



# Cautionary Statements Regarding Forward-Looking Information

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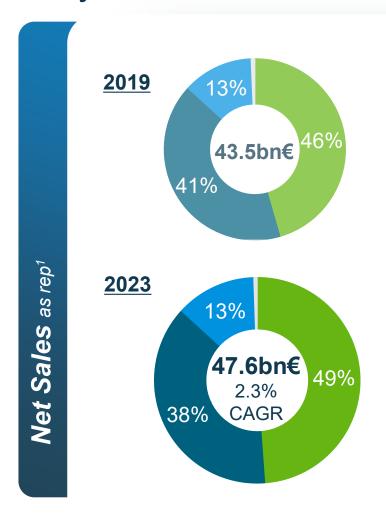
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# Bayer: A Global Leader in Health & Nutrition





## **Crop Science**

- · #1 in Seed & Traits with Leading Crop Protection Portfolio
- >200 bn€² exp. Global Ag Input Market & Related Adjacencies by 2030



## **Pharmaceuticals**

- Strong market positions in key therapeutic areas / resilient base
- Rebuilding R&D with technology platforms and improved productivity



## **Consumer Health**

- · Iconic brands with leading market positions
- 3-5% CAGR CH Global Market<sup>3</sup>

## Well Positioned in Growing Markets

to address

## **Major Societal Needs** and Ecological Challenges

with the

Power of Innovation.



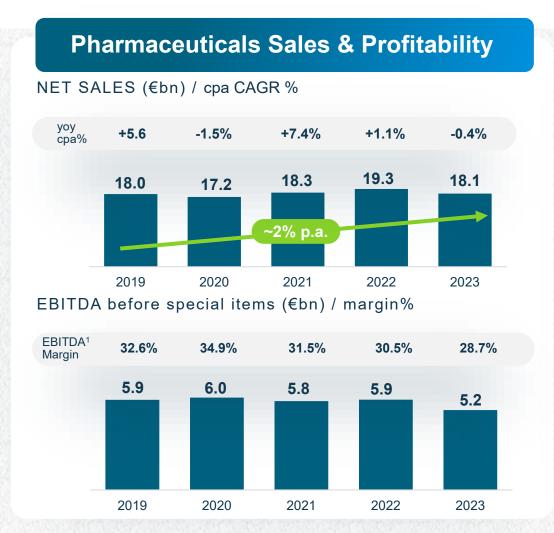
////////// Health for All, Hunger for None.

<sup>1</sup> As rep = as reported, Animal Health business not included, Environmental Science Professional business included in figures until sale completion in 2022 (no restatement

<sup>&</sup>lt;sup>2</sup> Company estimates; 3 Outlook, internal market model in-market sales OTC medicines, data from IQVIA, Nicholas Hall



# Leading Franchises Providing Sales Growth and Resilience, Margin Profile Impacted by LoE Transition and Strategy Execution



## **Key Drivers**

Growing sales contributions from recently launched Nubeqa and Kerendia

Strong Eylea and Radiology performance balancing increasing headwinds from China VBP program and first LoE's of Xarelto

Revision of R&D model and enhancement of capabilities through acquisitions of platform companies

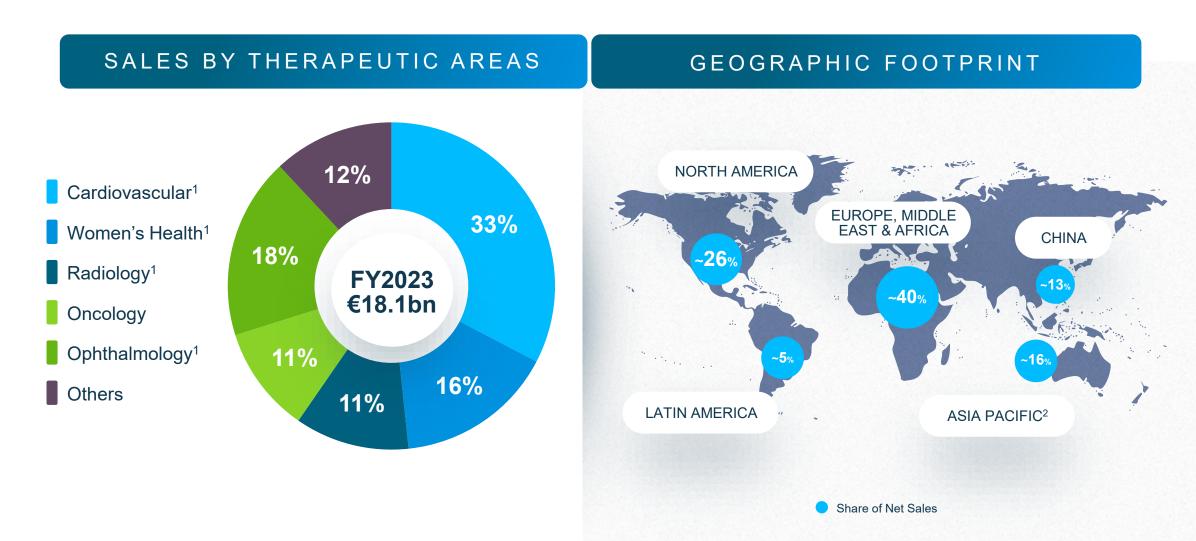
Continued shift of resources towards R&D and launch brands; U.S. re-entry with R&D and commercial footprint

Tight cost management to fund growth investments while mitigating inflation and margin diluting change in product mix

<sup>&</sup>lt;sup>1</sup> Before special item:



# Bayer Pharma Sales Diversified Across Therapeutic Areas and Geographies

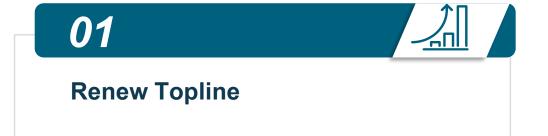


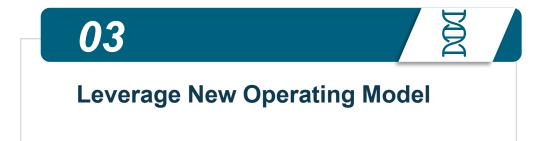
<sup>&</sup>lt;sup>1</sup> Strong market positions in the respective indication <sup>2</sup> excl. China



# Preparing for Long-Term Growth While Managing LOE Transition





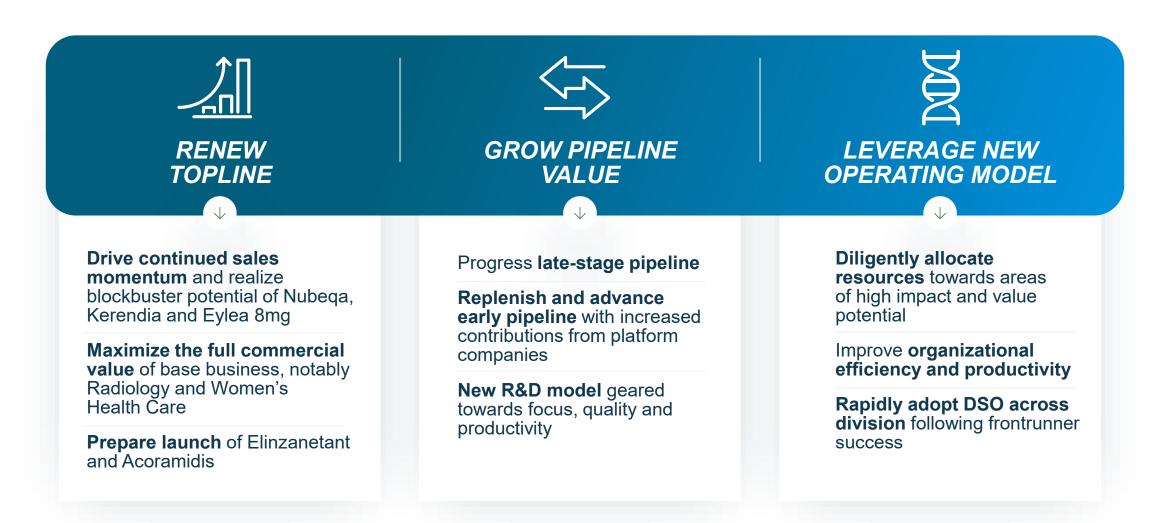




Financial Performance



# Bayer Pharma's Strategic Agenda





# Launch Assets and Late-Stage Pipeline Expected to Largely Offset LoEs on Stable Base Business



illustrative



Elinzanetant, Acoramidis, Asundexian Stroke

Nubeqa, Kerendia

Xarelto

Eylea

> Radiology and Other Late Lifecycle Assets

2023

€18.1bn

€1.1bn

€4.1bn

€3.2bn

€9.6bn

2024-2026 (cpa)

Elinzanetant, Acoramidis and Asundexian Stroke

**Growth:** Launch products

**Decline:** Xarelto

**Stable:** Eylea 8mg to sustain franchise sales and share

**Stable**: Ongoing growth in Radiology and stable Women's Health Care franchise balancing softness of other assets

>2027

Numerous
pipeline assets
to potentially fuel
long-term
growth

Rejuvenated portfolio

Steady base business



# Despite its Maturity, Key Parts of Our Base Business Are Benefitting from Strong Market Positions and Supportive Trends



Bayer Pharma's Base Business			Short- and Mid-term Drivers	
Net Sales 2023 <b>€9.6bn</b>	Radiology	SelectCARE Gadovist 1.0 SelectCARE PartnerCARE Primovist Gadovict Acid	Radiology: Building on leading positions in contrast media and fluid delivery systems to further expand into AI and digital imaging Market to grow mid-single digits annually	
	Women's Health Care excl. Elinzanetant	Yasmin* Y jaydess.	Women's Health (excl. Elinzanetant): Stable Business expected, benefiting from global presence and strong market positions	
	Base Oncology excl. Nubeqa	Xofigo Stiveres (cordenit) tablets	Other Late Lifecycle assets:	
	Base Cardiology excl. Xarelto & Kerendia	Adalat ASPIRIN <sub>CARDIO</sub> Glucobay	China business: Continued VBP pressure, with Cardioaspirin and Visanne to be potentially included in next VBP rounds	
	Others	Recombinant Factor VIII (octoog alfa)  Adempas: riociguat  Recombinant Factor VIII (octoog alfa)  BETASERON' IINTERFERON BETA-12b) (SAFFace)	Continued softness of selected mature assets expected	

Ongoing growth in Radiology and stable sales contributions from Women's Health balancing softness in remaining portfolio



# With Its Unparalleled Clinical Profile, Eylea Positioned to Continue Market Leadership in a Growing Market



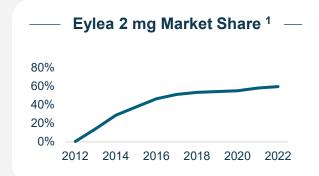




Growing ageing population

Rising prevalence of diabetes

Reduction in treatment burden in nAMD and DME remains unmet need – need for longer acting treatments



Eylea 2 mg is the standard of care in retinal diseases

Market leader as the #1 anti-VEGF treatment

## Position to Sustain Market Leadership with Eylea 8 mg

Eylea 8 mg: Potential to establish the next **standard in retinal diseases** 



- // Address unmet need with reduction in treatment burden only drug with approved unprecedented treatment interval of up to 5 months<sup>2</sup>
- II Potential to improve ophthalmology clinic capacities, enabling better care for patients treated for nAMD and DME

Approved in e.g. EU, Japan, UK, Canada

## Clinical differentiation:

Patient proportion in the Eylea 8 mg q16 groups achieving last assigned intervals ≥4 months at 96 week







<sup>&</sup>lt;sup>1</sup> Source: MARS MIDAS – EX US, BAYER panel scope: IQVIA: IQVIA MIDAS® Quarterly for the following countries: Argentina, Australia, Belgium, Brazil, Canada, Czech Republic, Germany, Greece, Italy, Japan, Korea, Rep. Of, Mexico, Poland, PR of China, Russian Fed., Saudi Arabia, Spain, Switzerland, Taiwan, Turkey, Unitted Kingdom, for ATC: S1P0; Volume sales (Standard Units), reflecting estimates of real-world activity. Copyright IQVIA. All rights reserved. Close-up: Chile, Farminform: Netherlands, Insight Helath: Austria, Nordic Pharma Insights: Sweden <sup>2</sup> Source: https://www.ema.europa.eu/en/documents/product-information/eylea-epar-product-information\_en.pdf <sup>3</sup> Source: https://www.bayer.com/media/en-us/affibercept-8-mg-first-to-achieve-sustained-vision-gains-with-more-than-70-of-patients-extended-to-intervals-between-16-and-24-weeks-in-wet-age-related-macular-degeneration-at-two-years/ <sup>4</sup> Source: https://www.bayer.com/media/en-us/affibercept-8-mg-in-diabetic-macular-edema-first-to-achieve-sustained-vision-gains-with-up-to-83-of-patients-extended-to-16-24-weeks-at-two-years/ <sup>5</sup> Randomized to Eylea 8mg q16 groups

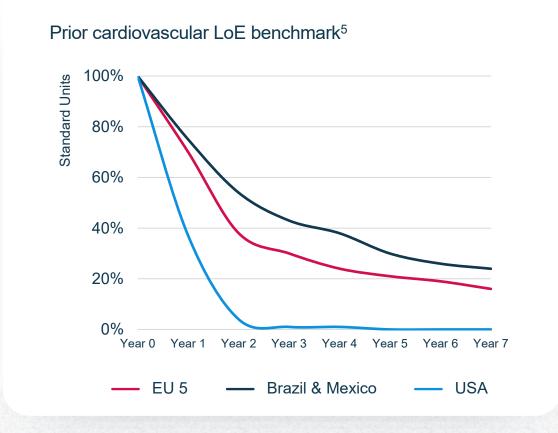




## **Xarelto's main patent expirations**

## **Historic Genericization Patterns of Small Molecules**

Countries	% of Total Xarelto Sales <sup>1</sup>	Compound patent expiry	Once-daily patent expiry
China	6%	End 2020	
Europe <sup>2</sup>	60%	April 2024	January 2026
Japan	10%	Mid 2024	
USA	13%	Beginning of 2025	2027
Others	11%	2020-2024 <sup>3</sup>	January 2026 (few markets <sup>4</sup> )

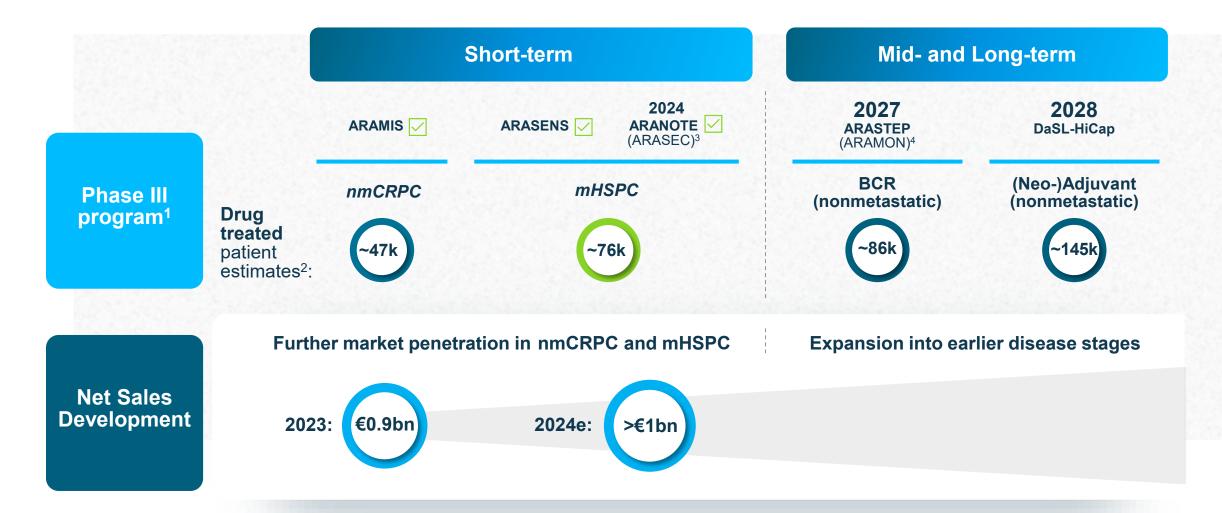


¹ Based on 2023 Actual Sales ² Once-daily patent currently being challenged in several European countries ³ In most markets end 2020, longer expiry dates in Brazil (2021), Korea (2021), Mexico (2023), Australia (2023), Malaysia (2024), and others ⁴ Such as e.g. Australia, Indonesia ⁵ Typical cardiovascular brand volume genericization based on the CV brands Crestor™, Lipitor™, Valsartan™, and Plavix™ (atypical curves excluded)



# Nubeqa Set for Continued Growth in Prostate Cancer Driven by Market Penetration and Label Expansion



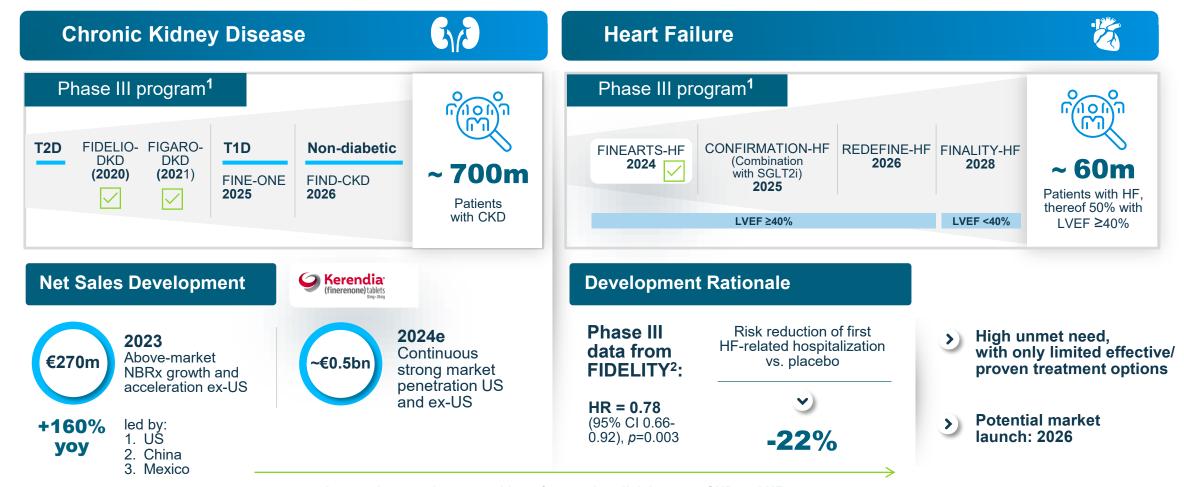


<sup>&</sup>lt;sup>1</sup> Stated timelines of the Phase III program refer to either launch dates of Nubeqa in this indication (ARAMIS, ARASENS) or estimated primary completion date of the respective study <sup>2</sup> 2030 Treated Estimates G7: U.S., EU5, JP <sup>3</sup> Not label generating; supports ARASTEP/ARANOTE submission



# Kerendia With Potential to Become Foundational Treatment for Broad Groups of Patients with Kidney Disease or Heart Failure





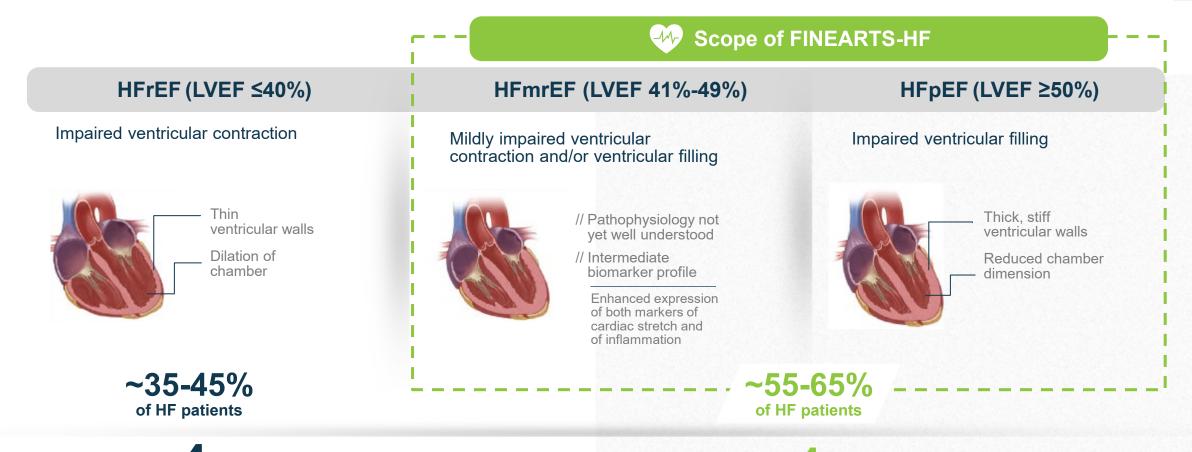
Leveraging growing recognition of strong interlink between CKD and HF

<sup>&</sup>lt;sup>1</sup> Timelines of the Phase III program refer to estimated primary completion dates of the respective study <sup>2</sup> Agarwal et al, EHJ 2022, 43 (6), 474–484.



# HF Is a Complex Disease With Major Differences in Each Subtype Requiring Different Treatment Approaches





treatments
with class I guideline recommendation



treatment
with class I guideline recommendation (SGLT2i)

14



# FINEARTS-HF Achieved Its Objective





Finerenone reached primary composite endpoint



Demonstrated consistency across all pre-specified subgroups



Finerenone demonstrated significant benefits in secondary efficacy endpoints

Reduced total HF events

Improved patientreported health status in patients with HF and I VFF ≥40%



Safety profile was in line with previous studies





# FINEARTS-HF Marks a Key Moment for Patients with HF and LVEF ≥40% and Their Caregivers





Summary of FINEARTS-HF and FINE-HEART

01

First MRA to demonstrate proven clinical benefit in all patients with HF and LVEF ≥40%

02

Offers a new potential treatment option for >50% of HF patients, in a highly underserved space

03

Potential to become a primary pillar of a multi-treatment strategy to improve highly patient-relevant health outcomes





# Getting Ready to Accelerate Kerendia's Growth



## CKD/T2D

- // Launched in 75 countries since 2021
- // Included in most key international guideline recommendations
- // >250k treated patients in US, JP & DE alone
- // THUNDERBALL study program ongoing to broaden the use across CKD subtypes

## **HEART FAILURE**

- // First dossier to be submitted soon
- // Fast speed to launch readiness
- MOONRAKER study program ongoing to accelerate clinical adoption and uptake

## **FINEARTS-HF**

Inflection point to unlock the full cardiorenal opportunity





HF indication offers significant standalone potential

CKD: Chronic kidney diesease; T2D: Type 2 diabetes mellitus 
<sup>1</sup> Kolkhof P, et al. Curr Opin Nephrol Hypertens 2015;24:417–424; <sup>2</sup> Grune J, et al. Hypertension 2018;71:599–608; <sup>3</sup> Kolkhof P, et al. J Cardiovasc Pharmacol 2014;64:69–78



# Asundexian is Targeting a High Unmet Need in Secondary Stroke Prevention



### **Unmet Need**

~1 in 4<sup>1</sup>

people have a stroke in their lifetime



Patients having a recurrent stroke within

the first year<sup>2</sup>

10%

the first 5 years<sup>2</sup>

25%



~ 27m

diagnosed patients per year in top 8 markets

Mortality rate increases with each recurrent stroke<sup>2</sup>



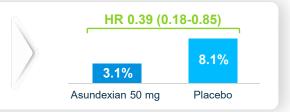
Recurrence rate of stroke unchanged over >20 years, despite increased SoC<sup>2</sup>

### Clinical Rationale and Status of Asundexian

### > Rationale

- Genetic correlation between FXIa deficiency and risk of stroke
- Asundexian: once-daily FXIa inhibitor with proven clinical safety in phase II program PACIFIC
- Phase II Study PACIFIC-STROKE

**Efficacy:** >60% reduction of stroke and TIA observed in patients with pre-existing atherosclerosis<sup>3</sup>



**Safety:** no significant increase of bleeding vs. placebo<sup>3</sup>

### > Phase III OCEANIC-STROKE

- ongoing despite early termination of atrial fibrillation program as etiology and SoC are materially different
- current status: U.S. FDA Fast Track Designation granted, data expected in HY2 2025

<sup>&</sup>lt;sup>1</sup> Feigin VL et al., *Lancet Neurol.* 2023, 22(12), 1160-1206. 7. Global Stroke Factsheet, *International Journal of Stroke* 2022, 17(1), 18-29 [Accessed: February 2024]. <sup>2</sup> Kolmos M et al., *J Stroke Cerebrovasc Dis.* 2021, 30(8),105935. <sup>3</sup> Shoamanesh A et al., *Lancet* 2022, 400, 997-1007; composite outcome of ischemic stroke and TIA in patients with any atherosclerosis was an exploratory post-hoc analysis



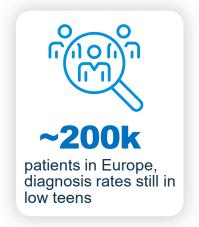
# Acoramidis<sup>1</sup> with Competitive Clinical Profile to Treat ATTR-CM, Complementing Our CVD Franchise in Europe



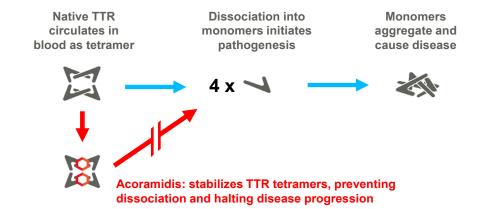
### **Unmet Need**

#### // ATTR-CM

- // Transthyretin amyloidosis cardiomyopathy, a progressive and fatal disease
- // Causes diastolic dysfunction and heart failure due to deposition of TTR amyloid in the heart



### // Pathogenic pathway



### **Profile and Deal Rationale of Acoramidis**

### **Profile**

- // Oral TTR stabilizer for patients with ATTR-CM
- // Pivotal Phase III study ATTRibute-CM: significant reduction of hospitalization burden, improved survival and preserved functional capacity and quality of life
- // Competitive efficacy and safety vs. standard of care (tafamidis)

### Rationale

- # Exclusive license to commercialize Acoramidis in Europe
- # High unmet need in an underserved disease, ~17k EU patients treated with tafamidis (~€1bn of annual sales) today
- // Focused market with small, well-defined patient population and specialized centers-of-excellence playing a key role
- # High synergies with Bayer's existing CV infrastructure
- // Filed for regulatory approval in Europe, expected launch in 2025

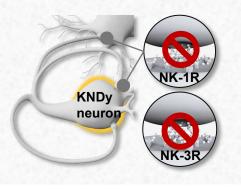


# Elinzanetant Offers a Differentiated Clinical Profile to Treat Symptoms Associated With Menopause



### **Differentiated Clinical Profile**

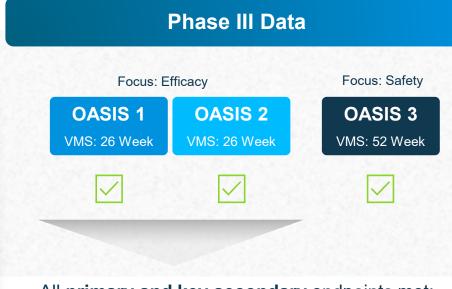
#### **Elinzanetant Characteristics**





Reduced sleep disturbance, hot flashes

- // Non-hormonal, oral, first dual neurokinin-1,3 receptor antagonist – first double mode of action in NK class
- Studied for the effective reduction
   of vasomotor symptoms (VMS), and sleep disturbances
- // Reduces the hyperactivity of the KNDy neuronal network involved in thermoregulation
- // Generally well tolerated



### All **primary and key secondary** endpoints met:





Menopause-related sleep and quality of life: Significant improvements



**Safety profile** consistent with previous published data



# Elinzanetant Targeted to Enter Large and Underserved Market in 2025



## **Market Opportunity**

## Unmet need

Women who experience<sup>1</sup>:

#### Hot flashes:

~4 in 5



Sleep disturbance:

~3 in 5





women per year entering menopause transition in US2

# 2/3

of women not choosing / not eliaible for hormone therapy<sup>3</sup>

## Well positioned for a successful launch

1 st

nonhormonal, oral NK1.3receptor antagonist



Differentiated clinical profile







in Women's Health globally with ~30% of sales in US

## Bayer Global Leader in Women's Health<sup>4</sup>







~€3bn

net sales

>60m patients served

100.000 **OB/Gyn reached** 

Strong foundation in Women's Healthcare for 100 years

Offering best in class solutions for women across all stages of their lives

Trusted relationships with patients and customers

Established strong commercial footprint, particularly in the U.S. as single biggest country

<sup>&</sup>lt;sup>1</sup> Source: Market Research - IPSOS - Global VMS Women Segmentation <sup>2</sup> Source: NIH. https://www.ncbi.nlm.nih.gov/books/NBK507826 <sup>3</sup> Source: Project Heat Market Research, 2018 SHA VMS Prescriber analysis <sup>4</sup> IQVIA Feb 2023, Rx market comprising contraception, menopause management & gynecological therapies



# The New Face of Bayer Pharma R&D



Building on 160 years of innovation, we've significantly transformed our organization and shaped our strategy

## New Bayer innovation strategy setting the path for scientific leadership and increased value for patients

- Diversified modalities
- Refocused therapeutic areas
- Increased R&D footprint in the US

# Extended capabilities and pipeline through strategic acquisitions

- BlueRock
- AskBio
- Vividion

# Fast-tracked our ambition through key R&D decisions

- New R&D operating model
- Leaner, simpler governance
- Rigorous portfolio health check

### **KEY FIGURES:**

€3.3bn spend on R&D

~5,800 FTEs at
Bayer Pharma R&D
(including platform companies)

**23 NMEs** and 31 projects in Phase 1-3

~120 deals signed in the last 4 years



# New Innovation Model to Rapidly Rebuild Pipeline



High Level of Focus, Quality and Productivity

## Focus



Narrowed research focus from eight to four core therapeutic areas

# Quality



Rigorous application of selection criteria have let to a more streamlined and differentiated pipeline

# **Capabilities**



Biotech-like R&D operating system with a mix of innovative and diverse therapeutic modality platforms

# **Productivity**

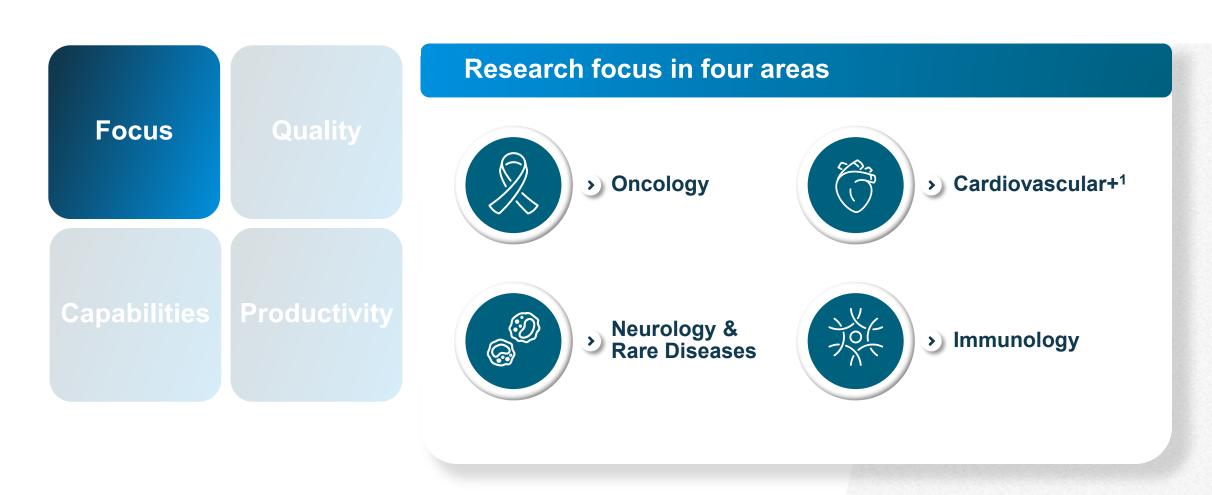


Shift to value creation, product-centric operating model, leaner governance with renewed leadership team



# Focus: Zeroing in on High Unmet Need With Great Value Potential

Four Therapeutic Areas in R&D





# Quality: Pursuing Leading Innovation Across all Focus Areas



Revised Target-Product-Profile of Our Assets



Prioritization of assets based on following selection criteria:

Value & Differentiation

Feasibility & Risk

Leading capabilities

Streamlined portfolio

Pruned pipeline by more than 40% to focus on the most valuable assets

Shift to breakthrough innovation

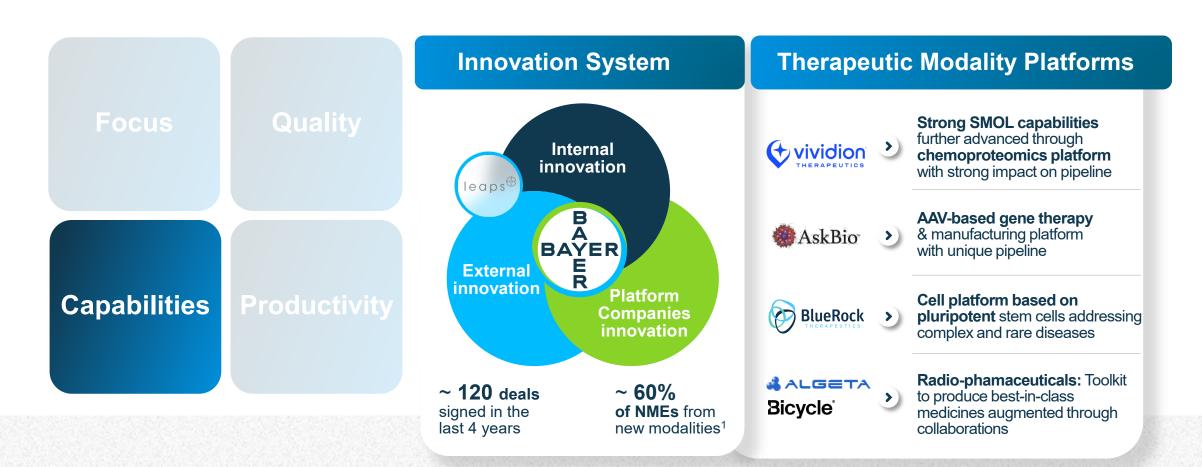
Vast majority of assets offering the potential to be first-or best-in-class



# Capabilities: Established Toolbox of Leading Modalities



Access to Leading Therapeutic Technology Platforms Through Acquisitions and Collaborations

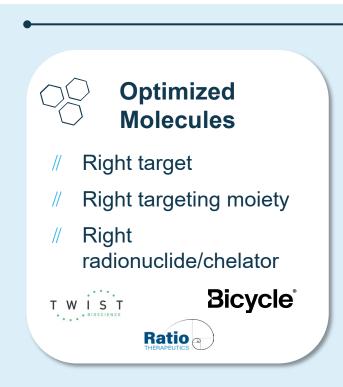




# Focus on Best-in-Class TRT's Enabled by a Strong Supply and Logistics Network Paired With Executional Excellence



TRT Strategy Overview



## Pillars of our TRT strategy



- // Continuous learning
- // Diversity of methods
- // Redundancy







- // Geographic flexibility
- // Right site network
- // Fast, iterative experimentation



Our foundation: Experience, Expertise, Evidence with <sup>223</sup>Ra-Cl<sub>2</sub> - Continuous learnings through >100K Patients treated



# Building on a Solid Foundation, We Continue to Enhance and Diversify Our TRT Portfolio



Overview TRT Development Pipeline



MOLECULES IN DEVELOPMENT

– based on rapid, iterative, (image-based) experimentation

## **Preclinical**

- 5 preclinical programs in total
- 2 in collaboration with **Bicycle**

## Phase 1

- Advancing of investigational <sup>225</sup>Ac labelled tumor-targeting conjugates:
  - // <sup>225</sup>Ac-Pelgifatamab
  - # 225Ac-PSMA-Trillium Next-generation small-molecule approach



# Productivity: Reaching Higher, Sustainable Level of Output

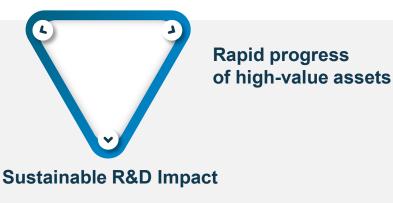


Achieve More and Better Solutions for Patients in a Time- and Cost-efficient Manner



- // Align target-disease link with unmet need and optimal therapeutic modality
- Early de-risking of assets by strengthening relevant capabilities (e.g. human disease understanding, biomarkers, data science, digital capabilities)
- Decrease in cycle times from IND to launch through tailored development approaches, removing stifling administration and by streamlining processes
- Shift to a product-centric operating model to foster innovation, agility and collaboration

Generation of highly innovative INDs





# Replenishment of Early Pipeline in Full Swing; Numerous First-In-Class Pipeline Candidates Transitioned into Phase II/III

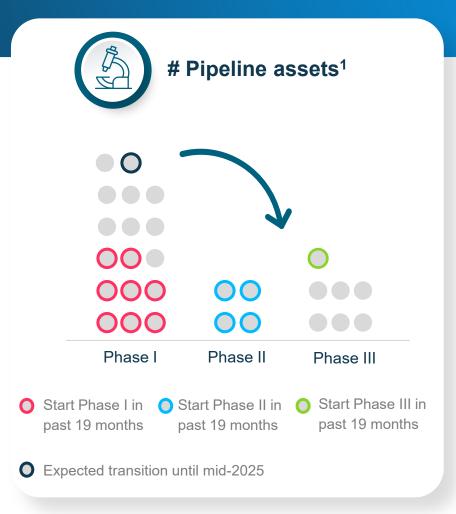


# Feeding from research into phase I

# Advancing higher number of INDs into Phase I

Selected examples:

- VVD Keap1 Act (advanced solid tumors) Demonstrating POC of Vividion's chemoproteomics platform
- PSMA-TAC Cancer (advanced prostate cancer)
  FIC/BIC opportunity
  in targeted radiotherapies
- VVD Stat3 Inhibitor (solid and heme cancers) Second asset from Vividion entering the clinic



Rejuvenate mid- / late-stage pipeline with several high-value assets

Actual / expected transitions to mid- and late-stage pipeline until mid-2025:

Selected examples:

Phase II Bemdaneprocel (Parkinson's Disease)

PSC-derived dopaminergic cell therapy; FIC potential

Anti-Alpha2-Antiplasmin mAB (Ischemic Stroke)

Effective thrombolytic with no

Effective thrombolytic with no increase in bleeding risk; FIC potential

Phase III HER2/mEGFR Inhibitor (Lung Cancer)
Targeting underserved NSCLC

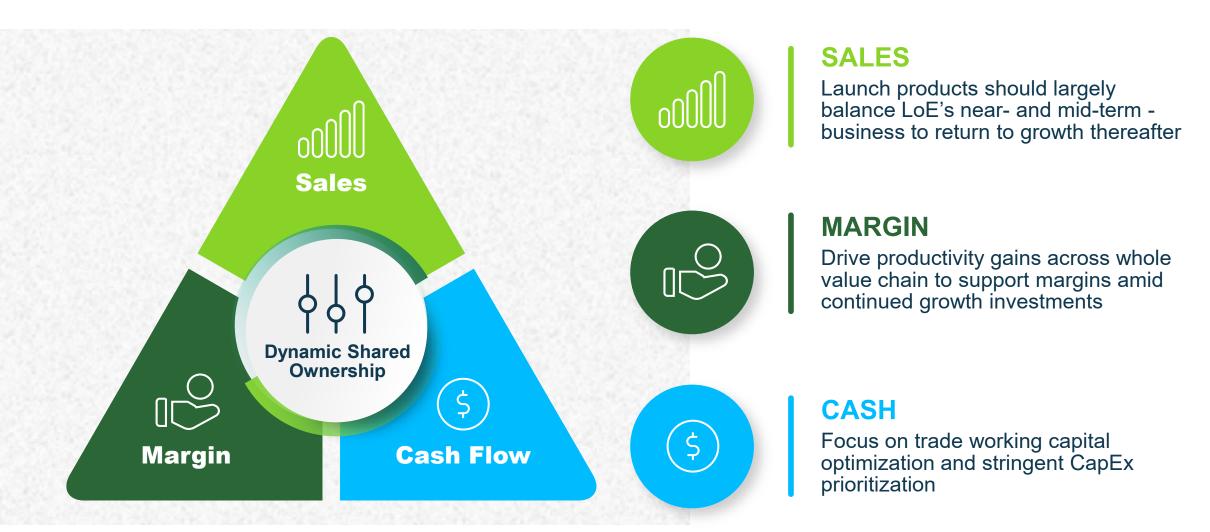
Targeting underserved NSCLC mutations; BIC potential

<sup>&</sup>lt;sup>1</sup> Pipeline status as of August 28, 2024; excluding future external / inorganic projects /// Bayer AG /// Pharmaceuticals /// September 2024



# Leveraging DSO to Enhance Productivity and Speed While Managing LoE Transition



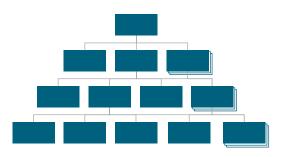




# DSO Will Drive Speed and Productivity Enhancing Innovation and Growth

## **New Operating Model**

FROM: Traditional hierarchic, org focus...



TO: ... mission-centric, value-focused operating model



Organization revolves around customers and products instead of functions

Teams to utilize **most** appropriate functional expertise when needed

Small clusters to operate with speed and efficient decision-making

## **Benefits**

- Customer centricity
- Product fit set up
- Faster decision-making
- Enhanced resource allocation
- Cost savings potential
- Improved long-term returns



# First Successes of Frontrunner Teams Demonstrate Huge Potential Across the Value Chain



## **Product Supply Inventory Management**

Set-up of cross-functional team to redefine **collaboration** with external suppliers

Potential to shorten throughput time by up to 90% from 30 days to mere single day

Enhancing supply flexibility for our patients and **improved** financial performance in terms of cash and costs



### **US Commercial Team**

Broke down franchise and functional silos to create customer and product squads

Squads are largely autonomous, cross-functional, entrepreneurial units with financial accountability

Flattened organization, e.g. 40% less managers



R&D

Supply

Commercial

Regions

## Early Clinical Development Oncology

Focusing on patient centered drug development across all modalities and biologies

Potential to accelerate clinical development with rapid learning cycles to explore ideas and assess progress every 90 days

Increases quality and speed of decision-making



## **Eylea Global Brand Team**

Set-up of small, mission-focused teams, empowered to make decisions at the lowest level possible

**Increased agility and ability** to address critical tasks much faster than in the previous set-up, e.g. achieving fast approval of Eylea 8mg





# 2024 Guidance and our Mid-Term Ambition Through 2026



<b>6</b>	2023	<b>2024e</b> at constant FX <sup>1</sup>
Net Sales	€18.1bn	0% to +3% <sup>2</sup>
EBITDA margin (before special items)	28.7%	26% to 29% <sup>2</sup>
Innovation		

## Mid-Term

## Support topline resilience during LoE's of major products:

- // Drive further launch uptake of Nubeqa and Kerendia
- // Launch of Eylea 8mg, Elinzanetant and Acoramidis
- // Maximize the full commercial value of base business

## **Drive productivity gains to support margins:**

- Continue tight cost management to fund growth investments while mitigating inflation and margin diluting change in product mix
- Improve organizational efficiency and productivity through DSO implementation

### Advance early assets to re-create promising mid-/late pipeline

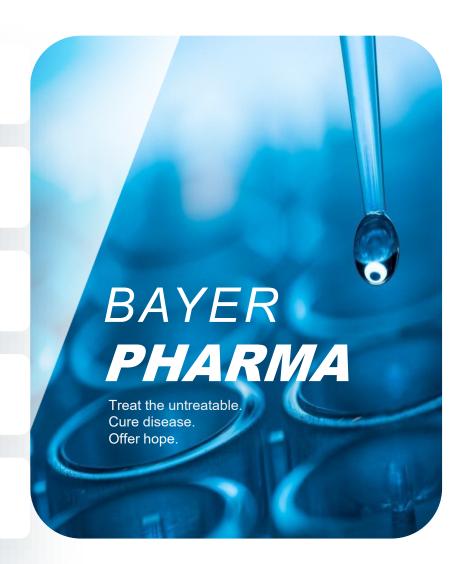
- Sustainable generation of highly innovative INDs
- # Rapid progress of high-value assets

<sup>&</sup>lt;sup>1</sup> Reflects our 2024 guidance at the average actual currencies for 2023; <sup>2</sup> Estimated Sales FX impact of ~-3% pts, estimated EBITDA Margin FX impact of ~-2% pts; currency assumptions based on month-end June 2024 spot rates (1 EUR=) 1.07 USD, 5.87 BRL, 7.80 CNY, 974 ARS, 35.16 TRY. Impact is calculated as difference to constant currencies = at average actual currencies for 2023



# Preparing for Long-term Growth While Managing LoE Transition

- Three strategic priorities:
  Renew topline grow pipeline value leverage new operating model
- Launch products should largely balance LoE's near- and mid-term, business expected to return to topline growth thereafter.
- Our advanced R&D capabilities and priorities will continue to shape a pipeline of higher quality and differentiated assets.
- Rapid rebuild of healthy early-/mid-stage pipeline is in full swing, three high potential products could enter market in 2025/2026.
- Productivity gains across the whole value chain will support margins amid continued growth investments.



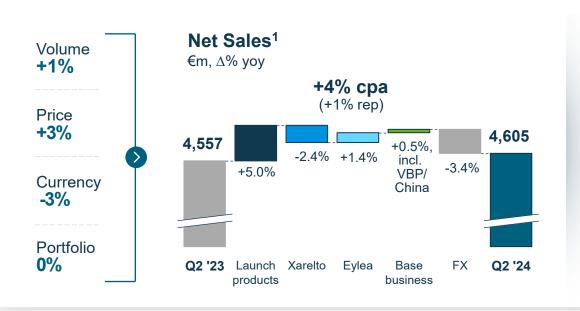




# Q2 2024: Growth of Launch Assets Overcompensates Xarelto Decline; Tight Cost Management Supports Margin Resilience



#### Pharmaceuticals Q2 2024







- // Launch products: Strong performance of Nubeqa and Kerendia
- // Xarelto sales decline in line with expected rising generic pressure
- // Eylea growing high single-digit %, led by Japan and Canada; launch of Eylea 8 mg gaining momentum
- // Base business: robust performance across major franchises more than offsets VBP pressure in China

- // Stringent OPEX management and resource shifts balancing unfavourable changes in product mix
- // PY margin included 280 bps benefit from reversal of incentive provisions
- // Negative currency effects weigh on margin (-220 bps)

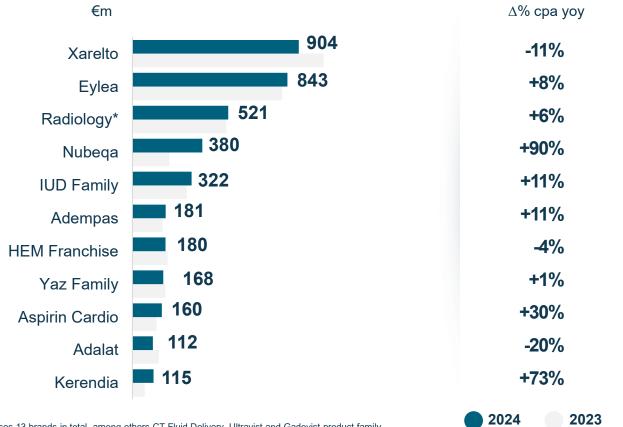


# Q2 2024: Growth Dynamics of Launch Assets Partly Offset by Expected Headwinds on Xarelto and Adalat



#### Pharmaceuticals Q2 2024

#### **Sales by Key Products**



### **Key Drivers**

**Xarelto:** sales impacted by generic pressure, especially in Canada and Europe; lower US royalties

**Eylea:** growing in all regions, particularly in Japan and Canada; ongoing launch of Eylea 8 mg

Nubeqa: continued growth led by US and Europe

**Kerendia:** growth driven by ongoing US market uptake and further business expansion in China

**Radiology:** CT Fluid Delivery and Ultravist performing particularly strong

**IUD Family:** volume and price increases especially in US and Brazil

Adempas: volume expansion in the US

**HEM Franchise:** competitive pressure especially in US

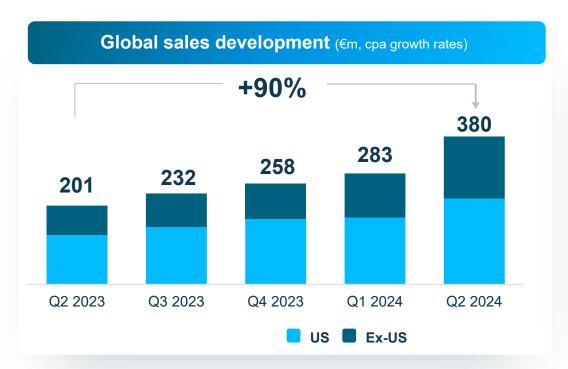
Yaz Family: positive business development in Europe

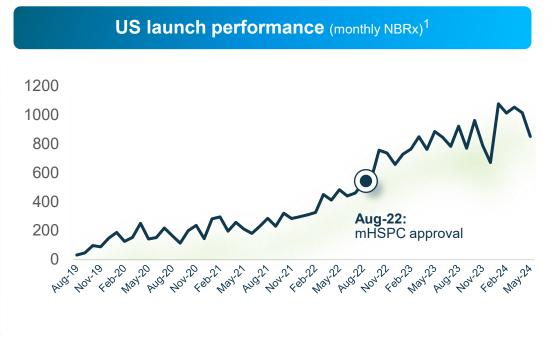
**Aspirin Cardio:** sales increase in China versus soft prior year

**Adalat:** volume decline due to continued impact from VBP in China



# Nubeqa Continues to Show Strong Uptake With Gains in All Regions







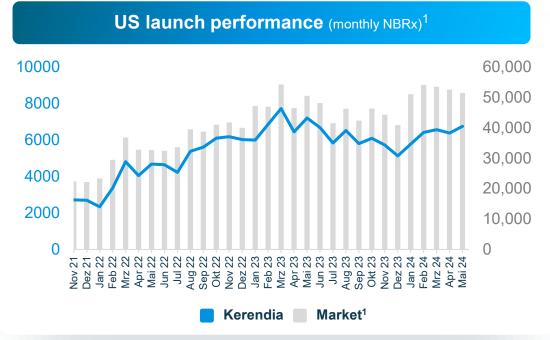
Nubeqa continues to be the fastest growing ARI<sup>2</sup> in the US

The mHSPC<sup>3</sup> launch continues to be a success in all markets, with particularly strong uptake in EMEA Nubeqa is approved in more than 87 countries today (mHSPC approvals in 79 markets)



## Kerendia Demonstrates Continued Launch Uptake







Solid growth momentum in the US; broad utilization in early disease stages confirms adoption of Kerendia across CKD stages

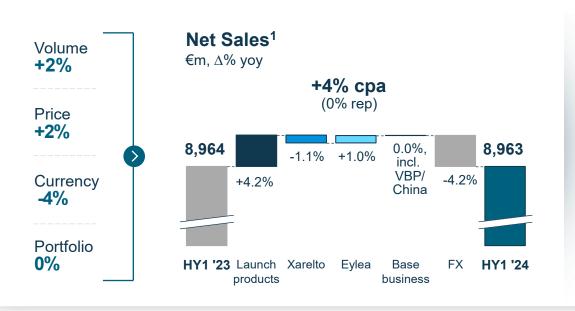
- Steady ex-US growth in key regions and countries, including China and LATAM with steep uptake after launch
- FINEARTS-HF Ph3 trial met primary endpoint in Heart Failure patients with LVEF ≥40%

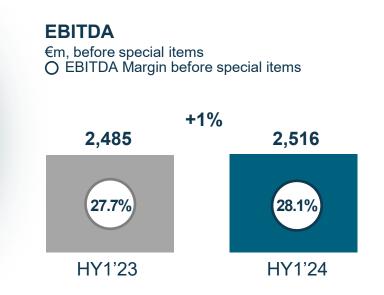


# HY1 2024: Launch Products and Eylea More Than Offset Xarelto LoE Impact, Tight Cost Management Holds Up Margin



#### Pharmaceuticals HY1 2024







- // Nubeqa and Kerendia continue to grow high double-digit %
- // Xarelto facing generic pressure in Europe and decline in North America
- // Eylea with sustained volume expansion; 8mg launched in first countries
- // Robust **Base business** as growth across major franchises offsets impact from VBP in China

- // Stringent OPEX management and resource shifts balancing unfavourable changes in product mix
- // PY margin included benefit from reversal of bonus provisions
- // Negative currency effects weigh on margin (-180 bps)

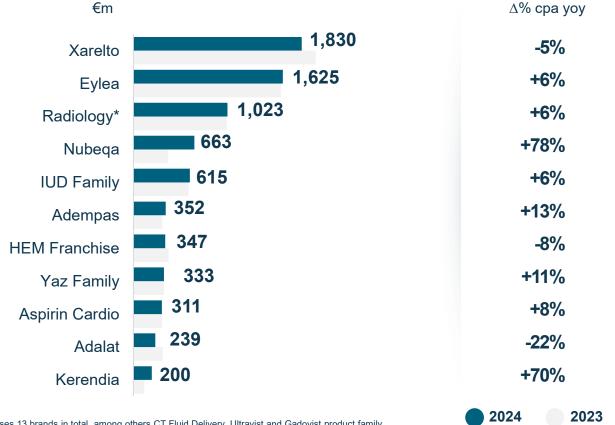


## HY1 2024: Strong Performance of Launch Assets, Eylea and Radiology More Than Offset Headwinds on Xarelto and Adalat



#### **Pharmaceuticals** HY1 2024

#### Sales by Key Products



### **Key Drivers**

**Xarelto:** generic pressure in Canada and Europe: lower US royalties

**Eylea:** growth particularly driven by Canada and Japan; first launches of Eylea 8 mg

Nubega: continued growth led by US, EU and China

Kerendia: growth driven by ongoing US market uptake and further business expansion in China

Radiology: CT Fluid Delivery and Ultravist performing particularly strong

**IUD Family:** Volume and price expansion, primarily in US. Latin America and China

Adempas: volume expansion in the US

**HEM Franchise:** competitive pressure especially in US

Yaz Family: recovery from soft prior year

Aspirin Cardio: growth in Europe, Latin America and China

Adalat: continued impact from VBP in China



## Pharmaceuticals: R&D Developments (since last update on April 30, 2024)

#### Phase I Phase II Phase III Initiation of HER2/mEGFR Initiation of sGC Activator Inhibitor in advanced Non-Oral in Chronic Kidney small Cell Lung Cancer with Disease (ALPINE-1) HER2 activating mutations (SOHO-02) Initiation of AB-1005 in Parkinson's Disease (REGENERATE-PD) Discontinuation of Runcaciguat (Non-proliferative diabetic retinopathy (NPDR)) Oncology

#### Commercial

Positive topline results of Nubega Phase III ARANOTE Study (mHSPC)

Positive topline results of Kerendia Phase III FINEARTS-HF Study (Heart Failure)

Submission of Elinzanetant for regulatory approval in U.S.

Cardiovascular+1

**Neurology & Rare Diseases** 

**Others** 









<sup>1</sup> Including Precision Cardiovascular, Nephrology & Acute Care 2 Exclusive commercialization rights acquired for EU markets; pending marketing authorization approval. Submission to EMA under responsibility of BridgeBio





# Due to Its Distinct Structural and Pharmacological Properties, Finerenone's Clinical Profile Significantly Differs from Other MRAs

#### Structural and pharmacological properties of MRAs<sup>2</sup>

	Spironolactone	Eplerenone	Finerenone
MRA Class Steroidal		Steroidal	Non-steroidal
Potency	High	Low	High
Selectivity	Low	Medium	High
Metabolites	Multiple, active	No active	No active
Tissue distribution <sup>3</sup>	Kidney>>heart (>6-fold)	Kidney>heart (~3-fold)	Balanced (1:1)
Indication and key studies	HF with LVEF ≥40%: TOPCAT study failed <sup>4</sup>	HF with LVEF ≥40%: not tested	Significant risk reduction in HF with LVEF ≥40% and patients with CKM
stadies	HF with LVEF <40%: class 1 recommendation <sup>1-3</sup> (RALES study)	HF with LVEF <40%: class 1 recommendation <sup>1-3</sup> (EPHESUS study)	
First	1960	2002	2021

#### **Characteristics of Finerenone**

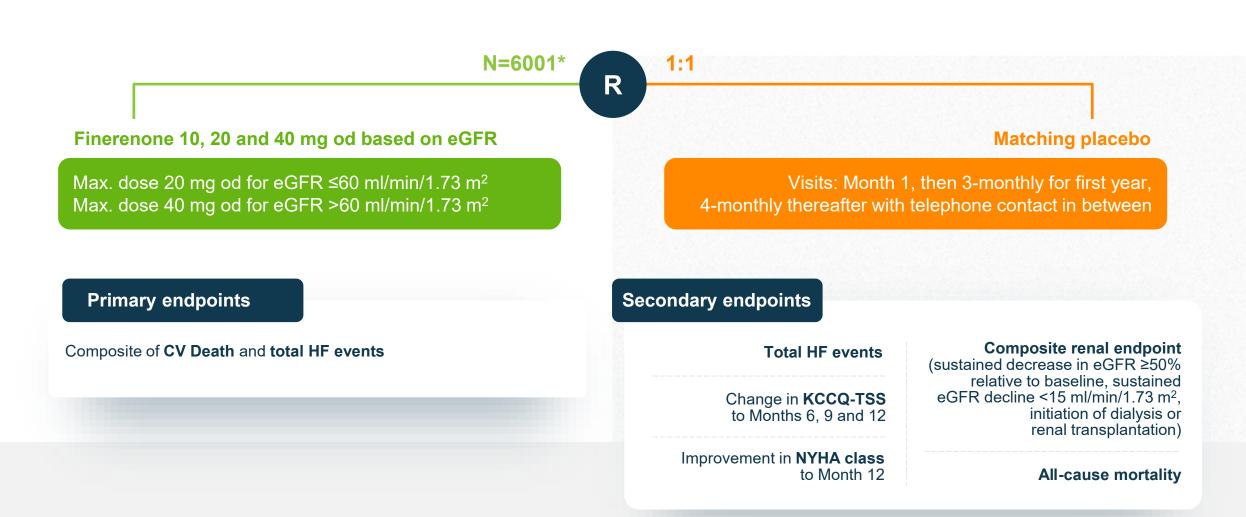
- // Significant molecular and pharmacological differences that explain cardiorenal clinical effects<sup>4</sup>
- // High selectivity for the MR over other steroid hormone receptors, which prevents antiandrogenic and progestational side effects<sup>4</sup>
- // Balanced cardiac and kidney distribution
- **Low incidence** of hyperkalaemia-related adverse events with clinical impact and permanent treatment discontinuation<sup>5</sup>

CKM: Cardiovascular-kidney-metabolic; HFpEF: Heart Failure with preserved ejection fraction; HFrEF: Heart Failure with reduced ejection fraction; LVEF: Left ventricular ejection fraction; MRA: Mineralocorticoid receptor antagonist <sup>1</sup> Kolkhof P, Nowack C, Eitner F. Curr Opin Nephrol Hypertens. 2015;24:417-424. <sup>2</sup> Modified from: Kolkhof B, Borden SA. Mol Cell Endocrinol. 2012;350:310-317. <sup>3</sup> Determined in rodents. <sup>4</sup> Kintscher U, Bakris GL, Kolkhof P, Kolkhof P, Howack E, Gebel M, Ruilope LM, Bakris GL, Fortham College LM, Bakris GL, Kolkhof P, Nowack C, Gebel M, Ruilope LM, Bakris GL, Kolkhof P, Nowack C, Gebel M, Ruilope LM, Bakris GL, Kolkhof P, Howack C, Gebel M, Ruilope LM, Bakris GL, Kolkhof P, Nowack C,

in CKD/T2D



# FINEARTS-HF Evaluates the Efficacy and Safety of Finerenone in Patients With HF and LVEF ≥40%

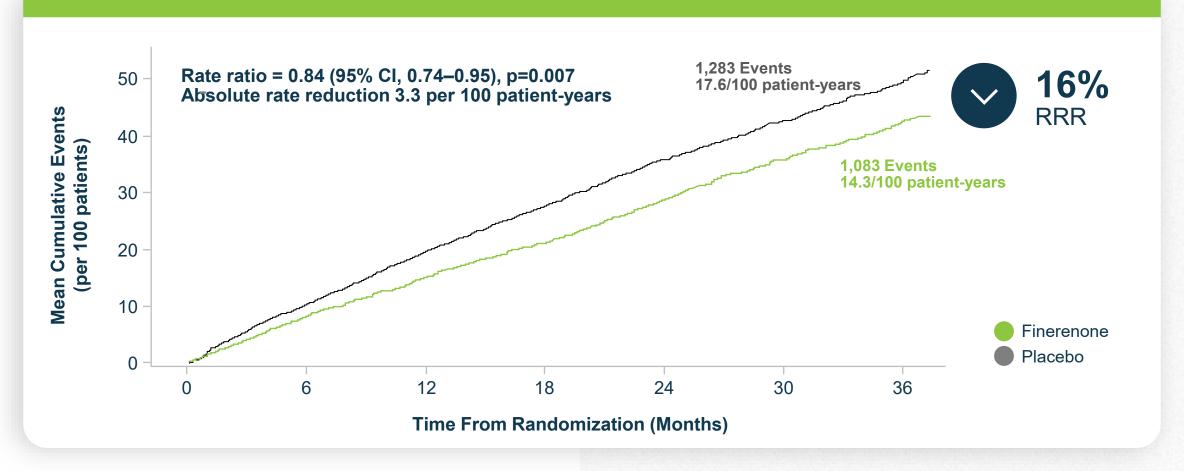


CV: Cardiovascular; eGFR: estimated glomerular filtration rate; HF: Heart Failure; LVEF: Left ventricular ejection fraction; KCCQ-TSS: Total symptom score of Kansas City Cardiomyopathy Questionnaire; NYHA: New York Heart Association; Od: once daily; R: Randomization \* 6016 randomized, 6001 included in efficacy analysis



# Finerenone Demonstrated Clinically Meaningful 16% Relative Risk Reduction in Composite of CV Death and Total HF Events

### **Primary Endpoint: Composite of CV Death and Total HF Events**





## Finerenone's Effects On Primary Outcome Were Consistent Regardless of LVEF and Background Therapy, Including SGLT2i

### **Primary Endpoint**

Key sub-groups

	Finerenone			Placebo			(2-2)	
Category	Events	n/N	<b>E/100</b> p-yrs	Events	n/N	<b>E/100</b> p-yrs	RR (95% CI)	
LVEF								
< 60%	877	512/2427	15.17	1061	594/2425	18.47	<b></b>	
≥ 60%	206	112/576	13.76	222	125/573	14.73	<b>-</b>	
SGLT2i								
Yes	176	95/393	21.77	234	122/424	26.50	-	
No	907	529/2610	14.02	1049	597/2574	16.48		
						(	0.5 1	
Rate ra	atios for the p	rimary endpoir	nt across all 17 p	re-specified s	subgroups		Favours Favours	

Finerenone Placebo



were in favour of finerenone

CI; Confidence interval; LVEF: Left ventricular ejection fraction; RR: Rate ratios; SGLT2i: Sodium-glucose cotransporter-2 inhibitors. Source; Solomon S, et al. NEJM 2024 [in press].



## FINEARTS-HF Also Reached Key Secondary Endpoints

### Secondary Endpoints, hierarchical testing

	Finerenone (N=3003)	Placebo (N=2998)	<b>Difference</b> [1] (95% CI)
Total HF Events	842	1024	RR: 0.82 (0.71, 0.94) p=0.0062
Change in KCCQ-TSS to Months 6, 9 and 12, LS mean (SE)	<b>7.99</b> (0.32)	<b>6.43</b> (0.32)	<b>Diff: 1.56</b> (0.79, 2.34) p<0.0001
Improvement in NYHA Class to Month 12, n/N (%)	<b>557/3002</b> (18.5%)	<b>553/2998</b> (18.4%)	<b>OR: 1.01</b> (0.88, 1.15)
Composite renal endpoint, n (%)	<b>75</b> (2.5%)	<b>55</b> (1.8%)	<b>HR: 1.33</b> (0.94, 1.89)
All-cause mortality, n (%)	<b>491</b> (16.4%)	<b>522</b> (17.4%)	<b>HR: 0.93</b> (0.83, 1.06)

<sup>[1]</sup> Treatment difference for Finerenone vs Placebo: HR: Hazard ratio; RR: Rate ratio; OR: Odds ratio; Diff: Difference in least squared means; Cl: Confidence interval; CV: Cardiovascular; HF: Heart failure; KCCQ-TSS: Total symptom score of Kansas City Cardiomyopathy Questionnaire; LS: Least squared; NYHA: New York Heart Association; SE: Standard error; Composite renal endpoint: Time to sustained decrease in estimated glomerular filtration rate (eGFR) ≥50% relative to baseline over at least 4 weeks, or sustained eGFR decline <15ml/min/1.73m2 or initiation of dialysis or renal transplantation



## **FINEARTS-HF: Conclusions**

- Among patients with HF with LVEF ≥40%, **finerenone reduced the risk of the primary composite outcome of cardiovascular death and total HF events**, reduced total HF events, and improved HF health status.
- > The benefit appears to be early and the curves continue to separate over time.
- > Findings were consistent across prespecified subgroups, including across LVEF and in those on SGLT2i's.
- Hyperkalemia was more common, and hypokalemia less common, in those receiving finerenone. Hyperkalemia leading to hospitalization was low, and there was no fatal hyperkalemia
- Subject to regulatory approval, these data support the use of finerenone in patients with HF and LVEF ≥40% (HFmr/pEF)



# In FINE-HEART, Finerenone Demonstrated Benefits Across Cardio-Kidney Secondary Endpoints

Outcomes		No. of patients with event (%)	IR per     100py	No. of patients with event (%)	IR per 100py	I		
Primary Endpoint								
V Death (excluding undetermined death)	<b>&gt;</b>	421 (4.4)	1.5	471 (5.0)	1.7	-	0.89 (0.78-1.01)	0.076
Prespecified Sensitivity Analysis: CV Death (including Undetermined death)		627 (6.6)	2.3	703 (7.4)	2.6	<b>⊢</b> ■-1	0.88 (0.79-0.98)	0.025
Secondary Endpoints								
Kidney Composite Endpoint	<b>&gt;</b>	557 (5.9)	2.3	685 (7.2)	2.8	<b>⊢</b> ■─	0.80 (0.72-0.90)	<0.001
HF Hospitalization		705 (7.4)	2.7	839 (8.8)	3.2	<b>⊢</b> ■─	0.83 (0.75-0.92)	<0.001
CV Death or HF Hospitalization	<b>&gt;</b>	1009 (10.6)	3.9	1168 (12.3)	4.5	⊢■→	0.85 (0.78-0.93)	<0.001
New-onset Atrial Fibrillation		286 (3.0)	1.3	345 (3.6)	1.6	-	0.83 (0.71-0.97)	0.018
Major adverse CV events	<b>&gt;</b>	1428 (15.0)	5.6	1554 (16.4)	6.2	H=-	0.91 (0.85-0.98)	0.010
All-Cause Death		1042 (11.0)	3.8	1136 (12.0)	4.2	H=-H	0.91 (0.84-0.99)	0.027
All-Cause Hospitalization	<b>&gt;</b>	4261 (44.8)	21.1	4401 (46.4)	22.2	H	0.95 (0.91 – 0.99)	0.025
All-Cause Death or All-Cause Hospitalization		4467 (47.0)	22.2	4653 (49.0)	23.5	H	0.94 (0.91 – 0.98)	0.007



### **FINE-HEART: Conclusions**

- >
- **FINE-HEART with ~19,000 patients** represents the largest analysis of efficacy and safety of the non-steroidal MRA finerenone across the CKM spectrum.
- >
- **Finerenone consistently shows benefits** across a range of highly patient-relevant cardio-kidney outcomes incl. all-cause mortality.
- **>** 
  - The incidence for the **primary endpoint of CV death** was numerically lower in patients treated with finerenone versus placebo, but narrowly missed statistical significance.
- >
- Finerenone was well tolerated across diseases.



## Pharmaceuticals – Pipeline Overview<sup>1</sup> (as of August 28, 2024)



<sup>&</sup>lt;sup>1</sup> Bayer and partner sponsored + 3rd party label enabling studies with first patient first visit







Full pipeline package available for download under:

https://www.bayer.com/en/pharma/development-pipeline







<sup>&</sup>lt;sup>2</sup> Conducted by Merck & Co

<sup>&</sup>lt;sup>3</sup> Including Precision Cardiovascular, Nephrology & Acute Care

<sup>&</sup>lt;sup>4</sup> Exclusive commercialization rights acquired for EU markets; pending marketing authorization approval. Submission to EMA under responsibility of BridgeBio



## Major R&D Milestones Expected Until Mid-2025

Phase I	Phase II	Phase III	Submission / Approval
Sema3A mAB: Primary compl. Phase I	Bemdaneprocel PD: Start Phase II	Vericiguat HFrEF: Primary compl. Phase III (VICTOR)	HER2/mEGFR Inhibitor in HER2mut NSCLC 2L: First submission
BRT-OpCT01 Primary Photoreceptor Diseases Start Phase I/II		Aflibercept RVO: 8 mg Primary compl. Phase III (QUASAR)	✓ <b>Darolutamide in mHSPC:</b> First submission to expand label
		(QUASAIT)	Finerenone HFmr/pEF: First submission
			Acoramidis ATTR-Cardiomyopathy: First approval <sup>3</sup>
			Elinzanetant VMS: First approval
>>> Phase transition (FPFV)			Gadoquatrane: First submission
<ul><li>New LCM</li><li>✓ First Submission / Approval</li></ul>			

**Immunology** 

Others

Oncology

Cardiovascular+2

**Neurology & Rare Diseases** 

<sup>&</sup>lt;sup>1</sup> After July 31st, 2024 <sup>2</sup> Including Precision Cardiovascular, Nephrology & Acute Care <sup>3</sup> Exclusive commercialization rights acquired for EU markets; pending marketing authorization approval. Submission to EMA under responsibility of BridgeBio



## Abbreviations (1/3)

AAV Adeno-associated virus	Compl. Co	ompletion
----------------------------	-----------	-----------

Ag Agriculture cpa Currency and portfolio adjusted

Al Artificial intelligence DME Diabetic macular edema

ARI Androgen receptor inhibitor DSO Dynamic shared ownership

ARS Argentine Peso EBITDA Earnings before interest, tax, depreciation, and amortization

ATTR-CM Transthyretin amyloidosis cardiomyopathy e.g. Exampli gratia (for example)

BCR Biochemical recurrence EMEA Europe, Middle East, and Africa

BIC Best-in-class EU European Union

bn billion EU5 France, Germany, Italy, Spain, United Kingdom

Bps Basis points Excl. Excluding

BRL Brazilian Real FDA U.S. Food and drug administration

CAGR Compound Annual Growth Rate FIC First-in-class

CH Consumer Health FPFV First patient first visit

CNY Chinese yuan renminbi FTE Full-time equivalent

CV Cardiovascular FX Foreign Exchange

CVD Cardiovascular diseases FY Full Year

CI Confidence interval Gyn Gynecologist

CKD Chronic kidney disease HF Heart failure



# Abbreviations (2/3)

HFmr/pEF	Heart failure with mildly reduced / preserved ejection fraction	NPDR	Non-proliferative diabetic retinopathy
HR	Hazard ratio	NSCLC	Non-small cell lung cancer
HY1 / HY2	Half year 1 / Half year 2	OB	Obstetricians
Incl.	Including	OTC	Over-the-counter
IND	Investigational New Drug	OPEX	Operating expenses
JP	Japan	р	Probability
k	thousands	p.a.	Per annum
LATAM	Latin America	Pts	Percentage points
LCM	Life cycle management	POC	Proof of concept
LoE	Loss of exclusivity	PSC	Pluripotent stem cells
LVEF	Left ventricular ejection fraction	PY	Prior year
m	million	Q16	Every 16 weeks
mg	milligram	R&D	Research & Development
mHSPC	Metastatic hormone sensitive prostate cancer	SGLT2i	Sodium-glucose Cotransporter 2 Inhibitors
nAMD	Neovascular age-related macular degeneration	SMOL	Small Molecuale
NBRx	New-to-brand prescriptions	SoC	Standard of Care
nmCRPC	Non-metastatic castration resistant prostate cancer	T1D	Type 1diabetes mellitus
NME	New molecular entity	T2D	Type 2 diabetes mellitus



## Abbreviations (3/3)

TIA Transient ischemic attack

TRT Targeted radionuclide therapy

TRY Turkish lira

TTR Transthyretin

UK United Kingdom

U.S. United States of America

USD United States Dollar

VBP Volume based procurement

VMS Vasomotor symptoms

vs versus

yoy Year-over-year

1L First line

2L Second line