



Pharmaceuticals —

Pipeline Overview and Progress

November 08, 2024 –
Investor Relations



Pharmaceuticals – Pipeline Overview¹ (as of November 08, 2024)

Phase I	Phase II	Phase III
HER2/mEGFR Inhibitor (BAY 2927088)	Congestive Heart Failure rAAV Gene Therapy (AB-1002) # Congestive Heart Failure (GenePHIT)	Darolutamide (AR Inhibitor) # Adjuvant Prostate Cancer (DASL-HiCaP) # Prostate Cancer with Biochemical Recurrence after Curative Radiotherapy (ARASTEP)
DGKzeta Inhibitor (BAY 2965501)	Anti-a2AP (BAY 3018250) # Acute Ischemic Stroke; Pulmonary Embolism (SIRIUS)	HER2/mEGFR Inhibitor # Advanced Non-small Cell Lung Cancer with HER2 Activating Mutations, 1L (SOHO-02)
CCR8 Ab (BAY 3375968)	sGC Activator Oral (BAY 3283142) # Chronic Kidney Disease (ALPINE-1)	Finerenone (MR Antagonist) # Heart Failure (HFmr/pEF) (FINEARTS-HF) # Non-diabetic Chronic Kidney Disease (FIND-CKD) # Chronic Kidney Disease in Type 1 Diabetes (FINE-ONE)
VVD KEAP1 Act (VVD-130037 aka NRF2 Inh, BAY 3605349)	Parkinson's Disease rAAV Gene Therapy (AB-1005) # Parkinson's Disease (REGENERATE-PD)	Vericiguat (sGC Stimulator) # Heart Failure (HFREF) (VICTOR ²)
DGKalpha Inh (BAY 2862789)		Asundexian (FXIa Inhibitor) # 2 ^o Stroke Prevention (OCEANIC-STROKE)
225Ac-Pelgifatamab (BAY 3546828)		Aflibercept 8mg (VEGF Inhibitor) # Retinal Vein Occlusion (QUASAR)
VVD STAT3 Inhibitor (VVD-130850, BAY 3630914)		Gadoquatrane (High Relaxivity Contrast Agent) # Magnetic Resonance Imaging (QUANTI-CNS, QUANTI-OBR)
225Ac-PSMA-Trillium (BAY 3563254)		
SOS1 Inhibitor (BAY 3498264)		
SEMA 3a (BAY 3401016)		
Anti-coagulant (BAY 3389934)		
Bemdaneprocel (Parkinson's Disease Cell Therapy) (BRT-DA01)		
Multiple System Atrophy rAAV Gene Therapy (AB-1005 aka AAV2-GDNF-MSA)		
Pompe Disease rAAV Gene Therapy (ACTUS-101)		
LGMD2I/R9 rAAV Gene Therapy (AB-1003 aka LION-101)		
GPR84 Antagonist (BAY 3178275)		
BAY 2701250		
		Submissions
		Darolutamide (AR Inhibitor) # US, EU: Prostate Cancer (mHSPC) (ARANOTE)
		Elinzanetant (Neurokinin-1,3 Rec Antagonist) # US, EU: Vasomotor Symptoms
		Aflibercept 8mg (VEGF-Inhibitor) # CN: Neovasc. Age-rel. Macular Degen. (nAMD)
		Acoramidis⁴ (TTR-Stabilizer) # EU: Transthyretin Amyloid Cardiomyopathy

- Oncology
- Cardiovascular+³
- Neurology & Rare Diseases
- Immunology
- Others

- New molecular entity
- Life cycle management

- Protein Therapeutics
- Cell Therapy
- Contrast Agent
- Genetic Medicine
- Radionuclide Therapy
- Small Molecule

¹ Bayer and partner sponsored + 3rd party label enabling studies with first patient first visit
² Conducted by Merck & Co ³ Including Precision Cardiovascular, Nephrology & Acute Care
⁴ Exclusive commercialization rights acquired for EU markets; pending marketing authorization approval. Submission to EMA under responsibility of BridgeBio



Pharmaceuticals – Pipeline Details Phase III¹ (as of November 08, 2024)

Therapeutic Area	Candidate Medication	Modality	Compound Origin	Indication	Ct.gov Identifier	Estimated/Actual Primary Completion	Status
Oncology	Darolutamide (AR Inhibitor)		Orion	Adjuvant Prostate Cancer (<i>DASL-HiCaP</i>)	NCT04136353	Q1 2028	Study ongoing
				Prostate Cancer with Biochemical Recurrence after Curative Radiotherapy (<i>ARASTEP</i>)	NCT05794906	Q1 2027	Study ongoing
	HER2/mEGFR Inhibitor		Bayer/Broad Institute	Advanced Non-small Cell Lung Cancer with HER2 Activating Mutations, 1L	NCT06452277	Q2 2026	Study ongoing
Cardiovascular+ ³	Finerenone (MR Antagonist)		Bayer	Heart Failure (HFmr/pEF) (<i>FINEARTS-HF</i>)	NCT04435626	Q2 2024	Study completed
				Non-diabetic Chronic Kidney Disease (<i>FIND-CKD</i>)	NCT05047263	Q1 2026	Study ongoing
				Chronic Kidney Disease in Type 1 Diabetes (<i>FINE-ONE</i>)	NCT05901831	Q3 2025	Study ongoing
	Vericiguat (sGC Stimulator)		Bayer	Heart Failure (HFrEF) (<i>VICTOR²</i>)	NCT05093933	Q1 2025	Study ongoing
	Asundexian (FX1a Inhibitor)		Bayer	2° Stroke Prevention (<i>OCEANIC-STROKE</i>)	NCT05686070	Q4 2025	Study ongoing
Others	Aflibercept 8mg (VEGF Inhibitor)		Regeneron	Retinal Vein Occlusion (RVO) (<i>QUASAR</i>)	NCT05850520	Q4 2024	Study ongoing
	Gadoquatrane (High Relaxivity Contrast Agent)		Bayer	Magnetic Resonance Imaging (<i>QUANTI-CNS, QUANTI-OBR</i>)	NCT05915702 NCT05915728	Q2 2024 Q2 2024	Studies completed





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³ Including Precision Cardiovascular, Nephrology & Acute Care

⁴ Phase II pilot study on sleep disturbances associated with menopause



Pharmaceuticals – Pipeline Details Phase II¹ (as of November 08, 2024)

Therapeutic Area	Candidate Medication	Modality	Compound Origin	Indication	Ct.gov Identifier	Estimated/Actual Primary Completion	Status
Cardiovascular+ ²	Congestive Heart Failure rAAV Gene Therapy (AB-1002)		AskBio	Congestive Heart Failure (<i>GenePHIT</i>)	NCT05598333	Q4 2026	Study ongoing
	Anti-α2AP (BAY 3018250)		Bayer	Acute Ischemic Stroke; Pulmonary Embolism (<i>SIRIUS</i>)	NCT06149520	Q3 2025	Study ongoing
	sGC Activator Oral (BAY 3283142)		Bayer	Chronic Kidney Disease (<i>ALPINE-1</i>)	NCT06522997	Q2 2026	Study ongoing
Neurology & Rare Diseases	Parkinson's Disease rAAV Gene Therapy (AB-1005)		AskBio	Parkinson's Disease (<i>REGENERATE-PD</i>)	NCT06285643	Q4 2027	Study ongoing

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



Pharmaceuticals – Pipeline Details Phase I¹ (as of November 08, 2024)

Therapeutic Area	Candidate Medication	Modality	Compound Origin	Indication	Ct.gov Identifier	Estimated/Actual Primary Completion	Status
Oncology	HER2/mEGFR Inhibitor (BAY 2927088)		Bayer/Broad Institute	Adv. Non-small Cell Lung Cancer w EGFR Mut. and/or HER2 Mut.	NCT05099172	Q4 2025	Study ongoing
	DGKzeta Inhibitor (BAY 2965501)		Bayer/DKFZ	Advanced Solid Tumors	NCT05614102	Q3 2026	Study ongoing
	CCR8 Ab (BAY 3375968)		Bayer	Advanced Solid Tumors	NCT05537740	Q4 2026	Study ongoing
	VVD KEAP1 Act (VVD-130037 aka NRF2 Inh, BAY 3605349)		Vividion	Advanced Solid Tumors	NCT05954312	Q4 2027	Study ongoing
	DGKalpha Inhibitor (BAY 2862789)		Bayer/DKFZ	Advanced Solid Tumors	NCT05858164	Q1 2027	Study ongoing
	225Ac-Pelgifatamab (BAY 3546828)		Lantheus	Advanced Prostate Cancer	NCT06052306	Q2 2027	Study ongoing
	VVD STAT3 Inhibitor (VVD-130850, BAY 3630914)		Vividion	Advanced Solid and Hematologic Tumors	NCT06188208	Q4 2027	Study ongoing
	225Ac-PSMA-Trillium (BAY 3563254)		Noria/PSMA Therapeutics*	Advanced Prostate Cancer	NCT06217822	Q2 2027	Study ongoing
SOS1 Inhibitor (BAY 3498264)		Bayer	Advanced Solid Cancers	NCT06659341	Q1 2027	Study ongoing	
Cardiovascular+ ²	SEMA 3a (BAY 3401016)		Bayer/Evotec	Alport Syndrome	n/a	Q1 2025	Study ongoing
	Anti-coagulant (BAY 3389934)		Bayer	Anti-coagulation	n/a	Q2 2024	Study ongoing
Neurology / Rare Diseases	Bemdaneprocel (Parkinson's Disease Cell Therapy) (BRT-DA01)		BlueRock	Parkinson's Disease	NCT04802733	Q2 2023	Study completed
	Multiple System Atrophy rAAV Gene Therapy (AB-1005 aka AAV2-GDNF-MSA)		AskBio	Multiple System Atrophy	NCT04680065	Q4 2025	Study ongoing
	Pompe Disease rAAV Gene Therapy (ACTUS-101)		AskBio	Pompe Disease	NCT03533673	Q3 2022	Study ongoing
	LGMD2I/R9 rAAV Gene Therapy (AB-1003 aka LION-101)		AskBio	Limb Girdle Muscular Dystrophy	NCT05230459	Q4 2028	Study ongoing
Others	GPR84 Antagonist (BAY 3178275)		Bayer	Diabetic Neuropathic Pain	n/a	Q1/2024	Study completed
	BAY 2701250		Bayer	Pulmonary Hypertension	NCT06048120	Q1 2025	Study ongoing

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*Bayer acquired Noria and PSMA Therapeutics in 2021



Pharmaceuticals – Pipeline Details Oncology¹ (as of November 08, 2024)

Candidate medication	Indication	Modality	Compound Origin	Phase I	Phase II	Phase III	Ct.gov Identifier	Estimated/Actual Primary Completion	Status
Darolutamide (AR Inhibitor)	Adjuvant Prostate Cancer (DASL-HiCaP)		Orion				NCT04136353	Q1 2028	Study ongoing
	Prostate Cancer with Biochemical Recurrence after Curative Radiotherapy (ARASTEP)						NCT05794906	Q1 2027	Study ongoing
HER2/mEGFR Inhibitor (BAY 2927088)	Advanced Non-small Cell Lung Cancer with HER2 Activating Mutations, 1L		Bayer/Broad Institute				NCT06452277	Q2 2026	Study ongoing
	Advanced Non-small Cell Lung Cancer with EGFR Mutation and/or HER2 Mutation						NCT05099172	Q4 2025	Study ongoing
DGKzeta Inhibitor (BAY 2965501)	Advanced Solid Tumors		Bayer/DKFZ				NCT05614102	Q3 2026	Study ongoing
CCR8 Ab (BAY 3375968)	Advanced Solid Tumors		Bayer				NCT05537740	Q4 2026	Study ongoing
VVD KEAP1 Act (VVD-130037 aka NRF2 Inh, BAY 3605349)	Advanced Solid Tumors		Vividion				NCT05954312	Q4 2027	Study ongoing
DGKalpha Inh (BAY 2862789)	Advanced Solid Tumors		Bayer/DKFZ				NCT05858164	Q1 2027	Study ongoing
225Ac-Pelgifatamab (BAY 3546828)	Advanced Prostate Cancer		Lantheus				NCT06052306	Q2 2027	Study ongoing
VVD STAT3 Inhibitor (VVD-130850, BAY 3630914)	Advanced Solid and Hematologic Tumors		Vividion				NCT06188208	Q4 2027	Study ongoing
225Ac-PSMA-Trillium (BAY 3563254)	Advanced Prostate Cancer		Noria/PSMA Therapeutics*				NCT06217822	Q2 2027	Study ongoing
SOS1 Inhibitor (BAY 3498264)	Advanced Solid Cancers		Bayer				NCT06659341	Q1 2027	Study ongoing

Protein Therapeutics
 Cell Therapy
 Contrast Agent
 Genetic Medicine
 Radionuclide Therapy
 Small Molecule

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*Bayer acquired Noria and PSMA Therapeutics in 2021



Pharmaceuticals – Pipeline Details Cardiovascular+^{1,3} (as of November 08, 2024)

Candidate Medication	Indication	Modality	Compound Origin	Phase I	Phase II	Phase III	Ct.gov Identifier	Estimated/Actual Primary Completion	Status
Finerenone (MR Antagonist)	Heart Failure (HFmr/pEF) (<i>FINEARTS-HF</i>)		Bayer				NCT04435626	Q2 2024	Study completed
	Non-diabetic CKD (<i>FIND-CKD</i>)			NCT05047263	Q1 2026	Study ongoing			
	CKD in Type 1 Diabetes (<i>FINE-ONE</i>)			NCT05901831	Q1 2027	Study ongoing			
Vericiguat (sGC Stimulator)	Heart Failure (HFrEF) (<i>VICTOR²</i>)		Bayer				NCT05093933	Q1 2025	Study ongoing
Asundexian (FXIa Inhibitor) (<i>BAY 2433334</i>)	2° Stroke Prevention (<i>OCEANIC-STROKE</i>)		Bayer				NCT05686070	Q4 2025	Study ongoing
Congestive Heart Failure rAAV Gene Therapy (<i>AB-1002</i>)	Congestive Heart Failure (<i>GenePHIT</i>)		AskBio				NCT05598333	Q4 2026	Study ongoing
Anti-α2AP (<i>BAY 3018250</i>)	Acute Ischemic Stroke; Pulmonary Embolism (<i>SIRIUS</i>)		Bayer				NCT06149520	Q3 2025	Study ongoing
sGC Activator (<i>BAY 3283142</i>)	Chronic Kidney Disease (CKD)		Bayer				NCT06522997	Q2 2026	Study ongoing
SEMA 3a (<i>BAY 3401016</i>)	Alport Syndrome		Bayer/Evotec				n/a	Q1 2025	Study ongoing
Anti-coagulant (<i>BAY 3389934</i>)	Anti-coagulation		Bayer				n/a	Q2 2024	Study ongoing

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



Pharmaceuticals – Pipeline Details Neurol./Rare Dis.¹ (as of November 08, 2024)

Candidate Medication	Indication	Modality	Compound Origin	Phase I	Phase II	Phase III	Ct.gov Identifier	Estimated/Actual Primary Completion	Status
Parkinson's Disease rAAV Gene Therapy <i>(AB-1005)</i>	Parkinson's Disease		AskBio				NCT06285643	Q4 2027	Study ongoing
Bemdaneprocel (Parkinson's Disease Cell Therapy) <i>(BRT-DA01)</i>	Parkinson's Disease		BlueRock				NCT04802733	Q2 2023	Study completed
Multiple System Atrophy rAAV Gene Therapy <i>(AB-1005 aka AAV2-GDNF-MSA)</i>	Multiple System Atrophy		AskBio				NCT04680065	Q4 2025	Study ongoing
Pompe Disease rAAV Gene Therapy <i>(ACTUS-101)</i>	Pompe Disease		AskBio				NCT03533673	Q3 2022	Study ongoing
LGMD2I/R9 rAAV Gene Therapy <i>(AB-1003 aka LION-101)</i>	Limb-Girdle Muscular Dystrophy 2i		AskBio				NCT05230459	Q4 2028	Study ongoing

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



Pharmaceuticals – Pipeline Details Others¹ (as of November 08, 2024)

Candidate Medication	Indication	Modality	Compound Origin	Phase I	Phase II	Phase III	Ct.gov Identifier	Estimated/Actual Primary Completion	Status
Aflibercept 8mg (VEGF Inhibitor)	Retinal Vein Occlusion (RVO) (<i>QUASAR</i>)		Regeneron				NCT05850520	Q4 2024	Study ongoing
Gadoquatrane (High Relaxivity Contrast Agent, HRCA)	Magnetic Resonance Imaging (<i>QUANTI-CNS, QUANTI-OBR</i>)		Bayer				NCT05915702 NCT05915728	Q2 2024 Q2 2024	Studies completed
GPR84 Antagonist (<i>BAY 3178275</i>)	Diabetic Neuropatic Pain		Bayer				n/a	Q1 2024	Study completed
BAY 2701250	Pulmonary Hypertension		Bayer				NCT06048120	Q1 2025	Study ongoing

¹ Bayer and partner sponsored + 3rd party label enabling studies with first patient first visit ² Phase II pilot study on sleep disturbances associated with menopause