



# Pharmaceuticals —

## Pipeline Overview

July 31, 2023 –  
Investor Relations



# Pharmaceuticals – Pipeline Overview<sup>1</sup> (as of July 31, 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) # Prostate Cancer with Biochemical Recurrence after Curative Radiotherapy (ARASTEP)
<b>PSMA SMOL TAC</b> (BAY 3563254)  ●	<b>mEGFR Inhibitor</b> (BAY 2927088)  ●	<b>Zabedoseritib</b> (IRAK4 Inh.) (BAY 1834845)  ● # Atopic Dermatitis (DAMASK)	<b>Finerenone</b> (MR Antagonist)  ○ # Heart Failure (HFmr/pEF) (FINEARTS-HF) # Non-diabetic CKD (FIND-CKD)
<b>VVD STAT3 Inh</b> (BAY 3630914)  ●	<b>DGKzeta Inhibitor</b> (BAY 2965501)  ●	<b>Runcaciguat</b> (sGC Activator) (BAY 1101042)  ● # Non-prolif. Diabetic Retinopathy (NPDR) (NEON-NPDR)	<b>Vericiguat</b> (sGC Stimulator)  ○ # Heart Failure (HFref) (VICTOR <sup>3</sup> )
<b>Anti-coagulant</b> (BAY 3389934)  ●	<b>CCR8 Ab</b> (BAY 3375968)  ●		<b>Asundexian</b> (FXIa Inhibitor)  ● # Stroke Prevention in Atrial Fibrillation (OCEANIC-AF) # 2 <sup>o</sup> Stroke Prevention (OCEANIC-STROKE)
<b>Next Generation Liver MRI</b> (BAY 3393081)  ●	<b>VVD KEAP1 Act</b> (VVD-13307 aka NRF2 Inh, BAY 3605349)  ●		<b>Elinzanetant</b> (Neurokinin-1,3 Rec Antagonist)  ● # Vasomotor Symptoms (OASIS)
	<b>Congestive Heart Failure rAAV Gene Therapy</b> (AB-1002 aka NAN-101)  ●		<b>Aflibercept 8mg</b> (VEGF Inhibitor)  ○ # Retinal Vein Occlusion (QUASAR)
	<b>sGC Activator Oral</b> (BAY 3283142)  ●		<b>Gadoquatrane</b> (High Relaxivity Contrast Agent)  ● # Magnetic Resonance Imaging (QUANTI-CNS, QUANTI-OBR)
	<b>Anti-a2AP</b> (BAY 3018250)  ●		
	<b>sGC Activator Inhale</b> (BAY 1211163)  ●		
	<b>SEMA 3a</b> (BAY 3401016)  ●		
	<b>Bemdaneprocel</b> (Parkinson's Disease Cell Therapy) (BRT-DA01)  ●		
	<b>Parkinson's Disease rAAV Gene Therapy</b> (AB-1005 aka AAV2-GDNF-PD)  ●		
	<b>Multiple System Atrophy rAAV Gene Therapy</b> (AB-1005 aka AAV2-GDNF-MSA)  ●		
	<b>Pompe Disease rAAV Gene Therapy</b> (ACTUS-101)  ●		
	<b>Huntington's Disease rAAV Gene Therapy</b> (AB-1001 aka BV-101)  ●		
	<b>LGMD2I/R9 rAAV Gene Therapy</b> (AB-1003 aka LION-101)  ●		
	<b>GPR84 Antagonist</b> (BAY 3178275)  ●		

- Oncology
- Cardiovascular+<sup>5</sup>
- Neurology & Rare Diseases
- Immunology
- Others

- New molecular entity
- Life cycle management

Submissions
<b>Aflibercept 8mg</b> (VEGF-Inhibitor)  ○ # EU, JP, US <sup>4</sup> ; Diabetic Macular Edema (DME) # EU, JP, US <sup>4</sup> , CN; Neovasc. Age-rel. Macular Degen. (nAMD)

<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 <sup>5</sup> Including Precision Cardiovascular, Nephrology & Acute Care



# Pharmaceuticals – Pipeline Details Phase III<sup>1</sup> (as of Jul 31, 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 2024	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
				Prostate Cancer with Biochemical Recurrence after Curative Radiotherapy ( <i>ARASTEP</i> )	<a href="#">NCT05794906</a>	Q1 2027	Study ongoing
Cardiovascular <sup>+3</sup>	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>2</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	
Others	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
	Aflibercept 8mg (VEGF Inhibitor)		Regeneron	Retinal Vein Occlusion (RVO) ( <i>QUASAR</i> )	<a href="#">NCT05850520</a>	Q4 2024	Study ongoing
	Gadoquatrane (High Relaxivity Contrast Agent)		Bayer	Magnetic Resonance Imaging ( <i>QUANTI-CNS, QUANTI-OBR</i> )	<a href="#">NCT05915702</a> <a href="#">NCT05915728</a>	Q4 2024 Q4 2024	Studies ongoing

<sup>1</sup> Bayer and partner sponsored + 3rd party label enabling studies with first patient first visit <sup>2</sup> Conducted by Merck & Co  
<sup>3</sup> Including Precision Cardiovascular, Nephrology & Acute Care





# Pharmaceuticals – Pipeline Details Phase II<sup>1</sup> (as of Jul 31, 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="https://clinicaltrials.gov/ct2/show/study/NCT04704154">NCT04704154</a>	Q1 2023	Study ongoing
Cardiovascular+ <sup>2</sup>	<b>Asundexian</b> (FXIa Inhibitor) (BAY 2433334)		Bayer	<b>Major Adverse Cardiac Events Prevention</b> (PACIFIC-AMI)	<a href="https://clinicaltrials.gov/ct2/show/study/NCT04304534">NCT04304534</a>	Q1 2022	Study completed; data presented at ESC in Aug. 2022
Immunology	<b>Zabedoseritib</b> (IRAK4 Inhibitor) (BAY 1834845)		Bayer	<b>Atopic Dermatitis</b> (DAMASK)	<a href="https://clinicaltrials.gov/ct2/show/study/NCT05656911">NCT05656911</a>	Q4 2023	Study ongoing
Others	<b>Runcaciguat</b> (sGC Activator) (BAY 1101042)		Bayer	<b>Non-prolif. Diabetic Retinopathy</b> (NPDR) (NEON-NPDR)	<a href="https://clinicaltrials.gov/ct2/show/study/NCT04722991">NCT04722991</a>	Q2 2024	Study ongoing

<sup>1</sup> Bayer and partner sponsored + 3rd party label enabling studies with first patient first visit <sup>2</sup> Including Precision Cardiovascular, Nephrology & Acute Care







# Pharmaceuticals – Pipeline Details Phase I<sup>1</sup> (as of Jul 31, 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 Q4 2022 Q1 2025	Study ongoing Study completed Study ongoing
	AhR Inhibitor (BAY 2416964)		Bayer/DKFZ	Advanced solid tumors	<a href="#">NCT04069026</a> <a href="#">NCT04999202</a>	Q2 2025 Q4 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
	VVD KEAP1 Act (VVD-13307 aka NRF2 Inh, BAY 3605349)		Vividion	Advanced solid tumors	<a href="#">NCT05954312</a>	Q4 2027	Study ongoing
Cardiovascular+ <sup>2</sup>	Congestive Heart Failure rAAV Gene Therapy (AB-1002 aka NAN-101)		AskBio	Congestive Heart Failure	<a href="#">NCT04179643</a>	Q4 2023	Study ongoing
	sGC Activator (BAY 3283142)		Bayer	Chronic Kidney Disease (CKD)	<a href="#">NCT05491642</a>	Q1 2023	Study completed
	Anti-a2AP (BAY 3018250)		Bayer	Acute Ischemic Stroke; Pulmonary Embolism	n/a	Q2 2023	Study ongoing
	sGC Activator (BAY 1211163)		Bayer	Acute Respiratory Distress Syndrome	<a href="#">NCT04609943</a>	Q1 2024	Study ongoing
	SEMA 3a (BAY 3401016)		Bayer/Evotec	Alport Syndrome	n/a	Q3 2024	Study ongoing
Neurology / Rare Diseases	Bemdaneprocel (Parkinson's Disease Cell Therapy) (BRT-DA01)		BlueRock	Parkinson's Disease	<a href="#">NCT04802733</a>	Q2 2023	Study ongoing, detailed Phase I trial data will be presented at the International Congress on Parkinson's Disease and Movement Disorders in Aug 2023
	Parkinson's Disease rAAV Gene Therapy (AB-1005 aka AAV2-GDNF-PD)		AskBio	Parkinson's Disease	<a href="#">NCT04167540</a>	Q4 2023	Study ongoing
	Multiple System Atrophy rAAV Gene Therapy (AB-1005 aka AAV2-GDNF-MSA)		AskBio	Multiple System Atrophy	<a href="#">NCT04680065</a>	Q1 2024	Study ongoing
	Pompe Disease rAAV Gene Therapy (ACTUS-101)		AskBio	Pompe Disease	<a href="#">NCT03533673</a>	Q3 2022	Study ongoing
	Huntington's Disease rAAV Gene Therapy (AB-1001 aka BV-101)		AskBio	Huntington's Disease	<a href="#">NCT05541627</a>	Q4 2025	Study ongoing
	LGMD2I/R9 rAAV Gene Therapy (AB-1003 aka LION-101)		AskBio	Limb Girdle Muscular Dystrophy	<a href="#">NCT05230459</a>	Q4 2028	Study ongoing
Others	GPR84 Antagonist (BAY 3178275)		Bayer	Diabetic Neuropathic Pain	n/a	Q1/2024	Study ongoing





# Pharmaceuticals – Pipeline Details Oncology<sup>1</sup> (as of Jul 31, 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 2024	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
	Prostate Cancer with Biochemical Recurrence after Curative Radiotherapy (ARASTEP)							<a href="#">NCT05794906</a>	Q1 2027	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 Q4 2022 Q1 2025	Study ongoing Study completed Study ongoing
AhR Inhibitor (BAY 2416964)	Advanced solid tumors		Bayer/DKFZ					<a href="#">NCT04069026</a> <a href="#">NCT04999202</a>	Q2 2025 Q4 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
VVD KEAP1 Act (VVD-13307 aka NRF2 Inh, BAY 3605349)	Advanced solid tumors		Vividion					<a href="#">NCT05954312</a>	Q4 2027	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		NoriaThx/PSMA Thx							
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







# Pharmaceuticals – Pipeline Details Neurol./Rare Dis.<sup>1</sup> (as of Jul 31, 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>Bemdaneprocel</b> (Parkinson's Disease Cell Therapy) ( <i>BRT-DA01</i> )	<b>Parkinson's Disease</b>		<b>BlueRock</b>					<a href="https://clinicaltrials.gov/ct2/show/study/NCT04802733">NCT04802733</a>	<b>Q2 2023</b>	Study ongoing, detailed Phase I trial data will be presented at the International Congress on Parkinson's Disease and Movement Disorders in Aug 2023
<b>Parkinson's Disease rAAV Gene Therapy</b> ( <i>AB-1005 aka AAV2-GDNF-PD</i> )	<b>Parkinson's Disease</b>		<b>AskBio</b>					<a href="https://clinicaltrials.gov/ct2/show/study/NCT04167540">NCT04167540</a>	<b>Q4 2023</b>	Study ongoing
<b>Multiple System Atrophy rAAV Gene Therapy</b> ( <i>AB-1005 aka AAV2-GDNF-MSA</i> )	<b>Multiple System Atrophy</b>		<b>AskBio</b>					<a href="https://clinicaltrials.gov/ct2/show/study/NCT04680065">NCT04680065</a>	<b>Q1 2024</b>	Study ongoing
<b>Pompe Disease rAAV Gene Therapy</b> ( <i>ACTUS-101</i> )	<b>Pompe Disease</b>		<b>AskBio</b>					<a href="https://clinicaltrials.gov/ct2/show/study/NCT03533673">NCT03533673</a>	<b>Q3 2022</b>	Study ongoing
<b>Huntington's Disease rAAV Gene Therapy</b> ( <i>AB-1001 aka BV-101</i> )	<b>Huntington's Disease</b>		<b>AskBio</b>					<a href="https://clinicaltrials.gov/ct2/show/study/NCT05541627">NCT05541627</a>	<b>Q4 2025</b>	Study ongoing
<b>LGMD2I/R9 rAAV Gene Therapy</b> ( <i>AB-1003 aka LION-101</i> )	<b>Limb-Girdle Muscular Dystrophy 2i</b>		<b>AskBio</b>					<a href="https://clinicaltrials.gov/ct2/show/study/NCT05230459">NCT05230459</a>	<b>Q4 2028</b>	Study ongoing



<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







# Pharmaceuticals – Pipeline Details Immunology<sup>1</sup> (as of Jul 31, 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
Zabedoseritib (IRAK4 Inhibitor) (BAY 1834845)	Atopic Dermatitis (DAMASK)		Bayer					<a href="https://clinicaltrials.gov/ct2/show/study/NCT05656911">NCT05656911</a>	Q4 2023	Study ongoing

<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



# Pharmaceuticals – Pipeline Details Others<sup>1</sup> (as of Jul 31, 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>Aflibercept 8mg</b> (VEGF Inhibitor)	<b>Retinal Vein Occlusion (RVO)</b> (QUASAR)		Regeneron					<a href="#">NCT05850520</a>	Q4 2024	Study ongoing
<b>Gadoquatrane</b> (High Relaxivity Contrast Agent, HRCA)	<b>Magnetic Resonance Imaging</b> (QUANTI-CNS, QUANTI-OBR)		Bayer					<a href="#">NCT05915702</a> <a href="#">NCT05915728</a>	Q4 2024 Q4 2024	Studies ongoing
<b>Runcaciguat</b> (sGC Activator) (BAY 1101042)	<b>Non-prolif. Diabetic Retinopathy (NPDR)</b> (NEON-NPDR)		Bayer					<a href="#">NCT04722991</a>	Q2 2024	Study ongoing
<b>GPR84 Antagonist</b> (BAY 3178275)	<b>Diabetic Neuropatic Pain</b>		Bayer					n/a	Q1 2024	Study ongoing
<b>Next Generation Liver MRI</b> (BAY 3393081)	<b>Contrast Media</b>		Bayer					n/a		

<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

