



# Pharmaceuticals —

## Pipeline Overview

February 15, 2023 –  
Investor Relations



# Pharmaceuticals – Pipeline Overview<sup>1</sup> (as of Feb 15, 2023)

Phase 0 <sup>2</sup>	Phase I	Phase II	Phase III
<b>DGKalpha Inh</b> (BAY 2862789)	<b>Elimusertib</b> (ATR Inhibitor) (BAY 1895344)	<b>Regorafenib</b> (combi Nivolumab) (BAY 734506) // Solid tumors (recurrent or metastatic)	<b>Copanlisib</b> (PI3K Inhibitor) // Non-Hodgkin Lymphoma (CHRONOS-4)
<b>PSMA TAC</b> (BAY 3546828)	<b>AhR Inhibitor</b> (BAY 2416964)	<b>Asundexian (FXIa Inhibitor)</b> (BAY 2433334) // Major Adverse Cardiac Events Prevention (PACIFIC-AMI)	<b>Darolutamide</b> (AR Inhibitor) // Prostate Cancer (mHSPC) (ARANOTE) // Adjuvant Prostate Cancer (DASL-HiCaP)
<b>PSMA SMOL TAC</b> (BAY 3563254)	<b>mEGFR Inhibitor</b> (BAY 2927088)	<b>Runcaciguat</b> (sGC Activator) (BAY 1101042) // Chronic Kidney Disease (CKD) (CONCORD)	<b>Finerenone</b> (MR Antagonist) // Heart Failure (HFmr/pEF) (FINEARTS-HF) // Non-diabetic CKD (FIND-CKD)
<b>VVD NRF2 Inh</b> (BAY 3605349)	<b>DGKzeta Inhibitor</b> (BAY 2965501)	<b>BDKRB1 Receptor Antagonist</b> (BAY 2395840) // Non-prolif. Diabetic Retinopathy (NPDR) (NEON-NPDR)	<b>Vericiguat</b> (sGC Stimulator) // Heart Failure (HFREF) (VICTOR <sup>3</sup> )
<b>VVD STAT3 Inh</b> (BAY 3630914)	<b>CCR8 Ab</b> (BAY 3375968)	<b>Gadoquatrane</b> (High Relaxivity Contrast Agent) (BAY 1747846) // Magnetic Resonance Imaging (HRCA-PAT)	<b>Asundexian</b> (FXIa Inhibitor) // Stroke Prevention in Atrial Fibrillation (OCEANIC-AF) // 2 <sup>o</sup> Stroke Prevention (OCEANIC-STROKE)
<b>SEMA 3a</b> (BAY 3401016)	<b>Congestive Heart Failure Gene Therapy</b> (AB-1002 formerly NAN-101)	<b>Adrenomedullin Pegol</b> (PEG-ADM) (BAY 1097761) // Acute Resp. Distress Syn. (ARDS) (SEAL)	<b>Elinzanetant</b> (Neurokinin-1,3 Rec Antagonist) // Vasomotor Symptoms (OASIS)
<b>LGMD2i Gene Therapy</b> (LION-101)	<b>sGC Activator</b> (BAY 3283142)	<b>Zabedoseritib</b> (IRAK4 Inh.) (BAY 1834845) // Atopic Dermatitis (DAMASK)	
<b>Next Generation Liver MRI</b> (BAY 3393081)	<b>Anti-a2AP</b> (BAY 3018250)		
	<b>P2X4 Antagonist</b> (BAY 2328065)		
	<b>BDKRB1 Receptor Antagonist</b> (BAY 2395840)		
	<b>sGC Activator</b> (BAY 1211163)		
	<b>Bemdaneprocel</b> (Parkinson's Disease Cell Therapy) (BRT-DA01)		
	<b>Parkinson's Disease Gene Therapy</b> (AB-1005 formerly AAV2-GDNF-PD)		
	<b>Multiple System Atrophy Gene Therapy</b> (AB-1005 formerly AAV2-GDNF-MSA)		
	<b>Pompe Disease Gene Therapy</b> (ACTUS-101)		
	<b>Huntington's Disease Gene Therapy</b> (BV-101)		
	<b>GPR84 Antagonist</b> (BAY 3178275)		

Submissions
<b>Darolutamide (AR Inhibitor) / ADT with Chemotherapy</b> // EU, Japan, China: mHSPC
<b>Aflibercept 8MG</b> // EU, US <sup>4</sup> : Diabetic Macular Edema (DME) // EU, US <sup>2</sup> : Neovasc. Age-rel. Macular Degen. (nAMD)

- Oncology
- Cardiovascular Diseases
- Women's Health
- Others

- New molecular entity
- Life cycle management

- 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 <sup>2</sup> Pre-clinical selected assets on path to IND <sup>3</sup> Conducted by Merck & Co <sup>4</sup> US submission made by Regeneron



# Pharmaceuticals – Pipeline Details Phase III<sup>1</sup> (as of Feb 15, 2023)

Therapeutic Area	Candidate medication	Modality	Compound Origin	Indication	Ct.gov Identifier	Estimated/actual primary completion	Status
Oncology	Copanlisib (PI3K Inhibitor)		Bayer	Non-Hodgkin Lymphoma ( <i>CHRONOS-4</i> )	<a href="#">NCT02626455</a>	Q1 2023	Study ongoing
	Darolutamide (AR Inhibitor)		Orion	Prostate Cancer (mHSPC) ( <i>ARANOTE</i> )	<a href="#">NCT04736199</a>	Q1 2024	Study ongoing
				Adjuvant Prostate Cancer ( <i>DASL-HiCaP</i> )	<a href="#">NCT04136353</a>	Q1 2028	Study ongoing
Cardiovascular Diseases	Finerenone (MR Antagonist)		Bayer	Heart Failure (HFmr/pEF) ( <i>FINEARTS-HF</i> )	<a href="#">NCT04435626</a>	Q3 2024	Study ongoing
				Non-diabetic CKD ( <i>FIND-CKD</i> )	<a href="#">NCT05047263</a>	Q1 2026	Study ongoing
	Vericiguat (sGC Stimulator)		Bayer	Heart Failure (HFrEF) ( <i>VICTOR<sup>3</sup></i> )	<a href="#">NCT05093933</a>	Q1 2025	Study ongoing
	Asundexian (FXIa Inhibitor)		Bayer	Stroke Prevention in Atrial Fibrillation ( <i>OCEANIC-AF</i> )	<a href="#">NCT05643573</a>	Q3 2025	Study ongoing
2° Stroke Prevention ( <i>OCEANIC-STROKE</i> )				<a href="#">NCT05686070</a>	Q4 2025	Study ongoing	
Women's Health	Elinzanetant (Neurokinin-1,3 Rec Antagonist)		KaNdy	Vasomotor Symptoms ( <i>OASIS-1, OASIS-2, OASIS-3, OASIS-4</i> )	<a href="#">NCT05042362</a> <a href="#">NCT05099159</a> <a href="#">NCT05030584</a> <a href="#">NCT05587296</a>	Q3 2023 Q2 2023 Q1 2023 Q1 2024	Studies ongoing

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

Antibody Biologic Cell Therapy Contrast Agent Gene Therapy Radiotherapy Small Molecule



# Pharmaceuticals – Pipeline Details Phase II<sup>1</sup> (as of Feb 15, 2023)

Therapeutic Area	Candidate medication	Modality	Compound Origin	Indication	Ct.gov Identifier	Estimated/actual primary completion	Status
Oncology	<b>Regorafenib</b> (combi Nivolumab) (BAY 734506)		Bayer	<b>Solid tumors</b> (recurrent or metastatic)	<a href="#">NCT04704154</a>	Q1 2023	Study ongoing
Cardiovascular Diseases	<b>Asundexian</b> (FXIa Inhibitor) (BAY 2433334)		Bayer	<b>Major Adverse Cardiac Events Prevention</b> (PACIFIC-AMI)	<a href="#">NCT04304534</a>	Q1 2022	Study completed; data presented at ESC in Aug. 2022
	<b>Runcaciguat</b> (sGC Activator) (BAY 1101042)		Bayer	<b>Chronic Kidney Disease (CKD)</b> (CONCORD)	<a href="#">NCT04507061</a>	Q1 2022	Study completed; detailed evaluation ongoing
Others	<b>BDKRB1 Receptor Antagonist</b> (BAY 2395840)		Bayer/Evotec	<b>Neuropathic Pain</b> (BRADINP)	<a href="#">NCT05219812</a>	Q4 2022	Study completed
	<b>Gadoquatrane</b> (High Relaxivity Contrast Agent) (HRCA) (BAY 1747846)		Bayer	<b>Magnetic Resonance Imaging</b> (HRCA-PAT)	<a href="#">NCT04307186</a>	Q3 2022	Study completed
	<b>Runcaciguat</b> (sGC Activator) (BAY 1101042)		Bayer	<b>Non-prolif. Diabetic Retinopathy (NPDR)</b> (NEON-NPDR)	<a href="#">NCT04722991</a>	Q4 2023	Study ongoing
	<b>Adrenomedullin Pegol</b> (PEG-ADM) (BAY 1097761)		Bayer	<b>Acute Resp. Distress Syn. (ARDS)</b> (SEAL)	<a href="#">NCT04417036</a>	Q4 2024	Study ongoing
	<b>Zabedoseritib</b> (IRAK4 Inhibitor) (BAY 1834845)		Bayer	<b>Atopic Dermatitis</b> (DAMASK)	<a href="#">NCT05656911</a>	Q2 2023	Study ongoing

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

Antibody
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 Small Molecule



# Pharmaceuticals – Pipeline Details Phase I<sup>1</sup> (as of Feb 15, 2023)

Therapeutic Area	Candidate medication	Modality	Compound Origin	Indication	Ct.gov Identifier	Estimated/actual primary completion	Status
Oncology	Elimusertib (ATR Inhibitor) (BAY 1895344)		Bayer	Advanced solid tumors, Non-Hodgkin's Lymphoma, Mantle Cell Lymphoma	<a href="#">NCT03188965</a> <a href="#">NCT04095273</a> <a href="#">NCT04267939</a>	Q4 2022 Q1 2023 Q1 2025	Studies ongoing
	AhR Inhibitor (BAY 2416964)		Bayer/DKFZ	Advanced solid tumors	<a href="#">NCT04069026</a> <a href="#">NCT04999202</a>	Q1 2025 Q2 2025	Studies ongoing
	mEGFR Inhibitor (BAY 2927088)		Bayer/Broad Institute	Advanced Non-small Cell Lung Cancer with EGFR Mutation and/or HER2 Mutation	<a href="#">NCT05099172</a>	Q4 2025	Study ongoing
	DGKzeta Inhibitor (BAY 2965501)		Bayer/DKFZ	Advanced solid tumors	<a href="#">NCT05614102</a>	Q3 2026	Study ongoing
	CCR8 Ab (BAY 3375968)		Bayer	Advanced solid tumors	<a href="#">NCT05537740</a>	Q4 2026	Study ongoing
Cardiovascular Diseases	Congestive Heart Failure Gene Therapy (AB-1002 formerly NAN-101)		AskBio	Congestive Heart Failure	<a href="#">NCT04179643</a>		Phase I study and planning activities for subsequent phases ongoing
	sGC Activator (BAY 3283142)		Bayer	Chronic Kidney Disease (CKD)	<a href="#">NCT05491642</a>	Q1 2023	Study ongoing
	Anti-a2AP (BAY 3018250)		Bayer	Acute Ischemic Stroke; Pulmonary Embolism		Q2 2023	Study planned
Women's Health	P2X4 Antagonist (BAY 2328065)		Bayer	Endometriosis	<a href="#">NCT03427788</a> <a href="#">NCT04027192</a>	Q4 2018 Q3 2020	Phase II decision expected in HY1 2023
	BDKRB1 Receptor Antagonist (BAY 2395840)		Bayer/Evotec	Endometriosis	<a href="#">NCT05517746</a>	Q4 2020	Phase II decision expected in HY1 2023
Others	sGC Activator (BAY 1211163)		Bayer	Acute Respiratory Distress Syndrome	<a href="#">NCT04609943</a>	Q2 2023	Study ongoing
	Bemdaneprocel (Parkinson's Disease Cell Therapy) (BRT-DA01)		BlueRock	Parkinson's Disease	<a href="#">NCT04802733</a>	Q2 2023	Study ongoing
	Parkinson's Disease Gene Therapy (AB-1005 formerly AAV2-GDNF-PD)		AskBio	Parkinson's Disease	<a href="#">NCT04167540</a>	Q4 2023	Study ongoing
	Multiple System Atrophy Gene Therapy (AB-1005 formerly AAV2-GDNF-MSA)		AskBio	Multiple System Atrophy	<a href="#">NCT04680065</a>	Q1 2024	Study ongoing
	Pompe Disease Gene Therapy (ACTUS-101)		AskBio	Pompe Disease	<a href="#">NCT03533673</a>	Q2 2025	Study ongoing
	Huntington's Disease Gene Therapy (BV-101)		AskBio	Huntington's Disease	<a href="#">NCT05541627</a>	Q4 2025	Study ongoing
	GPR84 Antagonist (BAY 3178275)		Bayer	Diabetic Neuropathic Pain	n/a	Q2/2024	Study ongoing

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

Antibody
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# Pharmaceuticals – Pipeline Details Oncology<sup>1</sup> (as of Feb 15, 2023)

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)	Non-Hodgkin Lymphoma (CHRONOS-4)		Bayer					<a href="#">NCT02626455</a>	Q1 2023	Study ongoing
Darolutamide (AR Inhibitor)	Prostate Cancer (mHSPC) (ARANOTE)		Orion					<a href="#">NCT04736199</a>	Q1 2024	Study ongoing
	Adjuvant Prostate Cancer (DASL-HiCaP)							<a href="#">NCT04136353</a>	Q1 2028	Study ongoing
Regorafenib (combi Nivolumab) (BAY 734506)	Solid tumors (recurrent or metastatic)		Bayer					<a href="#">NCT04704154</a>	Q1 2023	Study ongoing
Elimusertib (ATR Inhibitor) (BAY 1895344)	Advanced solid tumors, Non-Hodgkin's Lymphoma, Mantle Cell Lymphoma		Bayer					<a href="#">NCT03188965</a> <a href="#">NCT04095273</a> <a href="#">NCT04267939</a>	Q4 2022 Q1 2023 Q1 2025	Studies ongoing
AhR Inhibitor (BAY 2416964)	Advanced solid tumors		Bayer/DKFZ					<a href="#">NCT04069026</a> <a href="#">NCT04999202</a>	Q1 2025 Q2 2025	Studies ongoing
mEGFR Inhibitor (BAY 2927088)	Advanced Non-small Cell Lung Cancer with EGFR Mutation and/or HER2 Mutation		Bayer/Broad Institute					<a href="#">NCT05099172</a>	Q4 2025	Study ongoing
DGKzeta Inhibitor (BAY 2965501)	Advanced solid tumors		Bayer/DKFZ					<a href="#">NCT05614102</a>	Q3 2026	Study ongoing
CCR8 Ab (BAY 3375968)	Advanced solid tumors		Bayer					<a href="#">NCT05537740</a>	Q4 2026	Study ongoing
DGKalpha Inh (BAY 2862789)	Cancer		Bayer/DKFZ							
PSMA TAC (BAY 3546828)	Advanced Prostate Cancer		Lantheus (prev. Progenics)							
PSMA SMOL TAC (BAY 3563254)	Advanced Prostate Cancer		Noria Therapeutics/PSMA Therapeutics							
VVD NRF2 Inh (BAY 3605349)	Cancer		Vividion							
VVD STAT3 Inh (BAY 3630914)	Cancer		Vividion							


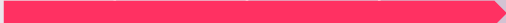




<sup>1</sup> Bayer and partner sponsored + 3rd party label enabling studies with first patient first visit <sup>2</sup> Pre-clinical selected assets on path to IND

Antibody 
 Biologic 
 Cell Therapy 
 Contrast Agent 
 Gene Therapy 
 Radiotherapy 
 Small Molecule





# Pharmaceuticals – Pipeline Details Women’s Health<sup>1</sup> (as of Feb 15, 2023)

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
<b>Elinzanetant</b> (Neurokinin-1,3 Rec Antagonist)	<b>Vasomotor Symptoms</b> (OASIS-1, OASIS-2, OASIS-3, OASIS-4)		KaNdy					<a href="#">NCT05042362</a> <a href="#">NCT05099159</a> <a href="#">NCT05030584</a> <a href="#">NCT05587296</a>	Q3 2023 Q2 2023 Q1 2023 Q1 2024	Studies ongoing
<b>P2X4 Antagonist</b> (BAY 2328065)	<b>Endometriosis</b>		Bayer					<a href="#">NCT03427788</a> <a href="#">NCT04027192</a>	Q4 2018 Q3 2020	Phase II decision expected in HY1 2023
<b>BDKRB1 Receptor Antagonist</b> (BAY 2395840)	<b>Endometriosis</b>		Bayer/Evotec					<a href="#">NCT05517746</a>	Q4 2020	Phase II decision expected in HY1 2023

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

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# Pharmaceuticals – Pipeline Details Other Ther. Areas<sup>1</sup> (as of Feb 15, 2023)

Candidate medication NCT	Indication	Modality	Compound Origin	Phase 0 <sup>2</sup>	Phase I	Phase II	Phase III	Ct.gov Identifier	Estimated/actual primary completion	Status
<b>BDKRB1 Receptor Antagonist</b> (BAY 2395840)	<b>Neuropathic Pain</b> (BRADiNP)		Bayer/Evotec					<a href="#">NCT05219812</a>	Q4 2022	Study completed
<b>Gadoquatrane</b> (High Relaxivity Contrast Agent (HRCA) (BAY 1747846)	<b>Magnetic Resonance Imaging</b> (HRCA-PAT)		Bayer					<a href="#">NCT04307186</a>	Q3 2022	Study completed
<b>Runcaciguat</b> (sGC Activator) (BAY 1101042)	<b>Non-prolif. Diabetic Retinopathy</b> (NPDR) (NEON-NPDR)		Bayer					<a href="#">NCT04722991</a>	Q4 2023	Study ongoing
<b>Adrenomedullin Pegol</b> (PEG-ADM) (BAY 1097761)	<b>Acute Resp. Distress Syn.</b> (ARDS) (SEAL)		Bayer					<a href="#">NCT04417036</a>	Q4 2024	Study ongoing
<b>Zabedoseritb</b> (IRAK4 Inhibitor) (BAY 1834845)	<b>Atopic Dermatitis (DAMASK)</b>		Bayer					<a href="#">NCT05656911</a>	Q2 2023	Study ongoing
<b>sGC Activator</b> (BAY 1211163)	<b>Acute Respiratory Distress Syndrome</b>		Bayer					<a href="#">NCT04609943</a>	Q2 2023	Study ongoing
<b>Bemdaneprocel</b> (Parkinson's Disease Cell Therapy) (BRT-DA01)	<b>Parkinson's Disease</b>		BlueRock					<a href="#">NCT04802733</a>	Q2 2023	Study ongoing
<b>Parkinson's Disease Gene Therapy</b> (AB-1005 formerly AAV2-GDNF-PD)	<b>Parkinson's Disease</b>		AskBio					<a href="#">NCT04167540</a>	Q4 2023	Study ongoing
<b>Multiple System Atrophy Gene Therapy</b> (AB-1005 formerly AAV2-GDNF-MSA)	<b>Multiple System Atrophy</b>		AskBio					<a href="#">NCT04680065</a>	Q1 2024	Study ongoing
<b>Pompe Disease Gene Therapy</b> (ACTUS-101)	<b>Pompe Disease</b>		AskBio					<a href="#">NCT03533673</a>	Q2 2025	Study ongoing
<b>Huntington's Disease Gene Therapy</b> (BV-101)	<b>Huntington's Disease</b>		AskBio					<a href="#">NCT05541627</a>	Q4 2025	Study ongoing
<b>GPR84 Antagonist</b> (BAY 3178275)	<b>Diabetic Neurpatic Pain</b>		Bayer					n/a	Q2 2024	Study ongoing
<b>LGMD2i Gene Therapy</b> (LION-101)	<b>Limb-Girdle Muscular Dystrophy 2i</b>		AskBio							
<b>Next Generation Liver MRI</b> (BAY 3393081)	<b>Contrast Media</b>		Bayer							

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

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