



### Driving our strategic agenda



**Grow potential blockbusters** 

Capture the full commercial value of the current portfolio



**Build & grow US business** 

**Shift in marketing & R&D** towards growth drivers



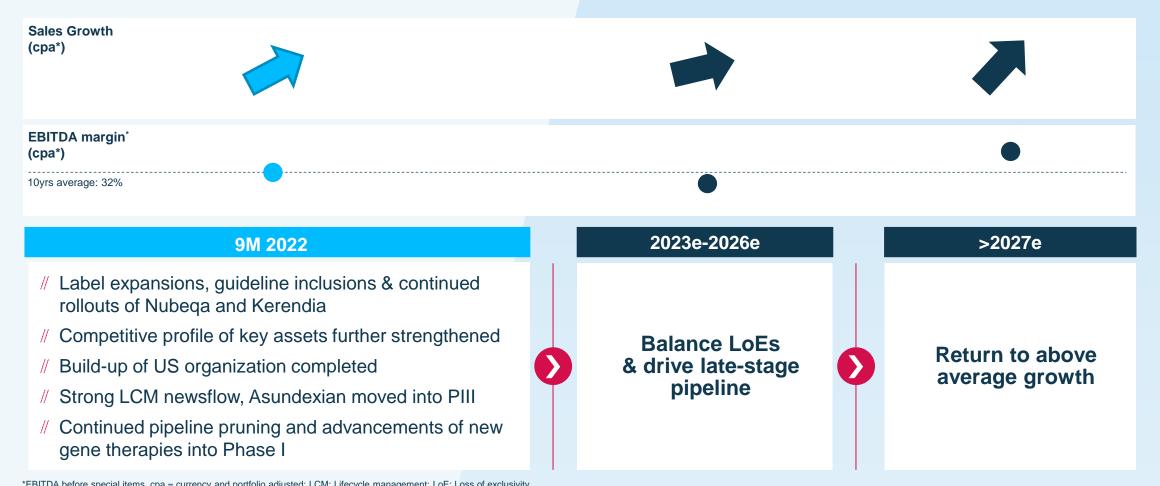
**Progress late-stage pipeline** 

Strengthen early pipeline

through increasing contributions from platform companies as well as partnering



# Investing in future growth while managing our P&L along the projected trajectory



\*EBITDA before special items, cpa = currency and portfolio adjusted; LCM: Lifecycle management; LoE: Loss of exclusivity



# In 9M 2022 we have absorbed significant headwinds that emerged during the year

#### **Geopolitical & macroeconomic events**

- // War in Ukraine
- // Inflation
- # Supply chain disruptions
- // Negative market dynamics, e. g. COVID-19 (China)
- # EUR devaluation



#### **Industry dynamics**

- // Limited or no ability to react on increasing COGS
- // Reimbursement & pricing pressure across the globe, e. g. VBP\*, IRA\*, etc.
- // New health patterns (IUD\*)
- # Reward for incremental innovation increasingly limited



#### Impact on Bayer Pharmaceuticals in 9M 2022

#### Sales

- // Price pressure Europe
- // China: VBP and COVID lockdowns

#### **EBITDA\*** margin

- // Lower sales
- // Cost increases in raw materials
- // Adverse FX impacts

| +8%   | reported     | 30.8% |
|-------|--------------|-------|
| +3%   | cpa*         | ~32%  |
| +3-4% | FY guidance* | ~32%  |

Pressure on sales and margin to continue in 2023 and beyond

\*EBITDA before special items, cpa = currency and portfolio adjusted; IRA: US Inflation Reduction Act; IUD: Intrauterine device; VBP: Volume-based procurement; FY guidance based on constant currencies and portfolio



# Nubeqa at #2 in nmCRPC already, further share gains and label expansions confirm >€3bn peak sales potential

# Sales more than doubling in 2022

- # Expanding market share in the US to >30% in nmCRPC
- # US label extension in August 2022 to treat patients with mHSPC



#### Sales drivers 2023

- # Continued market share gains in nmCRPC
- # mHSPC approvals in EU, JP, CN and other major regions
- // Potential to become foundational drug across prostate cancer indications

#### Phase 3 Clinical development program







- **2027** // BCR
  - # adjuvant (DaSL-HiCap)









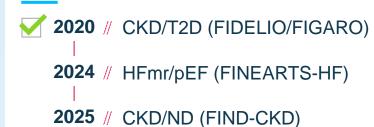
# Kerendia with strong launch momentum, ongoing guideline inclusions & potential label extensions to push peak sales to >€3bn

#### **Continued US market uptake** One of the strongest launch dynamics in CV despite initial COVID restrictions # Reimbursed access for majority of commercially insured and Medicare Part D patients # Recommended by ADA, AACE, KDIGO TRx development 3,000 Sales 2022e: >€100m 2,000 1.000

#### Sales drivers 2023

- # Broad utility and relevance across GPs and specialists
- // Ongoing US market penetration & upcoming reimbursements ex-US
- // Potential for further inclusion in treatments guidelines

#### Clinical development program





Peak sales potential >€3bn

AACE: American Association of Clinical Endocrinology; ADA: American Diabetes Association; CKD: Chronic kidney disease; HFmr/pEF: Heart failure with mildly reduced / preserved ejection fraction; ND: Non-diabetic

**ENTRESTO** 

KERENDIA



# Strong Aflibercept 8mg data reinforce leading clinical profile and competitive position of the Eylea franchise

#### **Leading medicine in wAMD and DME treatment**

Eylea Volume Development (vials + prefilled syringes)







2016 2017 2018 2019 2020 2021 2022e

- # Gold standard in efficacy and safety
- # High competitive hurdle: >8 million of treated years for patients and physicians
- // First biosimilar launches expected in 2023 (CA, JP)

#### Unparalleled clinical data further raising the bar

Aflibercept 8mg

Share of patients maintaining on dosing interval<sup>1)</sup>

| Injection      | PHOTON (DME) | PULSAR (wAMD) |
|----------------|--------------|---------------|
| every 12 weeks | 91%          | 79%           |
| every 16 weeks | 89%          | 77%           |

<sup>1)</sup> Comparator arms: Eylea every 8 weeks

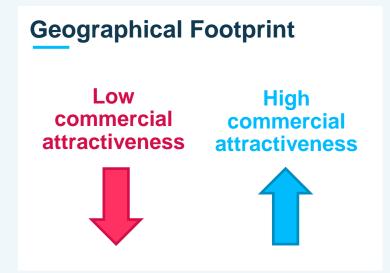
- Significant prolongation of injection intervals without compromising efficacy and safety
- Set to become new standard of care despite increasing competitive dynamics
- # Submissions in major markets in 2023, launch by 2024

**Commercial potential substantially strengthened** 

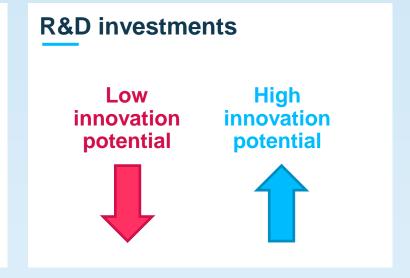
DME: diabetic macular edema; wAMD: wet age-related macular degeneration



### Continued shift of resources towards growth drivers









# Elinzanetant's unique clinical profile can offer a transformative approach for the treatment of vasomotor symptoms

#### **Market**

#### **Vasomotor Symptoms (VMS)**

- // Among most commonly-reported menopausal symptoms
- // Limited treatment options available, only ~1/3 of adoption







Hot flashes



Night sweats

~16m women each in U.S. and EU

#### **Elinzanetant characteristics**

- # First-in-class, non-hormonal, oral OD neurokinin-1,3 receptor antagonist (dual mode of action)
- // May reduce hyperactivity of KNDy neuronal network involved in thermoregulation
- // Demonstrated significant and rapid improvement in VMS in Phase II and was well-tolerated



#### **Phase III OASIS Program**

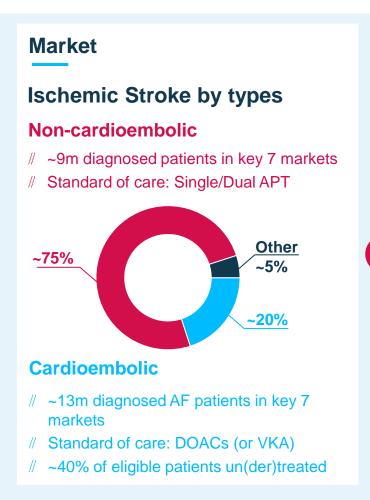
- # Four Phase III studies (OASIS-1 OASIS-4)
- // Investigating the efficacy and safety of elinzanetant 120mg once daily in menopausal women with VMS
- # Expected first study readouts: 2023

Potential launch: 2025

Peak sales potential >€1bn



# Landmark Phase III program started with oral factor XIa inhibitor Asundexian – peak sales of >€5bn projected



#### **Asundexian characteristics**

- // Potential first-in-class, once-daily, oral small molecule FXIa inhibitor
- // New potential treatment in thrombosis prevention
- # Broad Phase II study program PACIFIC confirmed consistent safety and near maximum FXIa inhibition

#### **Phase III OCEANIC Program**



- // Asundexian vs. apixaban in atrial fibrillation
- // FPFV in December 2022

#### **OCEANIC STROKE**

- # Asundexian + APT in acute non-cardioembolic ischemic stroke or high-risk TIA vs. placebo
- # Expected study readouts: 2025

Potential launch: 2026

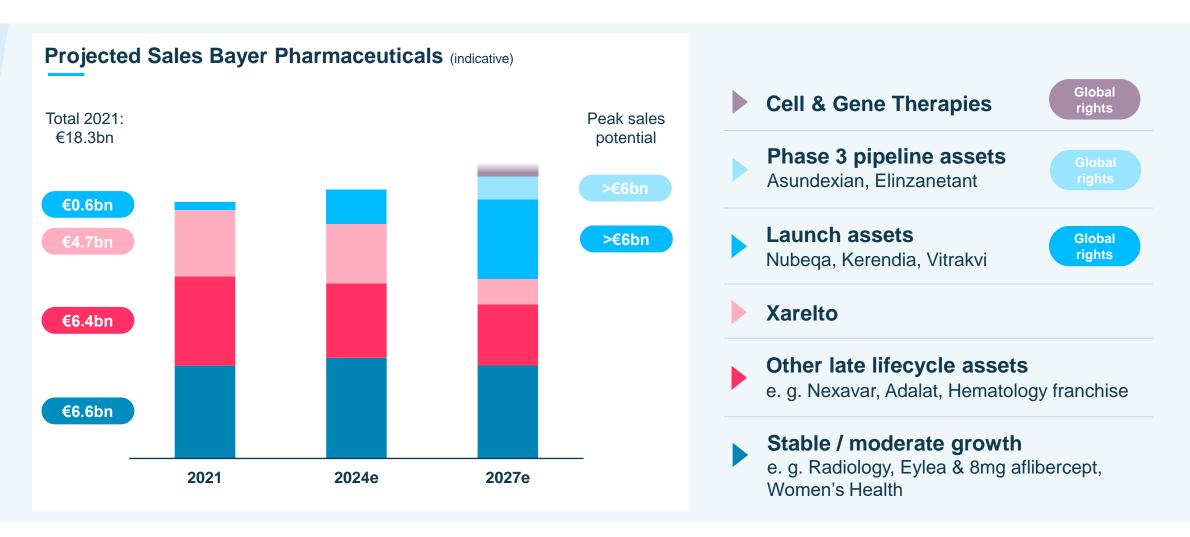
•

Peak sales potential >€5bn

AF: Atrial fibrillation; APT: Antiplatelet therapy; DOAC: Direct oral anticoagulant; FPFV: First patient first visit; SAPT: Single antiplatelet therapy; TIA: transient ischemic attack; VKA: Vitamin K Antagonist



# Launch assets and late-stage pipeline expected to more than offset losses of exclusivity and drive long-term growth





# Platform companies with industry-leading technologies increasingly contributing to replenishment of early pipeline









Cell platform based on pluripotent stem cells

AAV-based gene therapy & manufacturing platform

Chemoproteomics platform (Direct functional modulators, protein degraders)



# Phase I Parkinson's Disease (DA01)

- # Pluripotent stem cell-derived dopaminergic neurons implanted into the brain
- # First results expected in HY2 2023

# 5 assets in Phase I in rare and pathway diseases:

- // Parkinson's Disease
- // Multiple System Atrophy
- # Huntington's Disease
- // Pompe Diseases
- // Congestive Heart Failure

#### 2 new INDs planned in 2023

// high profile immunology and oncology targets

Fueled with ~25% of global R&D budget in 2023

IND: Investigational new drug



### Our Strategy is geared towards sustainable growth



- // Nubeqa and Kerendia starting to become key growth drivers
- // Combined peak sales potential for Nubeqa and Kerendia raised to >€6bn
- # Eylea franchise well positioned to continue leadership



- // Continuous shift of resources towards growth drivers
  - From low commercial attractive markets to high commercial attractive markets
  - // From mature portfolio to launch brands
  - # From low innovation potential to high innovation potential



- # Elinzanetant Potential transformative approach for the treatment of vasomotor symptoms
- # Landmark Phase III clinical program for asundexian started Peak sales potential ≥€5bn
- First study results from our C&GT Platform expected in 2023





## Pharmaceuticals – Pipeline Overview<sup>1</sup> (as of Dec 13, 2022)

| Phase 0 <sup>2</sup>                     |            | Phase I   |            | Phase II  |              | Phase III  |               |
|--|------------|---|------------|---|--------------|--|---------------|
| DGKalpha Inh (BAY 2862789)               | .Å. ●      | Elimusertib (ATR Inhibitor) (BAY 1895344)                           | , i.,      | Regorafenib (combi Nivolumab) (BAY 734506)  // Solid tumors (recurrent or metastatic)               | <i>♣</i> , O | Copanlisib (PI3K Inhibitor) (BAY 806946)  // Non-Hodgkin Lymphoma (CHRONOS-4)  | ,i, 0         |
| PSMA TAC (BAY 3546828)                   |            | AhR Inhibitor (BAY 2416964)   | •¥° ●      | Asundexian (FXIa Inhibitor) (BAY 2433334)   | Ŷ <b>^</b>   | Darolutamide (AR Inhibitor) (BAY 1841788)  |               |
| PSMA SMOL TAC (BAY 3563254)              |            | mEGFR Inhibitor (BAY 2927088)                                       | .i. •      | /// 2º Stroke Prevention (PACIFIC-STROKE) /// Major Adverse Cardiac Events Prevention (PACIFIC-AMI) | o**o         | # Prostate Cancer (mHSPC) (ARANOTE) # Adjuvant Prostate Cancer (DASL-HiCaP)  | <b>۵</b> گ، O |
| VVD NRF2 Inh (BAY 3605349)               | ٠. •       | <sup>227</sup> Th-Trastuzumab corixetan (HER2 TTC)<br>(BAY 2701439) |            | Runcaciguat (sGC Activator) (BAY 1101042)   | الله الله    | Finerenone (MR Antagonist) (BAY 948862)  | ,i, O         |
| VVD STAT3 Inh (BAY 3630914)              | .i. •      | DGKzeta Inhibitor (BAY 2965501)                                     | ,Å, •      | Chronic Kidney Disease (CKD) (CONCORD)  Non-prolif. Diabetic Retinopathy (NPDR) (NEON-NPDR)         |              | // Heart Failure (HFmr/pEF) (FINEARTS-HF)<br>// Non-diabetic CKD (FIND-CKD)  | ٠,٠٠٠         |
| <b>SEMA 3</b> <sup>a</sup> (BAY 3401016) | <b>Y</b> • | CCR8 Ab (BAY 3375968)   | Y          | BDKRB1 Receptor Antagonist (BAY 2395840)  | i o          | Vericiguat (sGC Stimulator) (BAY1021189)   | ,i, o         |
| LGMD2i Gene Therapy (LION-101)           | <b>§</b> • | Congestive Heart Failure Gene Therapy (NAN-101)                     | § •        | // Neuropathic Pain (BRADiNP)   |              | # Heart Failure (HFrEF) (VICTOR³)  |               |
| Next Generation Liver MRI (BAY 3393081)  | <b>ĕ</b> ● | sGC Activator (BAY 3283142)   | , Å, •     | Gadoquatrane (High Relaxivity Contrast Agent) (BAY 1747846)   |              | Asundexian (FXIa Inhibitor) (BAY 2433334)  // Stroke Prevention in Atrial Fibrillation (OCEANIC-AF)                          | .Å. •         |
| (DAT 3033001)                            |            | Anti-a2AP (BAY 3018250)   | Y •        | // Magnetic Resonance Imaging (HRCA-PAT)  Adrenomedullin Pegol (PEG-ADM) (BAY 1097761)              |              | Elinzanetant (Neurokinin-1,3 Rec Antagonist) (BAY 3427080)   | مني 🌑         |
|  |            | P2X4 Antagonist (BAY 2328065)                                       | , Å, •     | # Acute Resp. Distress Syn. (ARDS) (SEAL)   | <b>3</b> 3 ● | # Vasomotor Symptoms (OASIS)   | , ,           |
|  |            | BDKRB1 Receptor Antagonist (BAY 2395840)                            | , Å. •     |   |              | Aflibercept 8MG (BAY 865321)  // Diabetic Macular Edema (DME) (PHOTON4)  | y O           |
|  |            | Zabedosertib (IRAK4 Inhibitor) (BAY 1834845)                        | ,å, •      |   |              | // Neovasc. Age-rel. Macular Degen. (nAMD) (PULSAR)  |               |
|  |            | sGC Activator (BAY 12111163)  | ,å, •      |   |              | Submissions  |               |
|  |            | Parkinson's Disease Cell Therapy (BRT-DA-01)                        |            |   |              | Darolutamide (AR Inhibitor) / ADT with   | 1 0           |
|  |            | Parkinson's Disease Gene Therapy (AAV2-GDNF-PD)                     | ğ •        |   |              | Chemotherapy # EU, Japan, China: mHSPC   | <i>♣</i> 0    |
| Oncology                                 |            | Multiple System Atrophy Gene Therapy (AAV2-GDNF-MSA)                | <b>ĕ</b> ● |   |              | Aflibercept (VEGF inhibitor)  # EU: Retinopathy of prematurity   | 3 O           |
| Cardiovascular Diseases                  |            | Pompe Disease Gene Therapy (ACTUS-101)                              | <b>ĕ</b> ● |   |              | # EO. Reunopainy of prematurity  |               |
| Women's Health                           |            | Huntington's Disease Gene Therapy (BV-101)                          | § •        |   |              | Submission in preparation  |               |
| Others                                   |            |   |            |   |              | Aflibercept 8MG  // Diabetic Macular Edema (DME) (PHOTON <sup>4</sup> )  // Neovasc. Age-rel. Macular Degen. (nAMD) (PULSAR) | 3, O          |
| New therapeutic entity                   |            |   |            |   |              | 5 , ,,   |               |

🎢 Antibody 🦒 Biologic 💥 Cell Therapy 📋 Contrast Agent 🦉 Gene Therapy 💥 Radiotherapy 🎎 Small Molecule

<sup>1</sup> Bayer and partner sponsored + 3rd party label enabling studies with first patient first visit 2 Pre-clinical selected assets on path to IND 3 Conducted by Merck & Co 4 Conducted by Regeneron Pharmaceuticals



### Pharmaceuticals – Pipeline Details Phase III<sup>1</sup> (as of Dec 13, 2022)

| Therapeutic Area           | Candidate medication                            | Modality | Compound<br>Origin | Indication   | Ct.gov Identifier  | Estimated/actual primary completion      | Status   |
|----------------------------|---|----------|--------------------|--|--|--|--|
| Oncology                   | Copanlisib (PI3K Inhibitor)                     | å.       | Bayer              | Non-Hodgkin Lymphoma (CHRONOS-4)                           | NCT02626455  | Q1 2023                                  | Study ongoing                                    |
|                            | Darolutamide (AR Inhibitor)                     | *.       | Orion              | Prostate Cancer (mHSPC) (ARANOTE)                          | NCT04736199  | Q1 2024                                  | Study ongoing                                    |
|                            |   |          |                    | Adjuvant Prostate Cancer (DASL-HiCaP)                      | NCT04136353  | Q1 2028                                  | Study ongoing                                    |
| Cardiovascular<br>Diseases | Finerenone (MR Antagonist)                      | 羔        | Bayer              | Heart Failure (HFmr/pEF) (FINEARTS-HF)                     | NCT04435626  | Q3 2024                                  | Study ongoing                                    |
| Diseases                   |   |          |                    | Non-diabetic CKD (FIND-CKD)                                | NCT05047263  | Q1 2026                                  | Study ongoing                                    |
|                            | Vericiguat (sGC Stimulator)                     | *        | Bayer              | Heart Failure (HFrEF) (VICTOR³)                            | NCT05093933  | Q1 2025                                  | Study ongoing                                    |
|                            | Asundexian (FXIa Inhibitor)                     | *        | Bayer              | Stroke Prevention in Atrial Fibrillation (OCEANIC-AF)      | NCT05643573  | Q3 2025                                  | Study ongoing                                    |
| Women's Health             | Elinzanetant<br>(Neurokinin-1,3 Rec Antagonist) | <b>.</b> | KaNDy              | Vasomotor Symptoms<br>(OASIS-1, OASIS-2, OASIS-3, OASIS-4) | NCT05042362<br>NCT05099159<br>NCT05030584<br>NCT05587296 | Q2 2023<br>Q2 2023<br>Q1 2023<br>Q1 2024 | Studies ongoing                                  |
| Others                     | Aflibercept 8MG                                 | by       | Regeneron          | Diabetic Macular Edema (DME) (PHOTON4)                     | NCT04429503  | Q2 2022                                  | Primary completion date achieved. Data presented |
|                            |   |          |                    | Neovasc. Age-rel. Macular Degen. (nAMD) (PULSAR)           | NCT04423718  | Q3 2022                                  | at AAO in Oct. 2022                              |

<sup>1</sup> Bayer and partner sponsored + 3rd party label enabling studies with first patient first visit 3 Conducted by Merck & Co 4 Conducted by Regeneron Pharmaceuticals





















## Pharmaceuticals – Pipeline Details Phase II<sup>1</sup> (as of Dec 13, 2022)

| Therapeutic Area           | Candidate medication   | Modality    | Compound<br>Origin | Indication   | Ct.gov Identifier          | Estimated/actual primary completion | Status  |
|----------------------------|--|-------------|--------------------|--|----------------------------|-------------------------------------|---|
| Oncology                   | Regorafenib (combi Nivolumab) (BAY 734506)                           | هُمْ.       | Bayer              | Solid tumors (recurrent or metastatic)   | NCT04704154                | Q1 2023                             | Study ongoing   |
| Cardiovascular<br>Diseases | Asundexian (FXIa Inhibitor)<br>(BAY 2433334)                         | *.          | Bayer              | 2º Stroke Prevention (PACIFIC-STROKE)  Major Adverse Cardiac Events Prevention (PACIFIC-AMI) | NCT04304508<br>NCT04304534 | Q1 2022<br>Q1 2022                  | Studies completed; data presented at ESC in Aug. 2022 |
|                            | Runcaciguat (sGC Activator)<br>(BAY 1101042)                         | <b>.</b> *. | Bayer              | Chronic Kidney Disease (CKD) (CONCORD)   | NCT04507061                | Q1 2022                             | Study completed; detailed evaluation ongoing          |
| Others                     | BDKRB1 Receptor Antagonist (BAY 2395840)                             | ؞؞ؙ؞        | Bayer/Evotec       | Neuropathic Pain (BRADiNP)   | NCT05219812                | Q4 2022                             | Study ongoing   |
|                            | Gadoquatrane (High Relaxivity<br>Contrast Agent, HRCA) (BAY 1747846) | Ö           | Bayer              | Magnetic Resonance Imaging (HRCA-PAT)  | NCT04307186                | Q4 2022                             | Study ongoing   |
|                            | Runcaciguat (sGC Activator)<br>(BAY 1101042)                         | <u>ئ</u>    | Bayer              | Non-prolif. Diabetic Retinopathy (NPDR) (NEON-NPDR)  | NCT04722991                | Q4 2023                             | Study ongoing   |
|                            | Adrenomedullin Pegol (PEG-ADM) (BAY 1097761)                         | by          | Bayer              | Acute Resp. Distress Syn. (ARDS) (SEAL)  | NCT04417036                | Q4 2024                             | Study ongoing   |

1 Bayer and partner sponsored + 3rd party label enabling studies with first patient first visit





















## Pharmaceuticals – Pipeline Details Phase I<sup>1</sup> (as of Dec 13, 2022)

| Therapeutic<br>Area        | Candidate medication  | Modality | Compound<br>Origin       | Indication  | Ct.gov Identifier                         | Estimated/actual primary completion | Status  |
|----------------------------|---|----------|--------------------------|---|---|-------------------------------------|---|
|                            | Elimusertib (ATR Inhibitor) (BAY 1895344)                               | <b>.</b> | Bayer                    | Advanced solid tumors, Non-Hodgkin's Lymphoma, Mantle Cell Lymphoma         | NCT03188965<br>NCT04095273<br>NCT04267939 | Q4 2022 / Q1 2025                   | Studies ongoing   |
|                            | AhR Inhibitor (BAY 2416964)   | ,Å.      | Bayer/DKFZ               | Advanced solid tumors   | NCT04069026<br>NCT04999202                | Q1 2025 / Q2 2025                   | Studies ongoing   |
| Oncology                   | mEGFR Inhibitor (BAY 2927088)   | مگره     | Bayer/Broad<br>Institute | Advanced Non-small Cell Lung Cancer with EGFR Mutation and/or HER2 Mutation | NCT05099172                               | Q4 2025                             | Study ongoing   |
|                            | <sup>227</sup> <b>Th-Trastuzumab corixetan</b> (HER2 TTC) (BAY 2701439) |          | Bayer                    | Cancers with HER2 Expression  | NCT04147819                               | Q3 2026                             | Study ongoing   |
|                            | DGKzeta Inhibitor (BAY 2965501)   | *        | Bayer/DKFZ               | Cancer  | NCT05614102                               | Q3 2026                             | Study ongoing   |
|                            | CCR8 Ab (BAY 3375968)   |          | Bayer                    | Advanced solid tumors   | NCT05537740                               | Q4 2026                             | Study ongoing   |
|                            | Congestive Heart Failure Gene Therapy (NAN-101)                         | ğ        | AskBio                   | Congestive Heart Failure  | NCT04179643                               |                                     | Phase I study and planning activities for subsequent phases ongoing |
| Cardiovascular<br>Diseases | sGC Activator (BAY 3283142)   | مگی      | Bayer                    | Chronic Kidney Disease (CKD)  | NCT05491642                               | Q1 2023                             | Study ongoing   |
|                            | Anti-a2AP (BAY 3018250)   |          | Bayer                    | Acute Ischemic Stroke; Pulmonary Embolism                                   |   | Q2 2023                             | Study planned   |
| Women's<br>Health          | P2X4 Antagonist (BAY 2328065)   | , Å,     | Bayer                    | Endometriosis   | NCT03427788<br>NCT04027192<br>NCT04851483 | Q4 2018 / Q3 2020 /<br>Q4 2021      | Phase II decision expected in HY1 2023                              |
|                            | BDKRB1 Receptor Antagonist (BAY 2395840)                                | •        | Bayer/Evotec             | Endometriosis   | NCT05517746                               | Q4 2020                             | Phase II decision expected in HY1 2023                              |
|                            | Zabedosertib (IRAK4 Inhibitor) (BAY 1834845)                            | مگر      | Bayer                    | Atopic Dermatitis   |   | Q4 2017 / Q3 2020                   | Studies completed. Phase II decision taken for Atopic Dermatitis    |
|                            | sGC Activator (BAY 1211163)   | •        | Bayer                    | Acute Respiratory Distress Syndrome   | NCT04609943                               | Q2 2023                             | Study ongoing   |
|                            | Parkinson's Disease Cell Therapy (BRT-DA-01)                            |          | BlueRock                 | Parkinson's Disease   | NCT04802733                               | Q2 2023                             | Study ongoing   |
| Other                      | Parkinson's Disease Gene Therapy (AAV2-GDNF-PD)                         | ğ        | AskBio                   | Parkinson's Disease   | NCT04167540                               | Q4 2023                             | Study ongoing   |
|                            | Multiple System Atrophy Gene Therapy (AAV2-GDNF-MSA)                    | ğ        | AskBio                   | Multiple System Atrophy   | NCT04680065                               | Q1 2024                             | Study recruiting  |
|                            | Pompe Disease Gene Therapy (ACTUS-101)                                  | ¥        | AskBio                   | Pompe Disease   | NCT03533673                               | Q2 2025                             | Study ongoing   |
|                            | Huntington's Disease Gene Therapy (BV-101)                              | ¥        | AskBio                   | Huntington's Disease  | NCT05541627                               | Q4 2025                             | Study recruiting  |

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





















## Pharmaceuticals – Pipeline Details Oncology<sup>1</sup> (as of Dec 13, 2022)

| Candidate medication  | Indication   | Modality | Compound Origin                            | Phase 0 <sup>2</sup> | Phase I | Phase II | Phase III | Ct.gov Identifier                         | Estimated/actual primary completion | Status          |
|---|--|----------|--|----------------------|---------|----------|-----------|---|-------------------------------------|-----------------|
| Copanlisib (PI3K Inhibitor) (BAY 806946)                                | Non-Hodgkin Lymphoma (CHRONOS-4)   | مئہ      | Bayer                                      |                      |         |          |           | NCT02626455                               | Q1 2023                             | Study ongoing   |
| Darolutamide (AR Inhibitor) (BAY 1841788)                               | Prostate Cancer (mHSPC) (ARANOTE)  | مگرہ     | Orion                                      |                      |         |          |           | NCT04736199                               | Q1 2024                             | Study ongoing   |
|   | Adjuvant Prostate Cancer (DASL-HiCaP)  |          |  |                      |         |          |           | NCT04136353                               | Q1 2028                             | Study ongoing   |
| Regorafenib (combi Nivolumab) (BAY 734506)                              | Solid tumors (recurrent or metastatic)   | ؞؞ؙ؞     | Bayer                                      |                      |         |          |           | NCT04704154                               | Q1 2023                             | Study ongoing   |
| Elimusertib (ATR Inhibitor) (BAY 1895344)                               | Advanced solid tumors, Non-Hodgkin's<br>Lymphoma, Mantle Cell Lymphoma         | å,       | Bayer                                      |                      |         |          |           | NCT03188965<br>NCT04095273<br>NCT04267939 | Q4 2022<br>Q1 202<br>Q1 2025        | Studies ongoing |
| AhR Inhibitor (BAY 2416964)   | Advanced solid tumors  | مئی      | Bayer/DKFZ                                 |                      |         |          |           | NCT04069026<br>NCT04999202                | Q1 2025<br>Q2 2025                  | Studies ongoing |
| mEGFR Inhibitor (BAY 2927088)   | Advanced Non-small Cell Lung Cancer with<br>EGFR Mutation and/or HER2 Mutation | ؞ؠؙ؞     | Bayer/Broad<br>Institute                   |                      |         |          |           | NCT05099172                               | Q4 2025                             | Study ongoing   |
| <sup>227</sup> <b>Th-Trastuzumab corixetan</b> (HER2 TTC) (BAY 2701439) | Cancers with HER2 Expression   |          | Bayer                                      |                      |         |          |           | NCT04147819                               | Q3 2026                             | Study ongoing   |
| DGKzeta Inhibitor (BAY 2965501)   | Cancer   | *        | Bayer/DKFZ                                 |                      |         |          |           | NCT05614102                               | Q3 2026                             | Study ongoing   |
| CCR8 Ab (BAY 3375968)   | Advanced solid tumors  | Y        | Bayer                                      |                      |         |          |           | NCT05537740                               | Q4 2026                             | Study ongoing   |
| DGKalpha Inh (BAY 2862789)  | Cancer   | مد       | Bayer/DKFZ                                 |                      |         |          |           |   |                                     |                 |
| PSMA TAC (BAY 3546828)  | Advanced Prostate Cancer   |          | Lantheus (prev. Progenics)                 |                      |         |          |           |   |                                     |                 |
| PSMA SMOL TAC (BAY 3563254)   | Advanced Prostate Cancer   |          | Noria<br>Therapeutics/PSMA<br>Therapeutics |                      |         |          |           |   |                                     |                 |
| VVD NRF2 Inh (BAY 3605349)  | Cancer   | ٠        | Vividion                                   |                      |         |          |           |   |                                     |                 |
| VVD STAT3 Inh (BAY 3630914)   | Cancer   | •        | Vividion                                   |                      |         |          |           |   |                                     |                 |

<sup>1</sup> Bayer and partner sponsored + 3rd party label enabling studies with first patient first visit 2 Pre-clinical selected assets on path to IND























## Pharmaceuticals – Pipeline Details Cardiov. Diseases<sup>1</sup> (as of Dec 13, 2022)

| Candidate medication                                  | Indication  | Modality | Compound<br>Origin | Phase 0 <sup>2</sup> | Phase I | Phase II | Phase III | Ct.gov Identifier | Estimated/actual primary completion | Status  |
|---|---|----------|--------------------|----------------------|---------|----------|-----------|-------------------|-------------------------------------|---|
| Finerenone (MR Antagonist)                            | Heart Failure (HFmr/pEF) (FINEARTS-HF)                | ؞ڲؙ؞     | Bayer              |                      |         |          |           | NCT04435626       | Q3 2024                             | Study ongoing   |
| (BAY 948862)  | Non-diabetic CKD (FIND-CKD                            |          |                    |                      |         |          |           | NCT05047263       | Q1 2026                             | Study ongoing   |
| Vericiguat (sGC Stimulator) (BAY1021189)              | Heart Failure (HFrEF) (VICTOR <sup>3</sup> )          | *        | Bayer              |                      |         |          |           | NCT05093933       | Q1 2025                             | Study ongoing   |
| Asundexian (FXIa Inhibitor) (BAY 2433334)             | Stroke Prevention in Atrial Fibrillation (OCEANIC-AF) | o*o      | Bayer              |                      |         |          |           | NCT05643573       | Q3 2025                             | Study ongoing   |
|   | 2º Stroke Prevention<br>(OCEANIC-STROKE)              |          |                    |                      |         |          |           | NCT04304508       | Q1 2022                             | Phase II studies completed; data                                    |
|   | Major Adverse Cardiac Events Prevention (PACIFIC-AMI) | <b>a</b> |                    |                      |         |          |           | NCT04304534       | Q1 2022                             | presented at ESC in<br>Aug. 2022                                    |
| Runcaciguat (sGC Activator)<br>(BAY 1101042)          | Chronic Kidney Disease<br>(CKD) (CONCORD)             | •♣₀      | Bayer              |                      |         |          |           | NCT04507061       | Q1 2022                             | Study completed;<br>detailed evaluation<br>ongoing                  |
| Congestive Heart Failure<br>Gene Therapy<br>(NAN-101) | Congestive Heart Failure                              | <b>§</b> | AskBio             |                      |         |          |           | NCT04179643       |                                     | Phase I study and planning activities for subsequent phases ongoing |
| sGC Activator<br>(BAY 3283142)                        | Chronic Kidney Disease (CKD)                          | o.A.     | Bayer              |                      |         |          |           | NCT05491642       | Q1 2023                             | Study ongoing   |
| Anti-a2AP<br>(BAY 3018250)                            | Acute Ischemic Stroke; Pulmonary Embolism             |          | Bayer              |                      |         |          |           |                   | Q2 2023                             | Study planned   |
| SEMA 3 <sup>a</sup><br>(BAY 3401016)                  | Acute Kidney Injury, Alport Syndrome                  | 7        | Bayer/Evote<br>c   |                      |         |          |           |                   |                                     |   |

<sup>1</sup> Bayer and partner sponsored + 3rd party label enabling studies with first patient first vist 2 Pre-clinical selected assets on path to IND 3 Conducted by Merck & Co





















### Pharmaceuticals – Pipeline Details Women's Health<sup>1</sup> (as of Dec 13, 2022)

| Candidate medication   | Indication   | Modality   | Compound<br>Origin | Phase 0 <sup>2</sup> | Phase I | Phase II | Phase III | Ct.gov Identifier  | Estimated/actual primary completion      | Status   |
|--|--|------------|--------------------|----------------------|---------|----------|-----------|--|--|--|
| Elinzanetant<br>(Neurokinin-1,3 Rec Antagonist)<br>(BAY 3427080) | Vasomotor Symptoms<br>(OASIS-1, OASIS-2, OASIS-3, OASIS-4) | *.         | KaNDy              |                      |         |          |           | NCT05042362<br>NCT05099159<br>NCT05030584<br>NCT05587296 | Q2 2023<br>Q2 2023<br>Q1 2023<br>Q1 2024 | Studies ongoing  |
| P2X4 Antagonist<br>(BAY 2328065)                                 | Endometriosis  | *.         | Bayer              |                      |         |          |           | NCT03427788<br>NCT04027192<br>NCT04851483                | Q4 2018<br>Q3 2020<br>Q4 2021            | Studies completed;<br>Phase II decision<br>expected in HY1<br>2023 |
| BDKRB1 Receptor Antagonist<br>(BAY 2395840)                      | Endometriosis  | <b>å</b> . | Bayer/Evotec       |                      |         |          |           | NCT05517746  | Q4 2020                                  | Phase II decision<br>expected in HY1<br>2023                       |

1 Bayer and partner sponsored + 3rd party label enabling studies with first patient first visit 2 Pre-clinical selected assets on path to IND





















## Pharmaceuticals – Pipeline Details Other Ther. Areas<sup>1</sup> (as of Dec 13, 2022)

| Candidate medication  | Indication  | Modality | Compound Origin | Phase 0 <sup>2</sup> | Phase I | Phase II | Phase III | Ct.gov Identifier | Estimated/actual primary completion | Status   |
|---|---|----------|-----------------|----------------------|---------|----------|-----------|-------------------|-------------------------------------|--|
| Aflibercept 8MG (BAY 865321)                                      | Diabetic Macular Edema<br>(DME) (PHOTON⁴)           | مم       | Regeneron       |                      |         |          |           | NCT04429503       | Q2 2022                             | Primary completion date achieved. Data presented                 |
|   | Neovasc. Age-rel. Macular Degen. (nAMD) (PULSAR)    |          |                 |                      |         |          |           | NCT04423718       | Q3 2022                             | at AAO in Oct. 2022  |
| BDKRB1 Receptor Antagonist<br>(BAY 2395840)                       | Neuropathic Pain<br>(BRADiNP)                       | *        | Bayer/Evotec    |                      |         |          |           | NCT05219812       | Q4 2022                             | Study ongoing  |
| Gadoquatrane (High Relaxivity Contrast Agent (HRCA) (BAY 1747846) | Magnetic Resonance Imaging (HRCA-PAT)               | Ö        | Bayer           |                      |         |          |           | NCT04307186       | Q4 2022                             | Study ongoing  |
| Runcaciguat<br>(sGC Activator) (BAY 1101042)                      | Non-prolif. Diabetic Retinopathy (NPDR) (NEON-NPDR) | •        | Bayer           |                      |         |          |           | NCT04722991       | Q4 2023                             | Study ongoing  |
| Adrenomedullin Pegol<br>(PEG-ADM) (BAY 1097761)                   | Acute Resp. Distress Syn. (ARDS) (SEAL)             | مم       | Bayer           |                      |         |          |           | NCT04417036       | Q4 2024                             | Study ongoing  |
| Zabedosertib<br>(IRAK4 Inhibitor) (BAY 1834845)                   | Atopic Dermatitis                                   | *        | Bayer           |                      |         |          |           |                   |                                     | Studies completed. Phase II decision taken for Atopic Dermatitis |
| sGC Activator<br>(BAY 1211163)                                    | Acute Respiratory Distress Syndrome                 | <b>.</b> | Bayer           |                      |         |          |           | NCT04609943       | Q2 2023                             | Study ongoing  |
| Parkinson's Disease Cell Therapy (BRT-DA-01)                      | Parkinson's Disease                                 | <b>1</b> | BlueRock        |                      |         |          |           | NCT04802733       | Q2 2023                             | Study ongoing  |
| Parkinson's Disease Gene Therapy (AAV2-GDNF-PD)                   | Parkinson's Disease                                 | ğ        | AskBio          |                      |         |          |           | NCT04167540       | Q4 2023                             | Study ongoing  |
| Multiple System Atrophy Gene Therapy (AAV2-GDNF-MSA)              | Multiple System Atrophy                             | ğ        | AskBio          |                      |         |          |           | NCT04680065       | Q1 2024                             | Study recruiting   |
| Pompe Disease Gene Therapy (ACTUS-101)                            | Pompe Disease                                       | ğ        | AskBio          |                      |         |          |           | NCT03533673       | Q2 2025                             | Study ongoing  |
| Huntington's Disease Gene Therapy (BV-101)                        | Huntington's Disease                                | ğ        | AskBio          |                      |         |          |           | NCT05541627       | Q4 2025                             | Study recruiting   |
| LGMD2i Gene Therapy<br>(LION-101)                                 | Limb-Girdle Muscular Dystrophy 2i                   | ğ        | AskBio          |                      |         |          |           |                   |                                     |  |
| Next Generation Liver MRI<br>(BAY 3393081)                        | Contrast Media                                      | Ö        | Bayer           |                      |         |          |           |                   |                                     |  |

<sup>1</sup> Bayer and partner sponsored + 3rd party label enabling studies with first patient first visit 2 Pre-clinical selected assets on path to IND 4 Conducted by Regeneron Pharmaceuticals

















