a relevant mechanism in heart failure
- // Heart failure is still associated with significant mortality risk despite the availability of new therapeutic options
- // Potential for differentiation:
 - // New mode of action to be positioned on top of standard of care
 - // OD dosing and overall favorable safety and tolerability profile
- // Development in collaboration with Merck & Co.

Dose-response relationship between vericiguat dose and reduction in NT-proBNP, a surrogate marker for cardiac function

sGC: Soluble guanylate cyclase; NO: Nitric oxide; cGMP: Cyclic guanosinmonophosphate; OD: Once daily; PLA: Placebo; NT-proBNP: N-terminal prohormone of brain natriuretic peptide
¹ Gheorghiadu, M. et al: JAMA 2015; 314: 2251-2262



Expected Launches of Key Pipeline Assets



First launch in first indication

NTRK: Neurotrophic receptor tyrosine kinase; nmCRPC: Non-metastatic castration resistant prostate cancer; mHSPC: Metastatic hormone sensitive prostate cancer; HFrEF: Heart failure with reduced ejection fraction; HFpEF: Heart failure with preserved ejection fraction, iNHL: Indolent Non-Hodgkin Lymphoma TFPI: Tissue factor pathway inhibitor; WH: Women's Health; HEM: Hematology



Major Pharma Newsflow in 2019

Asset/Project	Mechanism	Intended Indication	Status	Milestone / data / presentation target
Darolutamide (ODM-201)	Androgen Receptor Antagonist	Non-metastatic castration-resistant prostate cancer	Phase III	Filings (US, JP, EU) February / March 2019
Vitakvi	TRK-Inhibitor	NTRK-Cancer	Launched (US)	EU-Launch in 2019e
LOXO-195	TRK-Inhibitor	NTRK -Cancer	Phase I/II	Primary completion August 2019e ¹
Xarelto	FXa-Inhibitor	Peripheral artery disease (VOYAGER PAD)	Phase III	Primary completion October 2019e ¹
Vericiguat	sGC-Modulator	Chronic heart failure (VITALITY-HFpEF)	Phase II	Primary completion Dec. 2019e ¹

¹ According to clinicaltrials.gov



Investor Handout Pharmaceuticals



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