Roche Group development pipeline

Marketed products development programmes

Roche Pharma global development programmes

Roche Pharma research and early development (pRED)

Genentech research and early development (gRED)

Changes to the development pipeline

Q2 2025 update

New to phase I

2 NMEs:
RG6505 PanRAS inhibitor – solid tumors
RG6327 NME - geographic atrophy

New to phase II

1 AI:
RG6237 emugrobart (GYM 329) – obesity

New to phase III

New to registration

1 AI (US):
RG7446 Tecentriq + lurbinectedin – 1L maintenance SCLC

Removed from phase I

4 NMEs:
RG6279 eciskafusp alfa ± T - solid tumors
RG6457 WRN covalent inhibitor - solid tumors
RG6614 USP1 inhibitor - solid tumors
RG7921 NME - RVO

Removed from phase II

Removed from phase III

1NME:
RG6058 tiragolumab + T – stage III unresectable 1L NSCLC

2 AIs:
RG6058 tiragolumab + T + Avastin – 1L HCC
RG7601 Venclexta + azacitidine – 1L MDS

Approvals

1 NME (EU):
RG6114 Itovebi + palbociclib + fulv.- 1L HR+ PIK3CA-mut. mBC

1 AI (EU):
RG6152 Xofluza - influenza, pediatric (0-1 year)

1 AI (US):
RG6321 Susvimo - DR

Status as of July 24, 2025

Roche Group development pipeline

Phase I (42 NMEs + 7 AIs)

RG6026	Columvi monotherapy + combos	heme tumors
RG6076	englumafusp alfa combos	heme tumors
RG6114	Itovebi	solid tumors
RG6160	cevostamab	r/r multiple myeloma
RG6171	giredestrant monotherapy + combos	solid tumors
RG6221	LTBR agonist	solid tumors
RG6330	divarasib monotherapy + combos	solid tumors
RG6344	mosperafenib (BRAF inhibitor (3))	solid tumors
RG6411	-	solid tumors
RG6468	-	solid tumors
RG6505	PanRAS inhibitor	solid tumors
RG6537	AR degrader	mCRPC
RG6538[1]	P-BCMA-ALLO1	r/r multiple myeloma
RG6540[1]	P-CD19 x CD20 - ALLO1	heme tumors
RG6561	-	solid tumors
RG6596[2]	HER2 TKI	HER2+ BC
RG6620	KRAS G12D inhibitor	solid tumors
RG6648[3]	cMET ADC	solid tumors
RG7828	Lunsumio monotherapy + combos	heme tumors
RG6794	CDK4/2i	HR+ HER2- BC
RG6810[4]	DLL3 ADC	SCLC
CHU	anti-latent TGF-β1 (SOF10)	solid tumors
CHU	DLL3 trispecific	solid tumors
CHU	codrituzumab	HCC
CHU	MINT91	solid tumors
CHU	CD137 switch	solid tumors
CHU	paluratide (RAS inhibitor)	solid tumors
CHU	anti-CLDN6 trispecific	CLDN6+ solid tumors
CHU	anti-CTLA-4 switch antibody	solid tumors
RG6382	CD19 x CD3	SLE
RG6377	-	IBD
RG6418*	selnoflast	inflammation
RG6421	TMEM16A potentiator	Muco-obstructive respiratory disease
RG6631	afimkibart (anti-TL1A)	MASH
RG7828	Lunsumio	SLE
CHU	anti-HLA-DQ2.5 x gluten peptides	celiac disease
CHU	anti-C1s recycling antibody	immunology
RG6652	GLP-1 RA (CT-996)	obesity +/- T2D
RG6035	Brainshuttle™ CD20	multiple sclerosis
RG6182	MAGL inhibitor	multiple sclerosis
RG6434	-	neurodegenerative disorders
RG6662	HTT miRNA GT (SPK-10001)	Huntington's disease
RG6120	zifibancimig	nAMD
RG6209	-	DME
RG6327	-	geographic atrophy
RG6006	zosurabalpin	bacterial infections
RG6436	LepB inhibitor	complicated urinary tract infection
CHU	REVN24	acute diseases
CHU	BRY10	chronic diseases

Phase II (18 NMEs + 8 AIs)

RG6107	PiaSky	sickle cell disease
RG6171	giredestrant	endometrial cancer
RG6180	autogene cevumeran	solid tumors
RG6797	SPK-8011QQ	hemophilia A
RG6512	FIXa x FX (NXT007)	hemophilia
RG6287	-	immunology
RG6536	vixarelimab	IPF/SSc-ILD
RG6631	afimkibart (anti-TL1A)	atopic dermatitis
RG6237	emugrobart (GYM 329)	obesity
RG6615[5]	zilebesiran	hypertension
RG6641	GLP-1/GIP RA (CT-868)	T1D with BMI ≥ 25
RG6640	GLP-1/GIP RA (CT-388)	obesity +/- T2D
RG6849[6]	petrelintide	obesity +/-T2D
RG6042	tominersen	Huntington's
RG6102	trontinemab	Alzheimer's
RG6168	Enspryng	DMD
RG6237	emugrobart (GYM 329) + Evrysdi	SMA
	emugrobart (GYM 329)	FSHD
RG6289	nivegacetor (gamma-secretase modulator)	Alzheimer's
RG6356	Elevidys	0 to <4 year old DMD
RG7816	alogabat	Angelman syndrome
RG7935	prasinezumab	Parkinson's
RG6179	vamikibart	DME
RG6351	anti-Tie2 agonist	DME
RG6501	OpRegen	geographic atrophy
CHU	anti-IL-8	endometriosis

New Molecular Entity (NME)
Additional Indication (AI)
Oncology / Hematology
Immunology

Cardiovascular, Renal & Metabolism
Neurology
Ophthalmology
Other

Status as of July 24, 2025

RG-No - Roche/Genentech; CHU - Chugai managed; [1]Poseida led studies undergoing integration into Roche portfolio; [2]Zion Pharma managed; [3]MediLink managed; [4]Innovent managed; [5]Alnylam Pharmaceuticals managed; [6]Zealand Pharma managed *also developed in neurology; T: Tecentriq; RA: Receptor agonist

Roche Group development pipeline

Phase III (7 NMEs + 28 AIs)

RG3502	Kadcyla + T	HER-2+ eBC high-risk
RG6026	Columvi + Polivy + R-CHP	1L DLBCL
	Columvi	r/r MCL
RG6107	PiaSky	aHUS
RG6114	Itovebi + fulvestrant	post CDKi HR+ PIK3CA-mut. BC
	Itovebi + Phesgo	1L HER2+ PIK3CA-mut. mBC
	Itovebi + CDK4/6i + letrozole	1L ES PIK3CA-mut. HR+ HER2- advanced BC
RG6171	giredestrant + everolimus	post-CDK4/6 ER+/HER2- BC
	giredestrant + palbociclib	1L ET sensitive ER+/HER2-mBC
	giredestrant	ER+ BC adj
	giredestrant + Phesgo	1L ER+/HER2+ BC
	giredestrant + CDK4/6i	1L ET resistant ER+/HER2- BC
RG6330	divarasib	2L NSCLC
RG7446	Tecentriq + platinum chemo	NSCLC periadj
	Tecentriq + BCG	NMIBC, high-risk
	Tecentriq	ctDNA+ high-risk MIBC
RG7828	Lunsumio + lenalidomide	2L+ FL
	Lunsumio + Polivy	2L+ DLBCL
RG6149	astegolimab	COPD
RG6299	sefaxersen (ASO factor B)	IgA nephropathy
RG6631	afimkibart (anti-TL1A)	ulcerative colitis
	afimkibart (anti-TL1A)	Crohn's disease
RG7159	Gazyva	membranous nephropathy
	Gazyva	systemic lupus erythematosus
	Gazyva	childhood onset idiopathic nephrotic syndrome*
RG1594	Ocrevus higher dose	PPMS
RG6168	Enspryng	MOG-AD
	Enspryng	autoimmune encephalitis
RG6356	Elevidys	amb. 8 to <18y & non amb. DMD
RG7845	fenebrutinib	RMS
	fenebrutinib	PPMS
RG6168	Enspryng	TED
RG6179	vamikibart	UME
RG6321	Susvimo	wAMD, 36-week
RG7716	Vabysmo	CNV

Registration US & EU (1 NME + 4 AIs)

RG7446	Tecentriq + lurbinectedin[1]	1L maintenance SCLC
RG7828	Lunsumio SC	3L+ FL
RG7159	Gazyva	lupus nephritis
RG6152	Xofluza[1]	influenza direct transmission
RG6356	Elevidys[2;3]	DMD

T:Tecentriq
*also known as pediatric nephrotic syndrome (PNS)
[1]Filed in US
[2]Approved in US, filed in EU
[3]US rights with Sarepta

New Molecular Entity (NME)
Additional Indication (AI)
Oncology / Hematology
Immunology
Cardiovascular, Renal & Metabolism
Neurology
Ophthalmology
Other

Status as of July 24, 2025

Expected regulatory submissions*

New Molecular Entities: Lead and additional indications

New Molecular Entity (NME)
Additional Indication (AI)
Oncology / Hematology
Immunology

Cardiovascular, Renal & Metabolism
Neurology
Ophthalmology
Other

*Filing timelines reflect the anticipated filing of a potential indication; projects shown are in phase II and phase III
✓ Indicates submission to health authorities has occurred
Unless stated otherwise submissions are planned to occur in US and EU
T:Tecentriq, RA:Receptor agonist
[1]Alnylam Pharmaceuticals managed

2025		2026		2027		2027		2028 and beyond		2028 and beyond	
RG6171	**giredestrant + everolimus** post-CDK4/6 ER+/HER2- BC	RG6114	**Itovebi + fulvestrant** post CDKi HR+ PIK3CA-mut. BC	RG6114	**Itovebi + Phesgo** 1L HER2+ PIK3CA-mut. mBC	RG6356	**Elevidys** 0 to <4 year old DMD	RG6114	**Itovebi + CDK4/6i + letrozole** 1L ES PIK3CA-mut. HR+ HER2- advanced BC	RG6237	**emugrobart (GYM 329) + Evrysdi** SMA
RG6149	**astegolimab** COPD	RG6171	**giredestrant + palbociclib** 1L ET sensitive ER+/HER2- mBC	RG6171	**giredestrant** ER+ BC adj	RG6356	**Elevidys** amb. 8 to <18y & non amb. DMD	RG6180	**autogene cevumeran** solid tumors	RG6237	**emugrobart (GYM 329)** FSHD
RG6321	**Susvimo** wAMD (EU)	RG7845	**fenebrutinib** RMS &PPMS	RG6171	**giredestrant + Phesgo** 1L ER+/HER2+ BC	RG6179	**vamikibart** DME	RG6512	**FIXa x FX (NXT007)** hemophilia	RG7935	**prasinezumab** Parkinson's
		RG6179	**vamikibart** UME	RG6171	**giredestrant** endometrial cancer	RG6321	**Susvimo** wAMD, 36-week refill	RG6287	**NME** immunology	RG7816	**alogabat** ASD
		RG6321	**Susvimo** DME (EU)	RG6171	**giredestrant + CDK4/6i** 1L ET resistant ER+/HER2- BC			RG6536	**vixarelimab** IPF & SSc-ILD	RG6501	**OpRegen** geographic atrophy
				RG6330	**divarasib** 2L NSCLC			RG6631	**afimkibart (anti-TL1A)** Crohn's disease	RG6351	**anti-Tie2 agonist** DME
				RG6299	**sefaxersen (ASO factor B)** IgA nephropathy			RG6631	**afimkibart (anti-TL1A)** atopic dermatitis	RG6237	**emugrobart (GYM 329)** obesity
				RG6631	**afimkibart (anti-TL1A)** ulcerative colitis			RG6042	**tominersen** Huntington's	RG6615[1]	**zilebesiran** hypertension
								RG6102	**trontinemab** Alzheimer's	RG6640	**GLP-1/GIP RA (CT-388)** obesity +/- T2D
										RG6641	**GLP-1/GIP RA (CT-868)** T1D with BMI ≥ 25
										RG6849	**petrelintide** obesity +/-T2D

Status as of July 24, 2025

Expected regulatory submissions*

Marketed products: Additional indications

New Molecular Entity (NME)
Additional Indication (AI)
Oncology / Hematology
Immunology
Cardiovascular, Renal & Metabolism
Neurology
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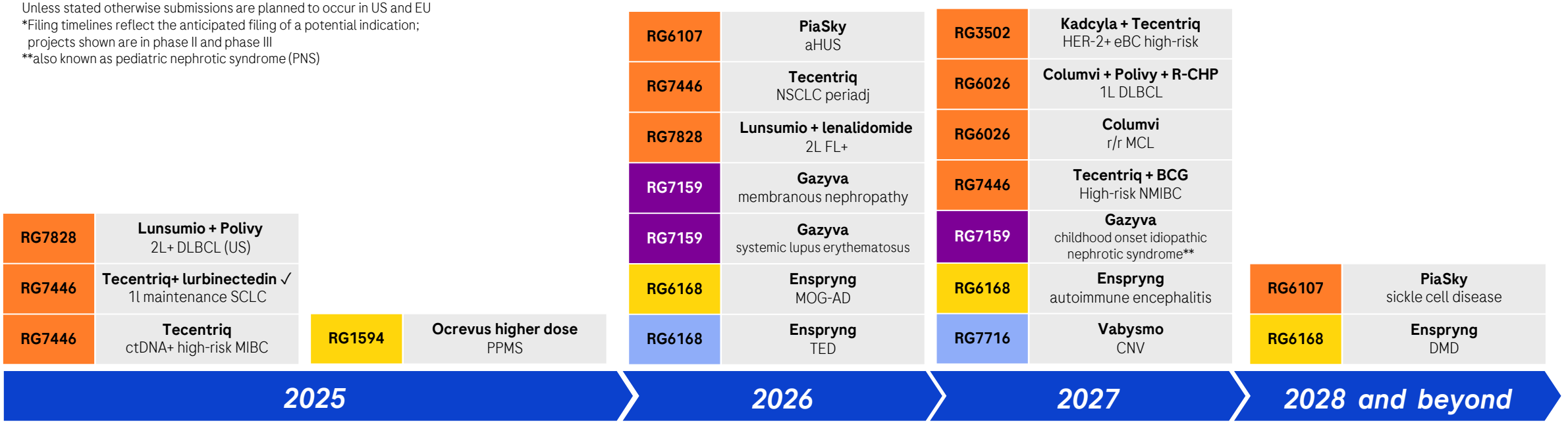
Other

✓ Indicates submission to health authorities has occurred
Unless stated otherwise submissions are planned to occur in US and EU
*Filing timelines reflect the anticipated filing of a potential indication; projects shown are in phase II and phase III
**also known as pediatric nephrotic syndrome (PNS)



Status as of July 24, 2025

Major pending approvals 2025

US

RG6152	**Xofluza** influenza direct transmission Filed Nov 2024
RG7828	**Lunsumio SC** 3L+FL Filed Nov 2024
RG7159	**Gazyva** lupus nephritis Filed Dec 2024
RG7446	**Tecentriq+ lurbinectedin** 1l maintenance SCLC Filed May 2025

EU

RG6356	**Elevidys** DMD (EU) Filed May 2024
RG7828	**Lunsumio SC** 3L+FL Filed Nov 2024
RG7159	**Gazyva** lupus nephritis Filed Jan 2025

China

RG7596	**Polivy + chemo** r/r DLBCL Filed May 2025

Japan-Chugai

RG7446	**Tecentriq** ENKL Filed Oct 2024
RG99	**CellCept** refractory nephrotic syndrome Filed March 2025
RG7446	**Tecentriq** unresectable thymic carcinoma Filed May 2025
RG7828	**Lunsumio + Polivy** 2L+ DLBCL Filed May 2025
RG7853	**Alecensa** ALK+ solid tumors Filed June 2025

ENKL : extranodal natural killer/T-cell lymphoma, nasal type

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Other

Status as of July 24, 2025

Major granted approvals 2025

US		EU		China		Japan-Chugai	
RG3625	**TNKase** stroke Feb 2025	RG6026	**Columvi + chemo** 2L DLBCL April 2024	RG7828	**Lunsumio** 3L+ FL Dec 2024	RG7446	**Tecentriq** Alveolar Soft Part Sarcoma Feb 2025
RG6321	**Susvimo** DME Feb 2025	RG6152	**Xofluza** influenza, pediatric (0-1 year) May 2025	RG6114	**Itovebi + palbociclib + fulvestrant** 1L HR+ PIK3CA-mut. mBC March 2025	RG6356	**Elevidys** DMD (ambulatory) May 2025
RG6321	**Susvimo** DR May 2025	RG6114	**Itovebi + palbociclib + fulvestrant** 1L HR+ PIK3CA-mut. mBC July 2025	RG1594	**Ocrevus** RMS & PPMS March 2025	RG7716	**Vabysmo** Angioid streaks May 2025
				RG6026	**Columvi + chemo** 2L DLBCL April 2025		

New Molecular Entity (NME)
Additional Indication (AI)
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Roche Pharma research and early development (pRED)

Genentech research and early development (gRED)

Alecensa (alectinib, RG7853)

CNS-active inhibitor of anaplastic lymphoma kinase

Indication	Adjuvant ALK+ NSCLC
Phase/study	**Phase III** **ALINA**
# of patients	N=257
Design	▪ **ARM A:** Alecensa 600mg BID ▪ **ARM B:** Platinum-based chemotherapy
Primary endpoint	▪ Disease-free survival
Status	▪ FPI Q3 2018 ▪ Study met its primary endpoint Q3 2023 ▪ Primary data presented at ESMO 2023 ▪ Filed in EU, China and Japan Q4 2023 ▪ Approved in US Q2 2024 (priority review) ▪ Data published in *NEJM* 2024; 390:1265-1276 ▪ Approved in US and EU Q2 2024
CT Identifier	NCT03456076

In collaboration with Chugai

ALK: Anaplastic lymphoma kinase; CNS: Central nervous system; NSCLC: Non-small cell lung cancer; OS: Overall survival, PFS :Progression-free survival; ASCO: American Society of Clinical Oncology; NEJM: New England Journal of Medicine; ESMO: European Society for Medical Oncology

Itovebi (inavolisib, RG6114, GDC-0077)

A potent, orally available, and selective PI3Kα inhibitor

Indication	PIK3CA-mutant HR-positive metastatic breast cancer (mBC)	post CDKi HR-positive PIK3CA-mutant breast cancer	PIK3CA mutant solid tumors and metastatic ER+ HER2-negative breast cancer
Phase/study	**Phase III INAVO120**	**Phase III INAVO121**	**Phase I**
# of patients	N=320	N=400	N=256
Design	▪ **ARM A:** Itovebi plus palbociclib plus fulvestrant ▪ **ARM B:** Placebo plus palbociclib plus fulvestrant	▪ **ARM A:** Itovebi plus fulvestrant ▪ **ARM B:** alpelisib plus fulvestrant	Monotherapy and in combination with standard of care (letrozole; letrozole plus palbociclib; fulvestrant) ▪ **Stage 1:** Dose escalation ▪ **Stage 2:** Dose expansion
Primary endpoint	▪ Progression-free survival	▪ Progression-free survival	▪ Safety, tolerability and pharmacokinetics
Status	▪ FPI Q1 2020 ▪ Recruitment completed Q3 2023 ▪ Study met its primary endpoint of PFS Q4 2023 ▪ Data presented at SABCS 2023 ▪ BTD granted by FDA Q2 2024 ▪ Filed in US (priority review) and EU Q2 2024 ▪ Data presented at ASCO 2024 and ASCO 2025 ▪ Approved in US Q3 2024 ▪ Published in NEJM 2024;391:1584-1596 ▪ Approved in EU July 2025	▪ FPI Q2 2023 ▪ Recruitment completed Q4 2024	▪ FPI Q4 2016 ▪ Preclinical/molecule discovery data presented at AACR 2017 ▪ Data presented at SABCS 2019, 2020 and 2021 ▪ Data published in JCO Sept 2024
CT Identifier	NCT04191499	NCT05646862	NCT03006172

ER: Estrogen receptor; HR: Hormone receptor; HER2: Human Epidermal growth factor Receptor 2; PIK3CA-mut: phosphatidylinositol 3-kinase, catalytic, alpha polypeptide mutated; AACR: American Association for Cancer Research; SABCS: San Antonio Breast Cancer Symposium; CDKi: Cyclin-dependent kinase inhibitor

Itovebi (inavolisib, RG6114, GDC-0077)

A potent, orally available, and selective PI3Kα inhibitor

Indication	1L HER2-positive PIK3CA mutant metastatic breast cancer (mBC)	1L endocrine-sensitive PIK3CA-mutated HR+, HER2-, advanced breast cancer
Phase/study	**Phase III** **INAVO122**	**Phase III** **INAVO123**
# of patients	N=230	N=450
Design	▪ **ARM A:** Itovebi plus Phesgo after induction therapy with Phesgo + taxane ▪ **ARM B:** Placebo plus Phesgo after induction therapy with Phesgo + taxane	▪ **ARM A:** Itovebi + CDK4/6i + letrozole ▪ **ARM B:** Placebo + CDK4/6i + letrozole
Primary endpoint	▪ Progression-free survival	▪ Progression free survival
Status	▪ FPI Q3 2023	▪ FPI April 2025
CT Identifier	NCT05894239	NCT06790693

HER2: Human Epidermal growth factor Receptor 2; PIK3CA-mut: Phosphatidylinositol 3-kinase, catalytic, alpha polypeptide mutated

Kadcyla (trastuzumab emtansine, RG3502)

First ADC for HER2-positive breast cancer

Indication	HER2-positive early breast cancer (BC) high-risk patients	HER2-positive early breast cancer (BC) high-risk patients
Phase/study	**Phase III KATHERINE**	**Phase III ASTEFANIA**
# of patients	N=1,484	N=1150
Design	▪ **ARM A:** Kadcyla 3.6mg/kg Q3W ▪ **ARM B:** Herceptin	▪ **ARM A:** Kadcyla plus Tecentriq ▪ **ARM B:** Kadcyla plus placebo
Primary endpoint	▪ Invasive disease-free survival	▪ Invasive disease-free survival
Status	▪ Stopped at pre-planned interim data analysis for efficacy Q4 2018 ▪ Data presented at SABCS 2018 ▪ BTD granted by FDA in Q1 2019 ▪ Filed in US (under RTOR) and EU Q1 2019 ▪ Approved in US Q2 2019 and in EU Q4 2019 ▪ Data published in *NEJM* 2019; 380:617-628 ▪ 7-year data presented at SABCS 2023 ▪ Data published in NEJM 2025; 392:249-257	▪ FPI Q2 2021 ▪ Recruitment completed Q4 2024
CT Identifier	NCT01772472	NCT04873362

In collaboration with Abbvie

ADC: antibody drug conjugate; BTD: Breakthrough therapy designation; HER2: Human Epidermal growth factor Receptor 2; SABCS: San Antonio Breast Cancer Symposium; RTOR: Real time oncology review; NEJM: New England Journal of Medicine

Tecentriq (atezolizumab, RG7446)

Anti-PD-L1 cancer immunotherapy – lung cancer

Indication	Periadjuvant NSCLC	1L maintenance extensive-stage SCLC
Phase/study	**Phase III** **IMpower030**	**Phase III** **IMforte**[1]
# of patients	N=450	N=450
Design	▪ **ARM A:** Tecentriq plus platinum-based chemotherapy ▪ **ARM B:** Platinum-based chemotherapy	▪ **ARM A:** Platinum-etoposide + Tecentriq followed by maintenance Tecentriq plus lurbinectedin ▪ **ARM B:** Platinum-etoposide + Tecentriq followed by maintenance Tecentriq
Primary endpoint	▪ Event-free survival	▪ Progression-free survival and overall survival
Status	▪ FPI Q2 2018 ▪ Recruitment completed Q3 2021	▪ FPI Q4 2021 ▪ Recruitment completed Jan 2024 ▪ Study met primary endpoints Q3 2024 ▪ Filed in US (priority review) Q2 2025
CT Identifier	NCT03456063	NCT05091567

[1]In collaboration with Jazz Pharma

SCLC: Small cell lung cancer; NSCLC: Non-small cell lung cancer; PD-L1: Programmed cell death-ligand 1; ASCO: American Society of Clinical Oncology; ESMO: European Society for Medical Oncology; WCLC: World Conference on Lung Cancer

Tecentriq (atezolizumab, RG7446)

Anti-PD-L1 cancer immunotherapy – urothelial carcinoma

Indication	High-risk non-muscle-invasive bladder cancer (NMIBC)	ctDNA+, high-risk muscle-invasive bladder cancer (MIBC)
Phase/study	**Phase III ALBAN**	**Phase III IMvigor011**
# of patients	N=516	N=240
Design	▪ **ARM A:** BCG induction and maintenance ▪ **ARM B:** Tecentriq plus BCG induction and maintenance	▪ **ARM A:** Tecentriq monotherapy ▪ **ARM B:** Placebo
Primary endpoint	▪ Event-free survival	▪ Disease-free survival
Status	▪ FPI Q4 2018 ▪ Recruitment completed Q4 2023	▪ FPI Q2 2021 ▪ Recruitment completed Q2 2025
CT Identifier	NCT03799835	NCT04660344

BCG: Bacille Calmette-Guérin; PD-L1: Programmed cell death-ligand 1

Columvi (glofitamab, RG6026)

Bispecific anti-CD20/CD3 antibody engaging T and B cells simultaneously

Indication	Relapsed or refractory Non-Hodgkin's lymphoma (NHL)		
Phase/study	**Phase I**	**Phase Ib**	**Phase I**
# of patients	N=700	N=140	N=18-36
Design	**Cohort 1:** Single-agent dose escalation study ▪ Initial dose escalation ▪ Expansion cohort in r/r DLBCL ▪ Expansion cohort in r/r FL ▪ Expansion cohort in r/r MCL ▪ All patients will receive pretreatment with a single dose of Gazyva (1000mg) **Cohort 2:** Columvi plus Gazyva (i.e. continuous treatment with Gazyva)	Dose escalation and expansion ▪ **ARM A:** Columvi plus Tecentriq ▪ **ARM B:** Columvi plus Polivy	Columvi SC ▪ Part 1 dose escalation
Primary endpoint	▪ Efficacy, safety, tolerability and PK	▪ Safety	▪ Safety
Status	▪ Data presented at ASH 2018, 2020, 2021, 2022, 2023, ICML 2019, 2021, EHA 2020, 2021, 2022 and ASCO 2021, 2022 and 2023 ▪ Data published in *J Clin Oncology* 2021; 39:18:1959-1970 and *NEJM* 2022; 387:2220-2231 ▪ Filed in EU Q2 2022 and US Q4 2022 ▪ Approved in Canada Q1, US Q2 and EU Q3 2023	▪ **ARM A:** FPI Q2 2018 ▪ **ARM B:** FPI Q4 2020 ▪ Recruitment completed Q2 2022 ▪ Data presented at ASH 2019, 2021	▪ FPI Q3 2021 ▪ Recruitment completed Q1 2024
CT Identifier	NCT03075696	NCT03533283	ISRCTN17975931

DLBCL: Diffuse large B cell lymphoma; FL: Follicular lymphoma; r/r: Relapsed or refractory; SC: subcutenous; PK: Pharmacokinetics; ASCO: American Society of Clinical Oncology; ASH: American Society of Hematology; EHA: European Hematology Association; ICML: International Conference on Malignant Lymphoma; NEJM: New England Journal of Medicine

Columvi (glofitamab, RG6026)

Bispecific anti-CD20/CD3 antibody engaging T and B cells simultaneously

Indication	Non-Hodgkin's lymphoma (NHL)	2L+ SCT-ineligible DLBCL
Phase/study	**Phase Ib**	**Phase III STARGLO**
# of patients	Part I: 15-60 Part II: ~66-104	N=270
Design	▪ **Part I:** Dose-finding for the combination of Columvi plus G/R-CHOP in r/r indolent NHL ▪ **Part II:** Dose expansion Columvi plus G/R-CHOP or R-CHOP in 1L DLBCL ▪ **Part III:** Columvi plus R-CHP plus Polivy	▪ **ARM A:** Columvi plus gemcitabine and oxaliplatin, followed by up to 4 cycles of Columvi monotherapy ▪ **ARM B:** Rituximab in combination with gemcitabine and oxaliplatin A single dose of Gazyva will be administered 7 days prior to the first dose of Columvi
Primary endpoint	▪ Safety	▪ Overall survival
Status	▪ Part I: FPI Q1 2018 ▪ Part II: FPI Q1 2021 ▪ Recruitment completed Q1 2023 ▪ Data presented at ASH 2021, 2022, 2023 and ASCO 2023	▪ FPI Q1 2021 ▪ Recruitment completed Q1 2023 ▪ Study met primary endpoint April 2024 ▪ Data presented at EHA 2024 ▪ Filed in EU and US Q3 2024 ▪ Approved in EU April 2025 ▪ 2yr follow-up data presented at ASCO 2025
CT Identifier	NCT03467373	NCT04408638

DLBCL: Diffuse large B cell lymphoma; SCT: Stem cell transplant; CHOP: Cyclophosphamide, doxorubicin, vincristine and prednisone; R: Rituxan/MabThera; G: Gazyva; NHL: Non-Hodgkin's lymphoma; ctDNA: Circulating tumor DNA; ASH: American Society of Hematology; EOT PET-CR: End of treatment PET-complete response rate

Columvi (glofitamab, RG6026)

Bispecific anti-CD20/CD3 antibody engaging T and B cells simultaneously

Indication	2L+ SCT-eligible DLBCL	2L+ SCT-ineligible DLBCL	1L DLBCL fit (IPI 2-5)
Phase/study	**Phase Ib**	**Phase Ib**	**Phase III SKYGLO**
# of patients	N=40	N=112	N=1130
Design	▪ Columvi plus R-ICE (single-arm study)	▪ **ARM A:** Columvi IV plus CELMoD (CC-220 and CC-99282) ▪ **ARM B:** Lunsumio SC plus CELMoD (CC-220 and CC-99282)	▪ **ARM A:** Columvi plus Polivy plus R-CHP ▪ **ARM B:** Polivy plus R-CHP
Primary endpoint	▪ Objective response rate within 3 cycles	▪ Safety, DLT, RPTD	▪ Progression-free survival
Status	▪ FPI Q4 2022 ▪ Recruitment completed Q2 2024	▪ FPI Q3 2019	▪ FPI Q4 2023
CT Identifier	NCT05364424	NCT05169515	NCT06047080

DLBCL: Diffuse large B cell lymphoma; DLT: Dose-limiting toxicity, RPTD: Recommended Phase II Dose; R-ICE: Rituxan plus ifosfamide, carboplatin, and etoposide; IV: Intravenous; SC: Subcutaneous; ; R-CHP: Rituxan, cyclophosphamide, hydroxydoxorubicin, prednisone; IPI: International prognostic index

Columvi (glofitamab, RG6026)

Bispecific anti-CD20/CD3 antibody engaging T and B cells simultaneously

Indication	**Relapsed or refractory mantle cell lymphoma (MCL)**
Phase/study	**Phase III** **GLOBRYTE**
# of patients	N=182
Design	▪ **ARM A:** Columvi monotherapy ▪ **ARM B**: Bendamustine + rituximab or rituximab + lenalidomide
Primary endpoint	▪ Progression-free survival by IRC
Status	▪ FPI Q4 2023 ▪ BTD granted by FDA Q2 2024
CT Identifier	NCT06084936

IRC: Independent review committee

Lunsumio (mosunetuzumab, RG7828)

Bispecific anti-CD20/CD3 antibody engaging T and B cells simultaneously

Indication	3L+ FL, 3L+ DLBCL & other relapsed or refractory NHL	Relapsed or refractory LBCL & MCL
Phase/study	**Phase I/II**	**Phase Ib/II**
# of patients	N=713	N=235
Design	▪ Dose escalation of Lunsumio monotherapy and in combination with Tecentriq ▪ Expansion cohorts for r/r FL, r/r DLBCL and SC in r/r NHL	Dose escalation of Lunsumio plus Polivy ▪ **ARM A:** Lunsumio SC plus Polivy ▪ **ARM B:** Rituximab plus Polivy
Primary endpoint	▪ Safety, tolerability, dose/schedule, PK and response rates	▪ Safety/tolerability and response
Status	▪ Filed in EU and rolling submission in US Q4 2021; Filed in US (priority review) Q2 2022 ▪ Approved in EU Q2 2022 and US Q4 2022 ▪ DLBCL data published in *J. Clin. Oncol.* 2022; 40(5)481-491 and *Blood Advances* 2023; 7 (17): 4926–4935 ▪ FL data published in the *Lancet Oncology* 2022;23(8):1055-1065 ▪ Recruitment completed Q1 2023 ▪ 3-year data in r/r FL presented at ASH 2023 ▪ Positive readout for Lunsumio mono SC in 3L+ FL Q2 2024 ▪ Lunsumio monotherapy SC in 3L+ FL filed in US and EU Q4 2024	▪ FPI Q3 2018 ▪ Initial data presented at ASCO 2021 and ASH 2021, 2022 ▪ Data presented at ASH 2023 ▪ Data published in *Nature Medicine* 2023; 30, 229–239 ▪ Recruitment completed Q1 2024
CT Identifier	NCT02500407	NCT03671018

FL: Follicular lymphoma; DLBCL: Diffuse large B cell lymphoma; r/r: Relapsed/refractory; NHL: Non-Hodgkin's lymphoma; R: Rituximab; SC: Subcutaneous; CHOP: Cyclophosphamide, doxorubicin, vincristine, and prednisone; CHP: Cyclophosphamide, doxorubicin, and prednisone; PK: Pharmacokinetics; BTD: Breakthrough Therapy Designation; ASH: American Society of Hematology; ASCO: American Society of Clinical Oncology

Lunsumio (mosunetuzumab, RG7828)

Bispecific anti-CD20/CD3 antibody engaging T and B cells simultaneously

Indication	2L+ SCT ineligible DLBCL
Phase/study	**Phase III** **SUNMO**
# of patients	N=222
Design	▪ **ARM A:** Lunsumio plus Polivy ▪ **ARM B:** R + GemOx
Primary endpoint	▪ Progression-free survival
Status	▪ FPI Q2 2022 ▪ Recruitment completed Q4 2024 ▪ Study met dual primary endpoints (ORR, PFS) April 2025 ▪ Data presented at EHA, ICML 2025
CT Identifier	NCT05171647

DLBCL: Diffuse large B cell lymphoma; SCT: Stem cell transplant; R: Rituxan/MabThera; GemOx: Gemcitabin und Oxaliplatin

Lunsumio (mosunetuzumab, RG7828)

Bispecific anti-CD20/CD3 antibody engaging T and B cells simultaneously

Indication	1L DLBCL & 2L DLBCL following 1L induction	FL
Phase/study	**Phase I/II**	**Phase Ib/II**
# of patients	N=187	N=183
Design	▪ **Cohort A:** Lunsumio monotherapy (after a response to prior systemic chemotherapy) ▪ **Cohort B:** Lunsumio monotherapy (1L treatment in elderly/frail) ▪ **Cohort C:** Lunsumio SC plus Polivy in 1L elderly/unfit	Non-Randomized: ▪ Lunsumio plus lenalidomide in R/R FL safety run-in for phase III ▪ Lunsumio SC plus lenalidomide in 1L FL Randomized ▪ Lunsumio SC plus lenalidomide vs Lunsumio IV plus lenalidomide
Primary endpoint	▪ Safety/tolerability and response	▪ Safety/tolerability and response
Status	▪ FPI Q2 2019 – Cohort B ▪ FPI Q3 2019 – Cohort A ▪ FPI Q1 2021 – Cohort C ▪ Recruitment completed Q1 2023 ▪ Cohort B presented at ASH 2020 (Cohort B) and ASH 2022 ▪ Cohort C presented at ASH 2023	▪ FPI Q3 2020 ▪ Initial data presented at ASH 2021 and ASH 2022 ▪ Recruitment completed Q2 2023
CT Identifier	NCT03677154	NCT04246086

FL: Follicular lymphoma; DLBCL: Diffuse large B cell lymphoma; SC: Subcutaneous; ASH: American Society of Hematology

Lunsumio (mosunetuzumab, RG7828)

Bispecific anti-CD20/CD3 antibody engaging T and B cells simultaneously

Indication	2L+ FL	Relapsed or refractory CLL
Phase/study	**Phase III CELESTIMO**	**Phase Ib/II**
# of patients	N=474	N=137
Design	▪ **ARM A**: Lunsumio plus lenalidomide ▪ **ARM B:** Rituximab plus lenalidomide	▪ Lunsumio monotherapy (3L+ CLL) ▪ Lunsumio + venetoclax ▪ Lunsumio + BTKi + venetoclax
Primary endpoint	▪ Progression-free survival	▪ Safety, dose-limiting toxicity and RPTD
Status	▪ FPI Q4 2021	▪ FPI Q1 2022
CT Identifier	NCT04712097	NCT05091424

FL: Follicular lymphoma; r/r: Relapsed/refractory; RPTD: Recommended Phase II Dose; CLL: Chronic lymphocytic leukemia

Polivy (polatuzumab vedotin, RG7596)

ADC targeting CD79b to treat B cell malignancies

Indication	1L DLBCL
Phase/study	**Phase III** **POLARIX**
# of patients	N=879
Design	▪ **ARM A:** Polivy plus R-CHP ▪ **ARM B:** R-CHOP
Primary endpoint	▪ Progression-free survival
Status	▪ Data presented at ASH 2021 and 2022 and 2024 ▪ Filed in EU, Japan and China Q4 2021 and in the US Q3 2022 ▪ Published in *NEJM* 2022 27;386(4):351-363 ▪ Approved in EU Q2 2022, Japan Q3 2022, China Q1 2023 and US April 2023
CT Identifier	NCT03274492

In collaboration with Pfizer

DLBCL: diffuse large B cell lymphoma; R-CHP: Rituxan, cyclophosphamide, hydroxydoxorubicin, prednisone; R-CHOP: Rituxan, cyclophosphamide, doxorubicin, vincristine, and prednisone; ASH: American Society of Hematology, NEJM: New England Journal of Medicine

Venclexta (venetoclax, RG7601)

Novel small molecule Bcl-2 selective inhibitor – chronic lymphocytic leukemia

Indication	Untreated fit chronic lymphocytic leukemia (CLL) patients	Newly diagnosed higher-risk myelodysplastic syndromes (MDS)
Phase/study	**Phase III CristaLLo**	**Phase III VERONA**
# of patients	N=166	N=531
Design	▪ **ARM A:** Venclexta plus Gazyva ▪ **ARM B:** Fludarabine plus cyclophosphamide plus rituximab or bendamustine plus rituximab	▪ **ARM A:** Venclexta plus azacitidine ▪ **ARM B:** Placebo plus azacitidine
Primary endpoint	▪ MRD negativity rate in peripheral blood at 15 months	▪ Overall survival
Status	▪ FPI Q2 2020 ▪ Recruitment completed Q1 2023 ▪ Study met primary endpoint in Q2 2024 ▪ Primary analysis presented at ASH 2024	▪ FPI Q4 2020 ▪ Recruitment completed Q3 2022 ▪ The study did not meet the primary endpoint at the final analysis in Q2 2025
CT Identifier	NCT04285567	NCT04401748

Joint project with AbbVie, in collaboration with The Walter and Eliza Hall Institute

Bcl-2: B-cell lymphoma 2; BTD: Breakthrough therapy designation; MRD: Minimal Residual Disease; ASH: American Society of Hematology; ASCO: American Society of Clinical Oncology; EHA: European Hematology Association; RTOR: Real time oncology review; NEJM: New England Journal of Medicine

Hemlibra (emicizumab, RG6013)

Factor VIII mimetic for treatment of hemophilia A

Indication	Hemophilia A patients with and without inhibitors to Factor VIII	Hemophilia A mild to moderate patients without inhibitors to Factor VIII
Phase/study	**Phase III HAVEN 5**	**Phase III HAVEN 6**
# of patients	N=85	N=70
Design	Patients with Hemophilia regardless of FVIII inhibitor status on prophylactic or episodic treatment prior to study entry: ▪ **ARM A**: Hemlibra prophylaxis QW ▪ **ARM B**: Hemlibra prophylaxis Q4W ▪ **ARM C**: No prophylaxis (control arm)	Patients with mild or moderate Hemophilia A without FVIII inhibitors ▪ Hemlibra QW (1.5mg/kg), Q2W (3.0mg/kg) or Q4W (6.0mg/kg) (patient's preference)
Primary endpoint	▪ Number of bleeds over 24 weeks	▪ Safety and efficacy
Status	▪ FPI Q2 2018 ▪ Recruitment completed Q1 2019 ▪ Filed in China Q2 2020 ▪ Approved in China Q2 2021 ▪ Data published Res Pract Thromb Haemost. 2022 Mar 7;6(2):e12670	▪ FPI Q1 2020, recruitment completed Q1 2021 ▪ Interim data presented at ASH 2021 and primary data presented at ISTH 2022 ▪ Filed in EU Q4 2021 ▪ Data presented at ASH 2022 ▪ Approved in EU for moderate Hemophilia A Q1 2023 ▪ Data published in Lancet Haematology 2023; 10(3) e168-e177
CT Identifier	NCT03315455	NCT04158648

In collaboration with Chugai

ASH: American Society of Hematology; ISTH: International Society on Thrombosis and Haemostasis

PiaSky (crovalimab, RG6107, SKY59)

A humanized monoclonal antibody against complement C5

Indication	Paroxysmal nocturnal hemoglobinuria (PNH) patients switching from a C5 inhibitor
Phase/study	**Phase III** **COMMODORE 1**
# of patients	N=89 (ARMs A/B)
Design	▪ **ARM A:** PiaSky ▪ **ARM B:** Eculizumab ▪ **ARM C:** Patients switching to PiaSky (crovalimab) from ravulizumab, higher than labeled doses of eculizumab & C5 SNP patients (descriptive-arm)
Primary endpoint	▪ Safety
Status	▪ FPI Q3 2020 ▪ Study results in Q1 2023 supported the favorable benefit-risk profile of crovalimab, as seen in the pivotal COMMODORE 2 study ▪ Data presented at EHA 2023 ▪ Filed in US and EU Q2 2023 ▪ Published in Am J Hematol. 2024; 1-11. doi:10.1002/ajh.27413 ▪ Approved in the US Q2 2024 and in EU in Q3 2024
CT Identifier	NCT04432584

In collaboration with Chugai

ASH: American Society of Hematology; PNH: Paroxysmal nocturnal hemoglobinuria; PK/PD: Pharmacokinetics/Pharmacodynamics

PiaSky (crovalimab, RG6107, SKY59)

A humanized monoclonal antibody against complement C5

Indication	Paroxysmal nocturnal hemoglobinuria (PNH) C5 inhibitor naive patients	Paroxysmal nocturnal hemoglobinuria (PNH) C5 inhibitor naive patients (China only)
Phase/study	**Phase III** **COMMODORE 2**	**Phase III** **COMMODORE 3**
# of patients	N=204	N=51
Design	▪ **ARM A:** PiaSky ▪ **ARM B:** Eculizumab	▪ PiaSky loading dose IV on Day 1, followed by weekly PiaSky SC doses for 4 weeks

Primary endpoint	▪ Non-inferiority of crovalimab compared to eculizumab:
	  ▪ % patients with transfusion avoidance from baseline through week 25
	  ▪ % patients with haemolysis control, as measured by LDH <=1.5ULN from week 5-25
		▪ Percentage of patients with transfusion avoidance from baseline through week 25
		▪ Mean percentage of participants with hemolysis control (week 5 through week 25)

Status	▪ FPI Q4 2020 ▪ Recruitment completed Q2 2022 ▪ Study met its primary endpoint Q1 2023 ▪ Data presented at EHA 2023 ▪ Filed in US and EU Q2 2023 ▪ Published in Am J Hematol. 2024; 1-10. doi:10.1002/ajh.27412 ▪ Approved in the US Q2 2024 and in the EU in Q3 2024	▪ FPI Q1 2021; Recruitment completed Q3 2021 ▪ Study met its co-primary endpoints Q1 2022 ▪ Data presented at ASH 2022 ▪ Published in *Am J Hematol* 2023;98(9):1407-1414 ▪ Approved in China Q1 2024
CT Identifier	NCT04434092	NCT04654468

In collaboration with Chugai

LDH: Lactate Dehydrogenase; ULN: Upper Limit of Normal; IV: Intravenous; SC: Subcutaneous, ASH: American Society of Hematology

PiaSky (crovalimab, RG6107, SKY59)

A humanized monoclonal antibody against complement C5

Indication	Atypical hemolytic uremic syndrome (aHUS) - adults	Atypical hemolytic uremic syndrome (aHUS) - paediatric
Phase/study	**Phase III COMMUTE-a**	**Phase III COMMUTE-p**
# of patients	N=90	N=35
Design	Single-arm study of aHUS patients ▪ **Cohort 1**: not previously treated with C5i ▪ **Cohort 2:** switching from C5i ▪ **Cohort 3:** known C5 polymorphism	Single-arm study of aHUS patients ▪ **Cohort 1:** not previously treated with C5i ▪ **Cohort 2:** switching from C5i ≤18y/o ▪ **Cohort 3:** previously treated with C5i (includes participants with known C5 polymorphism)
Primary endpoint	▪ Cohort 1+3: proportion of patients with complete TMA response anytime between baseline and week 25 ▪ Cohort 2: proportion of patients with maintained TMA control from baseline through week 25	▪ Cohort 1: proportion of patients with complete TMA response anytime between baseline and week 25 ▪ Cohort 2: proportion of patients with maintained TMA control from baseline through week 25
Status	▪ FPI Q4 2021 ▪ Recruitment completed Q2 2025	▪ FPI Q4 2021 ▪ Recruitment completed Q1 2025
CT Identifier	NCT04861259	NCT04958265

In collaboration with Chugai

aHUS: Atypical Hemolytic Uremic Syndrome; C5i: C5 inhibitor; TMA: thrombotic microangiopathy

PiaSky (crovalimab, RG6107, SKY59)

A humanized monoclonal antibody against complement C5

Indication	Sickle cell disease (SCD) acute treatment	Sickle cell disease (SCD) chronic VOC prevention
Phase/study	**Phase Ib CROSSWALK-a**	**Phase IIa CROSSWALK-c**
# of patients	N=30	N=90
Design	▪ **ARM A:** PiaSky ▪ **ARM B:** Placebo	▪ **ARM A:** PiaSky ▪ **ARM B:** Placebo
Primary endpoint	▪ Safety	▪ VOC rate, up to 48 weeks
Status	▪ FPI Q1 2022 ▪ Recruitment completed Q3 2024	▪ FPI Q1 2022 ▪ Recruitment completed Q3 2024
CT Identifier	NCT04912869	NCT05075824

In collaboration with Chugai
VOC: Vaso-occlusive crises

Elevidys (delandistrogene moxeparvovec, RG6356, SRP-9001)

rAAVrh74.MHCK7.Micro-dystrophin gene therapy

Indication	Duchenne muscular dystrophy (DMD)
Phase/study	**Phase II** **ENVOL**
# of patients	N=21
Design	Open label single arm study in 0 to <4 year old DMD boys who will receive a single intravenous (IV) infusion of Elevidys on Day 1, separated into 4 cohorts: ▪ **Cohort A**: ~ 10 participants who are 3 years of age ▪ **Cohort B:** ~ 4 participants who are 2 years of age ▪ **Cohort C:** ~ 4 participants who are > 6 months to < 2 years of age ▪ **Cohort D:** ~ 3 participants who are <= 6 months of age
Primary endpoint	▪ Safety
Status	▪ FPI Q4 2023 ▪ Cohort A: Recruitment completed Q3 2024
CT Identifier	NCT06128564

In collaboration with Sarepta
DMD: Duchenne muscular dystrophy

Enspryng (satralizumab, RG6168, SA237)

Anti-IL-6 receptor humanized monoclonal antibody

Indication	Myelin oligodendrocyte glycoprotein antibody disease (MOG-AD)	Autoimmune encephalitis (AIE)	Duchenne Muscular Dystrophy (DMD)
Phase/study	**Phase III METEOROID**	**Phase III CIELO**	**Ph II SHIELD DMD**
# of patients	N=152	N=152	N= 50
Design	▪ **ARM A**: Enspryng at weeks 0, 2, 4 (loading doses) and maintenance doses Q4W ▪ **ARM B:** Placebo	▪ **ARM A**: Enspryng at weeks 0, 2, 4 (loading doses) and maintenance doses Q4W ▪ **ARM B**: Placebo	Enspryng SC on day 1, week 2 and week 4 then Q4W from weeks 8 to 104 ▪ **GROUP 1:** ambulatory patients with fractures and non-ambulatory participants with or without a history of fractures ▪ **GROUP 2:** ambulatory patients who are fracture naive at baseline
Primary endpoint	▪ Time from randomization to the first occurrence of a MOG-AD relapse	▪ Efficacy (proportion of participants with mRS score improvement ≥ 1 from baseline and no use of rescue therapy at week 24 (NMDAR) and week 52 (LGI1) and safety	▪ Change from baseline to week 52 in Lumbar Spine (LS) BMD Z-score as measured by DEXA in Group 2
Status	▪ FPI Q3 2022 ▪ ODD granted by FDA in Q4 2021	▪ FPI Q3 2022 ▪ ODD granted for NMDAR AIE in US Q3 22 and for LGI1 AIE Q4 2024	▪ FPI April 2025
CT Identifier	NCT05271409	NCT05503264	NCT06450639

In collaboration with Chugai

In collaboration with Chugai; MG-AD: Myasthenia Gravis Activities of Daily Living; AChR: Acetylcholine receptor; MOG-AD: Myelin Oligodendrocyte Glycoprotein Antibody Disease, mRS: Modified Rankin Scale; AIE: Autoimmune encephalitis; NMDAR AIE: Anti-N-Methyl-D-Aspartic Acid Receptor Autoimmune Encephalitis; ODD: Orphan drug designation

Evrysdi (risdiplam, RG7916)

Oral SMN2 splicing modifier

Indication	Spinal muscular atrophy (SMA)	
Phase/study	**Phase II RAINBOWFISH**	**Phase II JEWELFISH**
# of patients	N=25	N=174
Design	▪ Infants aged from birth to 6 weeks who have been genetically diagnosed with SMA but are not yet presenting with symptoms	▪ Adult and pediatric patients with previously treated SMA type 1, 2 and 3
Primary endpoint	▪ Proportion of participants with two copies of the SMN2 gene and baseline CMAP>=1.5 millivolt who are sitting without support	▪ Safety, tolerability, PK/PD
Status	▪ FPI Q3 2019 ▪ Recruitment completed Q1 2022 ▪ Initial data presented at CureSMA , WMS 2021, MDA and WMS 2022 ▪ Primary data presented at WMS 2023 ▪ Filed in US and EU Q4 2021 ▪ Approved in US Q2 2022 and EU Q3 2023 ▪ 2-year data presented at WMS 2024	▪ Data presented at WMS 2017, AAN 2018, WMS 2018, CureSMA 2019, WMS 2019, CureSMA 2020 and 2021 ▪ 2-year data presented at WMS 2022 ▪ Data published J Neurol. 2024 Aug;271(8):4871-4884
CT Identifier	NCT03779334	NCT03032172

In collaboration with PTC Therapeutics and SMA Foundation

SMN: survival motor neuron; CMAP: compound muscle action potential; WMS: World Muscle Society; CureSMA: Annual SMA Conference; MDA: Muscular Dystrophy Association

Ocrevus (ocrelizumab, RG1594)

Humanized monoclonal antibody selectively targeting CD20+ B cells

Indication	Primary progressive multiple sclerosis (PPMS)
Phase/study	**Phase IIIb** **ORATORIO-HAND**
# of patients	N ~ 1,000
Design	120-week treatment period: ▪ **ARM A:** Ocrevus 600mg IV Q24W ▪ **ARM B:** Placebo
Primary endpoint	▪ Time to upper limb disability progression confirmed for at least 12 weeks
Status	▪ FPI Q3 2019 ▪ Primary endpoint met in Q2 2025
CT Identifier	NCT04035005

IV: intravenous

Ocrevus (ocrelizumab, RG1594)

Humanized monoclonal antibody selectively targeting CD20+ B cells

Indication	Primary progressive multiple sclerosis (PPMS)	Relapsing multiple sclerosis (RMS)	PPMS & RMS
Phase/study	**Phase IIIb GAVOTTE**	**Phase IIIb MUSETTE**	**Phase III Ocarina II**[1]
# of patients	N ~ 699	N ~ 786	N ~ 232
Design	120-week treatment period: ▪ **ARM A:** Ocrevus 600mg IV Q24W ▪ **ARM B:** Ocrevus 1200mg if BW <75kg or 1800mg if BW ≥75kg Q24W	120-week treatment period: ▪ **ARM A:** Ocrevus 600mg IV Q24W ▪ **ARM B:** Ocrevus 1200mg if BW <75kg or 1800mg if BW ≥75kg Q24W	▪ **ARM A:** Ocrevus IV ▪ **ARM B:** Ocrevus SC
Primary endpoint	▪ Superiority of Ocrevus higher dose versus approved dose on cCDP	▪ Superiority of Ocrevus higher dose versus approved dose on cCDP	▪ Serum Ocrevus area under the concentration-time curve (AUCW1-12) at week 12
Status	▪ FPI Q4 2020 ▪ Recruitment completed Q2 2023	▪ FPI Q4 2020 ▪ Recruitment completed Q4 2021 ▪ Primary endpoint not met; results support Ocrevus 600mg IV as optimal dose	▪ FPI Q2 2022 ▪ Recruitment completed Q4 2022 ▪ Primary endpoint met July 2023 ▪ Data presented at ECTRIMS 2023 ▪ Filed in EU Q3 2023 and US Q4 2023 ▪ SC formulation approved in EU Q2 2024 and US Q3 2024
CT Identifier	NCT04548999	NCT04544436	NCT05232825

[1]SC with Halozyme's rHuPH20/ Halozyme's human hyaluronidase
cCDP: Composite confirmed disability progression; IV: Intravenous; SC: Subcutaneous

Gazyva (obinutuzumab, RG7159)

Immunology development program

Indication	Lupus nephritis		Membranous nephropathy
Phase/study	**Phase II NOBILITY**	**Phase III REGENCY**	**Phase III MAJESTY**
# of patients	N=126	N=252	N=140
Design	▪ **ARM A:** Gazyva 1000mg IV plus MMF / mycophenolic acid ▪ **ARM B:** Placebo IV plus MMF/ mycophenolic acid	▪ **ARM A:** Gazyva 1000mg IV (6 doses through Week 52) plus MFF ▪ **ARM B:** Gazyva1000 mg IV (5 doses through Week 52) plus MFF ▪ **ARM C:** Placebo IV plus MFF	▪ **ARM A:** Gazyva 1000mg IV on top of renin-angiotensin inhibitors ▪ **ARM B:** Tacrolimus treatment for 12 months
Primary endpoint	▪ Percentage of participants who achieve complete renal response (CRR)	▪ Percentage of participants who achieve complete renal response (CRR)	▪ Percentage of patients who achieve complete remission at week 104
Status	▪ Primary endpoint met Q2 2019 ▪ BTD granted by the FDA Q3 2019 ▪ Data presented at ASN and ACR 2019 ▪ Published in *Ann Rheum Dis* 2022; 81(1):100-107	▪ FPI Q3 2020 ▪ Recruitment completed Q1 2023 ▪ Primary endpoint met Q3 2024 ▪ Filed in US and EU in Q1 2025 ▪ Published in NEJM 2025 Feb 7. doi: 10.1056/NEJMoa2410965.	▪ FPI Q2 2021 ▪ Recruitment completed Q4 2023
CT Identifier	NCT02550652	NCT04221477	NCT04629248

In collaboration with Biogen

BTD: Breakthrough therapy designation; IV: Intravenous; ASN: American Society of Nephrology; ACR: American College of Rheumatology; MMF: mycophenolate mofetil

Gazyva (obinutuzumab, RG7159)

Immunology development program

Indication	Systemic lupus erythematosus (SLE)	Childhood onset idiopathic nephrotic syndrome*
Phase/study	**Phase III** **ALLEGORY**	**Phase III** **INShore**
# of patients	N=300	N=80
Design	▪ **ARM A:** Gazyva 1000mg IV on Day 1 and Weeks 2, 24 and 26. ▪ **ARM B:** Placebo IV	▪ **ARM A:** Gazyva plus oral steroids ▪ **ARM B:** Mycophenolate mofetil (MMF) plus oral steroids
Primary endpoint	▪ Percentage of participants who achieve Systemic Lupus Erythematosus Responder Index (SRI) at week 52	▪ Percentage of participants with sustained complete remission at 1 year
Status	▪ FPI Q4 2021 ▪ Recruitment completed Q3 2024	▪ FPI Q1 2023 ▪ Recruitment completed Q3 2024
CT Identifier	NCT04963296	NCT05627557

In collaboration with Biogen
*also known as pediatric nephrotic syndrome (PNS); IV: Intravenous

Lunsumio (mosunetuzumab, RG7828, CD20 x CD3)

Bispecific anti-CD20/CD3 antibody engaging T and B cells simultaneously

Indication	Systemic lupus erythematosus (SLE)
Phase/study	**Phase I**
# of patients	N=15
Design	▪ **ARM A:** Lunsumio SC on either Day 1 or on Days 1 and 8 ▪ **ARM B:** Fractionated (divided) dose of mosunetuzumab SC on Days 1 and 8
Primary endpoint	▪ Safety
Status	▪ FPI Q1 2022 ▪ Recruitment completed Q3 2023 ▪ Data presented at EULAR 2025
CT Identifier	NCT05155345

In collaboration with Biogen
SC: subcutaneous

Xolair (omalizumab, RG3648)

Humanized monoclonal antibody that selectively binds to IgE

Indication	Food allergy
Phase/study	**Phase III** **OUtMATCH**[1]
# of patients	N=180
Design	▪ Xolair by SC injection either Q2W or Q4W for 16 to 20 weeks
Primary endpoint	▪ Proportion of participants that successfully consume a single dose of ≥600 mg of peanut protein without dose-limiting symptoms
Status	▪ Study met primary endpoint Q3 2023 ▪ Filed in US Q3 2023 ▪ Priority review granted by FDA Q4 2023 ▪ Approved US Q1 2024 ▪ Published in NEJM 2024; 390(10):889-899 ▪ Data for OUtMATCH Stage 2 and 3 presented at AAAAI 2025
CT Identifier	NCT03881696

In collaboration with Novartis; [1] Sponsor of the study is the National Institute of Allergy and Infectious Diseases (NIAID)
IgE: Immunoglobulin E; SC: Subcutaneous

Enspryng (satralizumab, RG6168, SA237)

Anti-IL-6 receptor humanized monoclonal antibody

Indication	Thyroid eye disease	
Phase/study	**Phase III SatraGo-1**	**Phase III SatraGo-2**
# of patients	N=120	N=120
Design	▪ **ARM A:** Satralizumab at weeks 0, 2, 4 (loading doses) and maintenance doses Q4W ▪ **ARM B:** Placebo	▪ **ARM A:** Satralizumab at weeks 0, 2, 4 (loading doses) and maintenance doses Q4W ▪ **ARM B:** Placebo
Primary endpoint	▪ Proportion of participants with active disease achieving ≥ 2 mm reduction in proptosis from baseline (Day 1) at week 24 in the study eye, provided there is no deterioration of proptosis (≥ 2mm increase) in the fellow eye	▪ Proportion of participants with active disease achieving ≥ 2 mm reduction in proptosis from baseline (Day 1) at week 24 in the study eye, provided there is no deterioration of proptosis (≥ 2mm increase) in the fellow eye
Status	▪ FPI Q4 2023 ▪ Recruitment completed Q1 2025	▪ FPI Q4 2023 ▪ Recruitment completed Q1 2025
CT Identifier	NCT05987423	NCT06106828

In collaboration with Chugai

Susvimo (PDS, RG6321)

First eye implant to achieve sustained delivery of a biologic medicine

Indication	Wet age-related macular degeneration (wAMD)		
Phase/study	**Phase III Archway**	**Phase II+III extension Portal**	**Phase IIIb Velodrome**
# of patients	N=418	N=1,000	N=442
Design	▪ **ARM A:** PDS 100mg/mL Q24W ▪ **ARM B:** Intravitreal ranibizumab Q4W	▪ Ex-LADDER/ex-Archway: PDS 100mg/mL Q24W ▪ Ex-Velodrome, not meeting Q36W criteria @ week 24: PDS 100mg/mL Q24W ▪ Ex-Velodrome (completed or withdrawn): PDS Q24W or Q36W (as per Velodrome randomization)	▪ **ARM A:** PDS 100mg/mL Q36W ▪ **ARM B:** PDS 100mg/mL Q24W
Primary endpoint	▪ Change in BCVA from baseline at the average of week 36 and week 40	▪ Long term safety efficacy	▪ Change in BCVA from baseline averaged over weeks 68 and 72
Status	▪ Study met primary endpoint Q2 2020 ▪ Data presented at ASRS 2020, 44/48 week data at Angiogenesis 2021 and 2-year data at Angiogenesis 2022 ▪ Filed in US (PRIME) and EU Q2 2021 ▪ Approved in US Q4 2021	▪ FPI Q3 2018	▪ FPI Q3 2021
CT Identifier	NCT03677934	NCT03683251	NCT04657289

BCVA: Best corrected visual acuity; wAMD: Wet age-related macular degeneration; ASRS: American Society of Retinal Specialists; PDS: Port Delivery System with ranibizumab; PRIME: Priority review

Susvimo (PDS, RG6321)

First eye implant to achieve sustained delivery of a biologic medicine

Indication	Diabetic macular edema (DME)	Diabetic retinopathy (DR) without center-involved diabetic macular edema (DME)
Phase/study	**Phase III Pagoda**	**Phase III Pavilion**
# of patients	N=634	N=174
Design	▪ **ARM A:** Intravitreal ranibizumab (X4) followed by PDS 100mg/mL Q24W ▪ **ARM B:** Intravitreal ranibizumab Q4W until PDS 100mg/mL is received	▪ **ARM A:** Intravitreal ranibizumab (X2) followed by PDS 100mg/mL (refill Q36W) ▪ **ARM B:** Q4W comprehensive clinical monitoring (with IVT ranibizumab as needed) until participants receive PDS 100mg/mL (refill Q36W)
Primary endpoint	▪ Change in BCVA from baseline at the average of week 60 and week 64	▪ Percentage of participants with a ≥2-step improvement from baseline on the ETDRS-DRSS at Week 52
Status	▪ FPI Q3 2019 ▪ Recruitment completed Q2 2021 ▪ Study met its primary endpoint Q4 2022 ▪ Data presented at Angiogenesis 2023 ▪ Filed in US Q2 2024 ▪ 2-year data presented at ASRS 2024 ▪ Approved in US Q1 2025	▪ FPI Q3 2020 ▪ Recruitment completed Q3 2021 ▪ Study met its primary endpoint Q4 2022 ▪ Data presented at Angiogenesis 2023 ▪ Filed in US Q2 2024 ▪ 2-year data presented at ASRS 2024 ▪ Approved in US Q2 2025
CT Identifier	NCT04108156	NCT04503551

BCVA: Best corrected visual acuity; ETDRS: Early Treatment Diabetic Retinopathy Study; DRSS: Diabetic Retinopathy Severity Scale; PDS: Port Delivery System with ranibizumab

Vabysmo (faricimab, RG7716)

Bispecific antibody for the eye which targets and inhibits two signalling pathways (Ang-2 and VEGF-A)

Indication	Center-involving diabetic macular edema (CI-DME)	
Phase/study	**Phase III YOSEMITE**	**Phase III RHINE**
# of patients	N=940	N=951
Design	▪ **ARM A:** Vabysmo 6.0 mg Q8W ▪ **ARM B:** Vabysmo 6.0 mg PTI up to Q16W ▪ **ARM C:** Aflibercept, 2.0 mg Q8W	▪ **ARM A:** Vabysmo 6.0 mg Q8W ▪ **ARM B:** Vabysmo 6.0 mg PTI up to Q16W ▪ **ARM C:** Aflibercept 2.0 mg Q8W
Primary endpoint	▪ Change from baseline in BCVA at 1 year	▪ Change from baseline in BCVA at 1 year
Status	▪ Study met primary endpoint Q4 2020 ▪ Data presented at Angiogenesis 2021 ▪ Filed in US and EU Q2 2021 ▪ Published in the *Lancet* 2022 19;399(10326):741-755. ▪ 2-year data presented at Angiogenesis 2022 ▪ Approved in US Q1 2022 and EU Q3 2022 ▪ Post-hoc data indicating fast retinal drying presented at ARVO 2023	
CT Identifier	NCT03622580	NCT03622593

Ang-2: Angiopoietin-2; VEGF: Vascular endothelial growth factor; PTI: Personalized Treatment Interval; BCVA: best corrected visual acuity, ARVO: Association for Research in Vision and Ophthalmology

Vabysmo (faricimab, RG7716)

Bispecific antibody for the eye which targets and inhibits two signalling pathways (Ang-2 and VEGF-A)

Indication	Wet age related macular degeneration (wAMD)	
Phase/study	**Phase III TENAYA**	**Phase III LUCERNE**
# of patients	N=671	N=658
Design	▪ **ARM A:** Vabysmo 6.0mg Q16W flexible after 4 IDs ▪ **ARM B:** Aflibercept 2.0mg Q8W after 3 IDs	▪ **ARM A:** Vabysmo 6.0mg Q16W flexible after 4 IDs ▪ **ARM B:** Aflibercept 2.0mg Q8W after 3 IDs
Primary endpoint	▪ Change from baseline in BCVA week 40, 44 & 48	▪ Change from baseline in BCVA week 40, 44 & 48
Status	▪ Study met primary endpoint Q1 2021 ▪ Data presented at Angiogenesis 2021 ▪ Filed in US and EU Q2 2021 ▪ Published in Lancet 2022 Feb 19;399(10326):729-740 ▪ Approved in US Q1 2022 and EU Q3 2022 ▪ 2-year data presented at ASRS 2022 ▪ Post-hoc data indicating fast retinal drying presented at ARVO 2023	
CT Identifier	NCT03823287	NCT03823300

BCVA: Best corrected visual acuity; Ang-2: Angiopoietin-2; VEGF: Vascular endothelial growth factor; IDs: Initiating doses; ASRS: American Society of Retina Specialists, ARVO: Association for Research in Vision and Ophthalmology

Vabysmo (faricimab, RG7716)

Bispecific antibody for the eye which targets and inhibits two signalling pathways (Ang-2 and VEGF-A)

Indication	Macular edema (ME) secondary to branch retinal vein occlusion (RVO)	Macular edema (ME) secondary to central retinal vein occlusion (RVO)
Phase/study	**Phase III** **BALATON**	**Phase III** **COMINO**
# of patients	N=570	N=750
Design	▪ **ARM A:** Vabysmo 6.0 mg Q4W/PTI ▪ **ARM B:** Aflibercept 2.0 mg Q4W	▪ **ARM A:** Vabysmo 6.0 mg Q4W/PTI ▪ **ARM B:** Aflibercept 2.0 mg Q4W
Primary endpoint	▪ Change from baseline in BCVA at week 24	▪ Change from baseline in BCVA at week 24
Status	▪ FPI Q1 2021 ▪ Recruitment completed Q1 2022 ▪ Study met its primary endpoint Q4 2022 ▪ Data presented at Angiogenesis 2023 ▪ Filed in US Q2 2023 and EU Q3 2023 ▪ Approved in US Q4 2023, approved in EU Q3 2024 ▪ Published in Ophthalmology Q1 2024 ▪ 72 week data presented at Angiogenesis 2024	
CT Identifier	NCT04740905	NCT04740931

PTI: Personalized Treatment Interval; BCVA: Best corrected visual acuity; Ang-2: Angiopoietin-2; VEGF: Vascular endothelial growth factor

Vabysmo (faricimab, RG7716)

Bispecific antibody for the eye which targets and inhibits two signalling pathways (Ang-2 and VEGF-A)

Indication	Myopic choroidal neovascularization (CNV)
Phase/study	**Phase III** **POYANG**
# of patients	n=280
Design	▪ **ARM A:** Vabysmo 6.0 mg Q4W PRN ▪ **ARM B:** Ranibizumab 0.5 mg Q4W PRN
Primary endpoint	▪ Change from Baseline in Best-Corrected Visual Acuity (BCVA) Averaged Over Weeks 4, 8, and 12
Status	▪ FPI Q1 2024 ▪ Recruitment completed Q2 2025
CT Identifier	NCT06176352

Ang-2: Angiopoietin-2; VEGF: Vascular endothelial growth factor; PRN: Pro re nata

Xofluza (baloxavir marboxil, RG6152, S-033188)

Small molecule, novel CAP-dependent endonuclease inhibitor

Indication	Influenza		
Phase/study	**Phase III** **miniSTONE 1 (0-1 year old)**	**Phase III** **miniSTONE 2 (1- <12 years old)**	**Phase IIIb** **CENTERSTONE**
# of patients	N=30	N=176	N=3,160
Design	Healthy pediatric patients from birth to <1 year with influenza-like symptoms receive Xofluza on Day 1	Healthy pediatric patients 1 to <12 years of age with influenza-like symptoms ▪ **ARM A:** Xofluza ▪ **ARM B:** Tamiflu	Reduction of direct transmission of influenza from otherwise healthy patients to household contacts ▪ **ARM A:** Xofluza ▪ **ARM B:** Placebo
Primary endpoint	▪ Safety	▪ Safety	▪ Percentage of household contacts who are PCR-positive for influenza by day 5 post randomization of index patients
Status	▪ FPI Q1 2019 ▪ Recruitment completed Q3 2023 ▪ Data presented at ESPID 2024 ▪ Filed in the EU Q2 2024 ▪ Approved in EU Q2 2025	▪ Primary endpoint met Q2 2019 ▪ Data presented at OPTIONS X 2019 ▪ Filed in US Q1 2020 and EU Q4 2021 ▪ Data published in *Pediatric Infectious Disease* 2020 Aug;39(8):700-705 ▪ Approved in the US (age 5 years and older) Q3 2022 , EU Jan 2023 and China (age 5 years and older) Q1 2023	▪ FPI Q4 2019 ▪ Recruitment Completed Q2 2024 ▪ Primary endpoint met Q3 2024 ▪ Data presented at OPTIONS XII 2024 ▪ Filed in US Q4 2024 ▪ Data published in NEJM 2025 Apr;392(16):1582-1593
CT Identifier	NCT03653364	NCT03629184	NCT03969212

In collaboration with Shionogi & Co., Ltd.
CAP: Catabolite Activating Protein

Roche Group development pipeline

Marketed products development programmes

Roche Pharma global development programmes

Roche Pharma research and early development (pRED)

Genentech research and early development (gRED)

Divarasib (KRAS G12C inhibitor, RG6330, GDC-6036)

A potent, orally available, and selective inhibitor of the KRAS G12C mutant protein

Indication	1L NSCLC	2L NSCLC	1L NSCLC
Phase/study	**Phase Ib KRASCENDO 170**	**Phase III KRASCENDO 1**	**Phase III KRASCENDO 2**
# of patients	N=60	N=320	N=600
Design	▪ **Cohort A**: Combination of divarasib plus pembrolizumab ▪ **Cohort B:** Combination of divarasib plus pembrolizumab plus carboplatin/cisplatin plus pemetrexed	▪ H2H vs KRAS G12Ci ▪ **ARM A**: divarasib ▪ **ARM B**: locally available G12Ci (sotorasib or adagrasib)	▪ **ARM A:** divarasib + pembrolizumab ▪ **ARM B:** pembrolizumab + carboplatin/cisplatin + pemetrexed
Primary endpoint	▪ Safety, tolerability	▪ PFS	▪ PFS ▪ OS
Status	▪ **Cohort A**: FPI Q2 2023 ▪ **Cohort B**: FPI Q1 2024	▪ FPI Q3 2024	▪ FPI expected Q4 2025
CT Identifier	NCT05789082	NCT06497556	NCT06793215

NSCLC: Non-small cell lung cancer; PD-L1: Programmed cell death-ligand

Divarasib (KRAS G12C inhibitor, RG6330, GDC-6036)

A potent, orally available, and selective inhibitor of the KRAS G12C mutant protein

Indication	Advanced or metastatic solid tumors with a KRAS G12C mutation	1L metastatic colorectal cancer (mCRC)
Phase/study	**Phase I**	**Phase Ib** **INTRINSIC**
# of patients	N=438	Modular design
Design	Monotherapy and combinations of divarasib with other anti-cancer therapies	Single arm studies: ▪ Cohort H: divarasib + Avastin + FOLFOX ▪ Cohort I: divarasib + Avastin + FOLFIRI
Primary endpoint	▪ Safety	▪ Safety
Status	▪ FPI Q3 2020 ▪ Data presented at WCLC 2022, ESMO 2022, WCLC 2024, ESMO 2024 ▪ Data published in *NEJM* 2023 24;389(8):710-721	▪ FPI Q1 2023
CT Identifier	NCT04449874	NCT04929223

WCLC: World Conference on Lung Cancer; ESMO: European Society for Medical Oncology; CRC: Colorectal cancer

Giredestrant (SERD (3), RG6171, GDC-9545)

A selective estrogen receptor degrader or downregulator

Indication	ER+ HER2-negative metastatic breast cancer (mBC)
Phase/study	**Phase I**
# of patients	N=181
Design	▪ Dose escalation and expansion at RPTD ▪ Giredestrant monotherapy and in combination with palbociclib and/or LHRH agonist
Primary endpoint	▪ Safety
Status	▪ FPI Q4 2017 ▪ Data presented at SABCS 2019, 2021 and ASCO 2020, 2021
CT Identifier	NCT03332797

ER: Estrogen receptor; HER2: Human Epidermal growth factor Receptor; RPTD: Recommended phase II dose; LHRH: Luteinizing hormone–releasing hormone; SABCS: San Antonio Breast Cancer Symposium; ASCO: American Society of Clinical Oncology

Giredestrant (SERD (3), RG6171, GDC-9545)

A selective estrogen receptor degrader or downregulator

Indication	Grade 1 endometrial cancer	1L ER-positive metastatic breast cancer (mBC)	Adjuvant ER-positive breast cancer (BC)
Phase/study	**Phase II endomERA**	**Phase III persevERA Breast Cancer**	**Phase III lidERA Breast Cancer**
# of patients	N=45	N=978	N=4,100
Design	▪ Giredestrant once a day (QD) on days 1 to 28 of each 28-day cycle for 6 cycles	▪ **ARM A:** Giredestrant plus palbociclib ▪ **ARM B:** Letrozole plus palbociclib	▪ **ARM A:** Giredestrant monotherapy ▪ **ARM B:** Tamoxifen or aromatase inhibitor
Primary endpoint	▪ Percentage of participants who have regression by 6 months	▪ Progression-free survival	▪ Invasive disease-free survival
Status	▪ FPI Q2 2020 ▪ Recruitment completed Q3 2024	▪ FPI Q4 2020 ▪ Recruitment completed Q1 2023	▪ FPI Q3 2021 ▪ Recruitment completed Q3 2023
CT Identifier	NCT05634499	NCT04546009	NCT04961996

ER: Estrogen receptor

Giredestrant (SERD (3), RG6171, GDC-9545)

A selective estrogen receptor degrader or downregulator

Indication	post-CDK4/6 ER-positive/HER2-negative breast cancer (BC)	1L ER-positive/HER2-positive breast cancer (BC)	ET resistant ER+/HER2-negative breast cancer (BC)
Phase/study	**Phase III evERA**	**Phase III heredERA**	**Phase III pionERA**
# of patients	N=224	N=812	N=1050
Design	▪ **ARM A**: giredestrant plus everolimus ▪ **ARM B**: exemestane plus everolimus	Induction Phesgo plus taxane followed by maintenance with either: ▪ **ARM A:** Giredestrant plus Phesgo ▪ **ARM B:** Phesgo	▪ **ARM A**: Giredestrant plus CDK4/6i ▪ **ARM B**: Fulvestrant plus CDK4/6i
Primary endpoint	▪ Progression-free survival	▪ Progression-free survival	▪ Progression-free survival in ESR1m and ITT
Status	▪ FPI Q3 2022 ▪ Recruitment completed Q3 2024	▪ FPI Q2 2022	▪ FPI Q4 2023
CT Identifier	NCT05306340	NCT05296798	NCT06065748

ER: Estrogen receptor; HER2: Human Epidermal growth factor Receptor; Phesgo: FDC of Perjeta and Herceptin for SC administration with Halozyme's rHuPH20/ Halozyme's human hyaluronidase; ITT: Intention to treat

Tiragolumab (anti-TIGIT, RG6058, MTIG7192A)

Monoclonal antibody targeting the immune checkpoint inhibitor TIGIT

Indication	Stage III unresectable 1L NSCLC	1L HCC
Phase/study	**Phase III SKYSCRAPER-03**	**Phase III SKYSCRAPER-14**
# of patients	N=800	N=650
Design	▪ **ARM A:** Tiragolumab plus Tecentriq for up to 12 months ▪ **ARM B:** Durvalumab for up to 12 months	▪ **ARM A:** Tecentriq plus Avastin plus tiragolumab ▪ **ARM B:** Tecentriq plus Avastin plus placebo
Primary endpoint	▪ Progression-free survival	▪ Progression-free survival (INV=Investigator-assessed); Overall survival
Status	▪ FPI Q3 2020 ▪ Recruitment completed Q2 2023 ▪ Primary endpoint of PFS not met July 2025.	▪ FPI Q3 2023 ▪ Recruitment completed Q3 2024 ▪ Primary endpoint of PFS not met Q2 2025. OS was not mature at this time, but no trend of OS benefit was observed.
CT Identifier	NCT04513925	NCT05904886

NSCLC: Non-small cell lung cancer; PD-L1: Programmed cell death-ligand 1; TPS: Tumor Proportion Score; PFS: Progression-free survival

NXT007 (FIXa x FX, RG6512)

Bispecific antibody which targets Factor IXa and Factor X

Indication	**Severe or Moderate Hemophilia A**
Phase/study	**Phase I/II (multiple-ascending dose)**
# of patients	N=40
Design	▪ Two loading doses of NXT007 SC (Q2W) followed by Q4W maintenance dosing
Primary endpoint	▪ Safety
Status	▪ FPI Q4 2023 ▪ Recruitment completed Q4 2024
CT Identifier	NCT05987449

In collaboration with Chugai
SC: subcutaneous; FIXa: Factor 9a; FX: Factor 10

Emugrobart (RG6237, GYM 329)

Recycling and antigen-sweeping monoclonal anti-latent myostatin antibody

Indication	Facioscapulohumeral Muscular Dystrophy (FSHD)	Spinal muscular atrophy (SMA)
Phase/study	**Phase II** **MANOEUVRE**	**Phase II/III** **MANATEE**[1]
# of patients	N=48	N=259

Design	▪ 4w baseline movement data collection (wearable device) followed by
	▪ **ARM A:** emugrobart SC Q4W for 52w
	▪ **ARM B:** Placebo SC Q4W for 52w
		▪ **PART I:** 24w DB + 72w open label +2y OLE
		  ▪ Cohort A-C - ambulant (2-4y/5-10y):emugrobart SC Q4W+Evrysdi vs. Placebo + Evrysdi
		  ▪ Cohort D - non-ambulant (5-10y): emugrobart SC Q4W+Evrysdi vs Placebo + Evrysdi
		▪ **PART II:** 72w DB + 2y OLE
		  ▪ ARM A: emugrobart SC Q4W + Evrysdi
		  ▪ ARM B: Placebo SC Q4W + Evrysdi

Primary endpoint	▪ Percent change in contractile muscle volume of quadriceps femoris muscles by MRI at week 52 and safety	▪ Change from baseline in RHS score after week 72 of treatment ▪ Safety, PK/PD and muscle biomarkers
Status	▪ FPI Q1 2023 ▪ Recruitment completed Q2 2024	▪ ODD granted by FDA in Q4 2021 for GYM329 ▪ FPI Part I ambulatory cohorts Q2 2022; non-ambulatory cohort July 2023 ▪ Recruitment completed Q4 2024
CT Identifier	NCT05548556	NCT05115110

[1]In collaboration with PTC Therapeutics and SMA Foundation; emugrobart (GYM 329) in collaboration with Chugai

DB: double blind; PK/PD: Pharmacokinetics/Pharmacodynamics; OLE: Open Label Extension; ODD: Orphan drug designation; RHS: Revised hammersmith scale ; MRI: Magnetic Resonance Imaging, SC: Subcutaneous

Emugrobart (RG6237, GYM 329)

Recycling and antigen-sweeping monoclonal anti-latent myostatin antibody

Indication	Obesity	
Phase/study	**Phase Ib**	**Phase II GYMINDA**
# of patients	N=30-36	N=234
Design	▪ **Cohort A** (n=15-18): Single dose emugrobart 50mg SC ▪ **Cohort B** (n=15-18): Multiple dosing 180mg SC Q4W week plus loading dose for first 3 doses	▪ 48w DB Tx period: Arm A : Tirzepatide + Placebo Arm B: Tirzepatide + GYM 329 (low SC Q4W) Arm C: Tirzepatide + GYM 329 (med SC Q4W) Arm D: Tirzepatide + GYM329 (high SC Q4W) Extension: Arm A-C switched to placebo Arm D re-randomized to GYM329 Q4W or placebo
Primary endpoint	▪ PK/PD, tolerability, safety	▪ Percent (%) change in body weight from baseline at Week 48
Status	▪ FPI Q2 2024	▪ FPI Q2 2025
CT Identifier		NCT06965413

emugrobart (GYM 329) in collaboration with Chugai
SC: Subcutaneous

Fenebrutinib (RG7845, GCD-0853)

Highly selective and reversible (noncovalent) bruton tyrosine kinase

Indication	Relapsing multiple sclerosis (RMS)		
Phase/study	**Phase III FENhance 1**	**Phase III FENhance 2**	**Phase II (Biomarker study) FENopta**
# of patients	N=746	N=751	N=109
Design	▪ **ARM A:** Fenebrutinib twice daily oral ▪ **ARM B:** Teriflunomide once daily oral	▪ **ARM A:** Fenebrutinib twice daily oral ▪ **ARM B:** Teriflunomide once daily oral	▪ **ARM A:** Fenebrutinib ▪ **ARM B:** Placebo
Primary endpoint	▪ Annualized relapse rate	▪ Annualized relapse rate	▪ Total number of new gadolinium-enhancing T1 lesions observed on MRI scans of the brain at 12 weeks
Status	▪ FPI Q1 2021 ▪ Recruitment completed Q1 2024	▪ FPI Q1 2021 ▪ Recruitment completed Q4 2023	▪ Data presented at EAN and ECTRIMS 2023 ▪ 48-week OLE data presented at ECTRIMS 2024 ▪ 96 week OLE data presented at CMSC 2025
CT Identifier	NCT04586010	NCT04586023	NCT05119569

IV: Intravenous; cCDP12: Composite 12-week confirmed disability progression

Fenebrutinib (RG7845, GCD-0853)

Highly selective and reversible (noncovalent) bruton tyrosine kinase

Indication	Primary progressive multiple sclerosis (PPMS)
Phase/study	**Phase III** **FENtrepid**
# of patients	N=985
Design	▪ **ARM A:** Fenebrutinib twice daily oral ▪ **ARM B:** Ocrevus 2x300mg IV Q24W
Primary endpoint	▪ Time to onset of cCDP12
Status	▪ FPI Q4 2020 ▪ Recruitment completed Q2 2023
CT Identifier	NCT04544449

MRI: Magnetic resonance imaging; EAN: European Academy of Neurology

Prasinezumab (anti-αSynuclein; RG7935)

Anti-alpha-synuclein antibody early-stage under investigation for Parkinson's disease

Indication	Early-stage Parkinson's disease	
Phase/study	**PASADENA** **Phase II**	**PADOVA** **Phase IIb**
# of patients	316	586
Design	▪ PART 1:ARM A: Prasinezumab IV Q4W (low dose) ▪ ARM B: Prasinezumab IV Q4W (high dose) ▪ ARM C: Placebo Q4W ▪ Part 2: ▪ COHORT A: Prasinezumab IV Q4W (low dose) vs Placebo Q4W ▪ COHORT B: Prasinezumab IV Q4W (high dose) vs Placebo Q4W ▪ Part 3:All low dose and high dose participants to receive low dose prasinezumab IV Q4W for an additional 5 years	▪ ARM A: Prasinezumab IV Q4W ▪ ARM B: Placebo Q4W ▪ OLE: Participant to enter the OLE once double-blind tx period has been completed
Primary endpoint	▪ Change from baseline in movement disorder society-unified Parkinson's disease rating scale (MDS-UPDRS) total score (sum of Parts I, II, and III) at week 52	▪ Time to Confirmed Motor Progression Event from BL to 28 days after last dose
Status	▪ Recruitment completed Q4 2018 ▪ Data presented at MDS & ADPD 2020-22 ▪ OLE data presented at MDS 2023 and ADPD 2024	▪ Recruitment completed Q1 2023 ▪ Primary endpoint missed, but numerical delay in motor progression and positive trends on multiple secondary and exploratory endpoints shown. ▪ Data presented at ADPD 2025
CT Identifier	NCT03100149	NCT04777331

In collaboration with Prothena

Tominersen (HTT ASO, RG6042)

Antisense oligonucleotide (ASO) targeting human HTT mRNA

Indication	Huntington's disease
Phase/study	**Phase II** **GENERATION HD2**
# of patients	N=300
Design	Patients aged 25 to 50 years with prodromal (very early subtle signs of HD) or early manifest HD ▪ **ARM A:** Tominersen 60mg Q16W via a lumbar puncture ▪ **ARM B:** Tominersen 100mg Q16W via a lumbar puncture ▪ **ARM C:** Placebo Q16W via a lumbar puncture
Primary endpoint	▪ Safety, biomarkers and efficacy
Status	▪ FPI Q1 2023 ▪ Recruitment completed Q4 2024
CT Identifier	NCT05686551

In collaboration with IONIS
HD: Huntington's Disease; HTT: Huntingtin

Trontinemab (BS-anti-Aβ mAb, RG6102)

A novel Brainshuttle™ bispecific 2+1 monoclonal antibody targeting Aβ

Indication	Prodromal or mild to moderate Alzheimer's Disease
Phase/study	**Phase I/II**
# of patients	N=210
Design	▪ **PART 1** (dose escalation): Q4W trontinemab or placebo for 28w (5 dosing cohorts) ▪ **PART 2** (expansion): Q4W trontinemab vs placebo for 28w (1.8mg/kg and 3.6mg/kg cohorts) ▪ **PART 3** (PK/PD): Q4W trontinemab vs placebo (1.8mg/kg); Q12W trontinemab vs placebo (3.6mg/kg) ▪ **PART 4** (open label extension): For all parts
Primary endpoint	▪ Part 1-4: Percentage of Participants with AEs ▪ Part 3: Change From baseline in brain amyloid load (via PET)
Status	▪ FPI Q1 2021 ▪ Data showing rapid, robust amyloid depletion presented at ADPD, CTAD 2024 and ADPD 2025
CT Identifier	NCT04639050

BS: Brainshuttle™; mAb: monoclonal antibody

Astegolimab (Anti-ST2, RG6149)

A monoclonal antibody that selective binds to ST2

Indication	Chronic obstructive pulmonary disease (COPD)	
Phase/study	**Phase IIb ALIENTO**	**Phase III ARNASA**
# of patients	N=1,290	N=1,290
Design	▪ **ARM A:** SC astegolimab Q2W ▪ **ARM B:** SC astegolimab Q4W ▪ **ARM C:** SC placebo Q2W	▪ **ARM A:** SC astegolimab Q2W ▪ **ARM B:** SC astegolimab Q4W ▪ **ARM C:** SC placebo Q2W
Primary endpoint	▪ Annualized rate of moderate and severe COPD exacerbations over the 52-week treatment period	▪ Annualized rate of moderate and severe COPD exacerbations over the 52-week treatment period
Status	▪ FPI Q4 2021 ▪ Recruitment completed Q1 2024 ▪ Primary endpoint met when astegolimab was given every two weeks (July 2025)	▪ FPI Q1 2023 ▪ Recruitment completed Q2 2024 ▪ Primary endpoint not met when astegolimab was given every two weeks (July 2025)
CT Identifier	NCT05037929	NCT05595642

In collaboration with Amgen

COPD: Chronic obstructive pulmonary disease, SC: Subcutaneous

Sefaxersen (ASO factor B, RG6299)

Antisense oligonucleotide that targets factor B

Indication	IgA nephropathy (IgAN)	
Phase/study	**Phase II***	**Phase III IMAGINATION**
# of patients	N=23	N=428
Design	▪ Sefaxersen SC at week 1 following Q4W dosing through week 25 ▪ Optional 48-week extension (Q4W)	▪ **ARM A:** Sefaxersen SC at week 1, 3, 5 following Q4W dosing for 104 weeks ▪ **ARM B:** Placebo
Primary endpoint	▪ % reduction in 24-hour urine protein excretion at week 29	▪ Change in UPCR at week 37 from baseline
Status	▪ FPI Q2 2020 ▪ Recruitment completed Q3 2023 ▪ Data presented at ASN 2024	▪ FPI Q3 2023
CT Identifier	NCT04014335	NCT05797610

In collaboration with IONIS

*Study run by IONIS, UPCR: Urine protein-to-creatinine ratio; SC: Subcutaneous; ASO: Antisense oligonucleotide

Afimkibart (anti-TL1A, RG6631)

A monoclonal antibody targeting TL1A, blocking TH1 and TH17 pathways

Indication	Moderate to severe ulcerative colitis	Moderate to severe ulcerative colitis
Phase/study	**Phase III** **AMETRINE-1**	**Phase III** **AMETRINE-2**
# of patients	N=400	N=350
Design	▪ **ARM A:** Afimkibart IV induction followed by afimkibart SC maintenance ▪ **ARM B:** Placebo IV followed by placebo SC maintenance	▪ **ARM A:** Afimkibart IV induction ▪ **ARM B:** Placebo IV
Primary endpoint	▪ Modified Mayo Score 0–2 (Stool Frequency Subscore = 0 or 1, Rectal Bleeding Subscore = 0, Endoscopic subscore = 0 or 1) at week 12 or week 52	▪ Modified Mayo Score 0–2 (Stool Frequency Subscore = 0 or 1, Rectal Bleeding Subscore = 0, Endoscopic subscore = 0 or 1) at week 12
Status	▪ FPI Q3 2024	▪ FPI Q4 2024
CT Identifier	NCT06589986	NCT06588855

TL1A: Tumor necrosis factor-like cytokine 1A; SC: subcutaneous; ; IV: Intravenous; TH: T helper cell

Afimkibart (anti-TL1A, RG6631)

A monoclonal antibody targeting TL1A, blocking TH1 and TH17 pathways

Indication	Moderate to severe Crohn's Disease	
Phase/study	**Phase III SIBERITE-1**	**Phase III SIBERITE-2**
# of patients	N=600	N=425
Design	▪ Treat-through design with no re-randomization after induction ▪ **ARM A:** Afimkibart IV induction followed by SC maintenance (high dose) ▪ **ARM B:** Afimkibart IV induction followed by SC maintenance (low dose) ▪ **ARM C:** Placebo IV followed by placebo SC maintenance	▪ Induction only ▪ **ARM A:** Afimkibart IV induction ▪ **ARM B:** Placebo IV

Primary endpoint	▪ Co-primary endpoints:
	  ▪ Clinical remission (CDAI <150) at w52
	  ▪ Decrease in SES-CD from BL ≥50% at w52
		▪ Co-primary endpoints:
		  ▪ Clinical remission (CDAI <150) at w12
		  ▪ Decrease in SES-CD from BL ≥50% at w12

Status	▪ FPI Q1 2025	▪ FPI Q2 2025
CT Identifier	NCT06819878	NCT06819891

TL1A: Tumor necrosis factor-like cytokine 1A; SC: subcutaneous; IV: Intravenous; CDAI: Crohn's Disease Activity Index; SES-CD: Simple Endoscopic Score for Crohn's Disease

Afimkibart (anti-TL1A, RG6631)

A monoclonal antibody targeting TL1A, blocking TH1 and TH17 pathways

Indication	Atopic dermatitis	Metabolic Dysfunction-associated Steatohepatitis (MASH)
Phase/study	**Phase II**	**Phase Ib**
# of patients	N=160	N=50
Design	▪ **ARM A:** High dose afimkibart SC ▪ **ARM B:** Med dose afimkibart SC ▪ **ARM C:** Low dose afimkibart SC ▪ **ARM D:** Placebo	▪ Afimkibart IV at w0, w2, w6, w10 + afimkibart SC from w14-50
Primary endpoint	▪ Percentage achieving EASI-75 Response (≥75% Improvement from baseline) at week 16	▪ Percentage of participants with AEs from baseline to w52
Status	▪ FPI April 2025	▪ FPI April 2025
CT Identifier	NCT06863961	NCT06903065

TL1A: Tumor necrosis factor-like cytokine 1A; SC: Subcutaneous; EASI-75: Eczema Area and Severity Index-75

Vamikibart (anti-IL-6, RG6179)

A monoclonal antibody that potently binds interleukin-6 (IL-6) cytokine

Indication	Diabetic macular edema (DME) and Uveitic macular edema (UME)	Diabetic macular edema (DME)	
Phase/study	**Phase I DOVETAIL**	**Phase II BARDENAS**	**Phase II ALLUVIUM**
# of patients	N=90	N=210-230	N=360-400
Design	▪ Part I: Multiple ascending dose study of intravitreal monotherapy ▪ Part II: monotherapy and in combination with anti-VEGF	▪ **ARM A:** Vamikibart plus ranibizumab ▪ **ARM B:** Ranibizumab plus sham control	▪ **Arm A:** 0.25 mg vamikibart Q8W ▪ **Arm B:** 1.0 mg vamikibart Q8W ▪ **Arm C:** 1.0 mg vamikibart Q4W ▪ **Arm D**: 0.5 mg ranibizumab Q4W
Primary endpoint	▪ Safety, tolerability, PK	▪ Mean change from baseline in BCVA averaged over week 44 and week 48	▪ Mean change from baseline in BCVA averaged over week 44 and week 48
Status	▪ FPI Q3 2019 ▪ Data presentation at ARVO 2023, ASRS 2023, ASRS 2024 and EURETINA 2024	▪ FPI Q4 2021 ▪ Recruitment completed Q2 2023	▪ FPI Q4 2021 ▪ Recruitment completed Q4 2023
CT Identifier		NCT05151744	NCT05151731

PK: Pharmacokinetics; BCVA: Best corrected visual acuity, ARVO: Association for Research in Vision & Ophthalmology

Vamikibart (anti-IL-6, RG6179)

A monoclonal antibody that potently binds interleukin-6 (IL-6) cytokine

Indication	Uveitic macular edema (UME)	
Phase/study	**Phase III MEERKAT**	**Phase III SANDCAT**
# of patients	N=225	N=225
Design	▪ **ARM A:** Vamikibart low-dose Q4W to week 12, followed by PRN ▪ **ARM B:** Vamikibart high-dose Q4W to week 12, followed by PRN ▪ **ARM C:** Sham control Q4W to week 12, followed by PRN	▪ **ARM A:** Vamikibart low-dose Q4W to week 12, followed by PRN ▪ **ARM B:** Vamikibart high-dose Q4W to week 12, followed by PRN ▪ **ARM C:** Sham control Q4W to week 12, followed by PRN
Primary endpoint	▪ Proportion of participants with ≥ 15 letter improvement from baseline in BCVA at week 16	▪ Proportion of participants with ≥ 15 letter improvement from baseline in BCVA at week 16
Status	▪ FPI Q1 2023 ▪ Recruitment completed Q2 2024	▪ FPI Q1 2023 ▪ Recruitment completed Q4 2024
CT Identifier	NCT05642312	NCT05642325

BCVA: Best corrected visual acuity; PRN: Pro re nata

CT-388 (GLP-1/GIP RA, RG6640)

Once-weekly subcutaneous injectable dual GLP-1/GIP receptor agonist

Indication	Overweight/obesity with or without type 2 diabetes	Overweight/obesity without type 2 diabetes	Overweight/obesity with type 2 diabetes
Phase/study	**Phase I**	**Phase II**	**Phase II**
# of patients	N=129	N=450	N=360
Design	▪ Single ascending dose, multiple ascending dose, multiple dose study, with low to high doses of CT-388 up to 24 weeks	▪ CT-388 (low/med/high dose) vs. placebo	▪ CT-388 (low/med/high dose) vs. placebo
Primary endpoint	▪ Safety and tolerability	▪ Efficacy: Percent change in body weight from baseline	▪ Percent Change in Body Weight from baseline ▪ Change in Glycated Hemoglobin (HbA1c) from baseline
Status	▪ Enrollment completed Q2 2024 ▪ Data from cohorts 11 and 12 presented at EASD 2024 (obesity without T2D) ▪ Positive topline results at 12 weeks in people with obesity + T2D Q4 2024 (Cohort 13) ▪ Data from cohorts 12 (effect on liver fat) and 13 (obesity with T2D) presented at ADA 2025	▪ FPI Q3 2024 ▪ Recruitment completed Q4 2024	▪ FPI Q4 2024
CT Identifier	NCT04838405	NCT06525935	NCT06628362

GLP-1: Glucagon-like peptide-1; GIP: Glucose-dependent insulinotropic polypeptide; RA: Receptor agonist; T2D: Type-2 diabetes

CT-996 (GLP-1 RA, RG6652)

Once-daily oral small molecule GLP-1 receptor agonist

Indication	Overweight/obesity with or without type 2 diabetes	Obesity without type 2 diabetes	Glycaemic control trial with T2D participants
Phase/study	**Phase I**	**Phase II**	**Phase II**
# of patients	N=118	N=340	N=240
Design	▪ Single ascending dose, multiple ascending dose, multiple part study, with low to high doses of CT-996 vs placebo up to 4 weeks	▪ ARM 1: Placebo ▪ ARM 2-8: CT-996 with various uptitration schedules and step sizes towards 5 different maxium dosages	▪ ARM 1: Placebo ▪ ARM 2: Commercially available incretin to be uptitrated in line with label ▪ ARM 3-9: CT-996 with various uptitration schedules and step sizes towards 5 different maxium dosages
Primary endpoint	▪ Safety and tolerability	▪ Percent change in body weight at week 30	▪ Percent change in HbA1c at week 30
Status	• FPI Q2 2023 • Positive topline results at 4 weeks in people with obesity without type 2 diabetes July 2024, data presented at EASD 2024	▪ FPI expected Q3 2025	▪ FPI expected Q3 2025
CT Identifier	NCT05814107		

GLP-1: Glucagon-like peptide-1; RA: Receptor agonist

CT-868 (GLP-1/GIP RA, RG6641)

Once-daily subcutaneous injectable dual GLP-1/GIP receptor agonist

Indication	**Type 1 diabetes with BMI ≥ 27**
Phase/study	**Phase II**
# of patients	N=96
Design	▪ **ARM A:** CT-868 low dose ▪ **ARM B:** CT-868 medium dose ▪ **ARM C:** CT-868 high dose ▪ **ARM D:** Placebo
Primary endpoint	▪ Efficacy: Change in HbA1c from baseline
Status	▪ FPI Q4 2023 ▪ Recruitment completed Q1 2025
CT Identifier	NCT06062069

GLP-1: Glucagon-like peptide-1; GIP: Glucose-dependent insulinotropic polypeptide; RA: Receptor agonis; BMI: Body Mass index; HbA1c: Hemoglobin A1c

Roche Group development pipeline

Marketed products development programmes

Roche Pharma global development programmes

Roche Pharma research and early development (pRED)

Genentech research and early development (gRED)

pRED oncology development programs

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Oncology					
englumafusp alfa (CD19-4-1BBL, RG6076)	R/R B cell non-Hodgkin's lymphoma	I	498	Part I: FPI Q3 2019 Part II: FPI Q3 2020 Part III: FPI Q3 2024 Combination study with Columvi Data presented at ASH 2022 and ICML 2023	NCT04077723
LTBR agonist (RG6221)	solid tumors	I	125	FPI Q3 2024	NCT06537310
mosperafenib (BRAFi (3), (RG6344))	solid tumors	I	292	FPI Q1 2022	ISRCTN 13713551
PanRAS inhibitor (RG6505)	solid tumors	I	345	FPI Q2 2025	NCT06884618

pRED neurology development programs

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Neurology					
Brainshuttle™-CD20 (RG6035)	Multiple sclerosis	I	119	FPI Q3 2021	ISRCTN16295177 NCT05704361
nivegacetor (gamma-secretase modulator, RG6289)	Alzheimer's disease	II	245	FPI Q2 2024	NCT06402838
alogabat (GABA-Aa5 PAM, RG7816)	Angelman syndrome	II	56	FPI Q3 2023	NCT05630066 (Aldebaran)
MAGL inhibitor (RG6182)	Multiple sclerosis	I	Up to 36	FPI Q3 2023	
selnoflast* (NLRP3i, RG6418)	Parkinson's disease	Ib	48	FPI Q3 2022	
NME (RG6434)	Neurodegenerative disorders	I		FPI Q4 2024	
HTT miRNA GT (SPK-10001, RG6662)	Huntington's disease	I	part A: 8 part B:45	FPI Q2 2025	NCT06826612

*molecule also in gRED development: Phase Ic in coronary artery disease

pRED immunology and ophthalmology development programs

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Immunology					
selnoflast* (NLRP3i, RG6418)	Asthma	Ib	60	FPI Q1 2024	
CD19 x CD3 (RG6382)	SLE	I	70	FPI Q4 2023	NCT05835986
NME (RG6377)	IBD	I		FPI Q2 2024	ISRCTN15555964
Ophthalmology					
zifibancimig (VEGF-Ang2 DutaFab, RG6120)	nAMD	I	251	FPI Q4 2020	NCT04567303 (BURGUNDY)
NME (RG6209)	DME	I	~70 (Part I)	FPI Q4 2022	
NME (RG6327)	geographic atrophy	I		FPI July 2025	
Other					
zosurabalpin (Abx MCP, RG6006)	A. baumannii infections	I	204	FPI Q4 2020	NCT04605718

*molecule also in gRED development: Phase Ic in coronary artery disease
Abx MCP: Antibiotic macrocyclic peptide

Roche Group development pipeline

Marketed products development programmes

Roche Pharma global development programmes

Roche Pharma research and early development (pRED)

Genentech research and early development (gRED)

gRED oncology development programs -1

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Oncology					
cevostamab (anti-FcRH5 x CD3; RG6160)	R/R multiple myeloma	I	355	FPI Q3 2017 LPI Q2 2023 Data presented at ASH 2020-2024	NCT03275103
	R/R multiple myeloma	I	120	FPI Q2 2021	NCT04910568
	BCMA-experienced R/R MM	I/II	140	FPI Q4 2022	NCT05535244
	R/R multiple myeloma	Ib	~110	FPI Q3 2023 In combination with elranatamab	NCT05927571
	Multiple myeloma platform study	I/II	50	FPI Q4 2023 Multiple molecules and combinations	NCT05583617
autogene cevumeran (Individualized Neoantigen-Specific Therapy (iNeST); RG6180)[1]	Adjuvant PDAC	II	260	FPI Q4 2023	NCT05968326 (IMcode003)
	Adjuvant bladder (MIUC)	II	362	FPI Q4 2024	NCT06534983 (IMcode004)
anti-CCR8 (RG6411)	Solid tumors	I	110	FPI Q4 2022	NCT05581004

Partner: [1]BioNTech

gRED oncology development programs -2

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Oncology					
AR degrader (RG6537)[1]	mCRPC	I	~160	FPI Q2 2023	NCT05800665
NME (RG6468)	Solid tumors	I	110	FPI Q4 2023	NCT06031441
NME (RG6561)	Solid tumors	I	310	FPI Q4 2024	NCT06488716
KRAS G12D inhibitor (RG6620)	Solid tumors with KRAS G12D mutations	I	410	FPI Q4 2024	NCT06619587

Partner: [1]Jemincare

gRED immunology and ophthalmology development programs

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Immunology					
NME (RG6287, GDC-8264)	Cardiac surgery associated acute kidney injury (CS-AKI)	II	404	FPI Q1 2025	NCT06602453
TMEM16A potentiator (RG6421, GDC-6988)	Muco-obstructive respiratory disease	Ic	128	FPI Q4 2024	NCT06603246
Vixarelimab (RG6536)[1]	Idiopathic pulmonary fibrosis / Systemic sclerosis-associated interstitial lung disease	II	320	FPI Q2 2023	NCT05785624
Ophthalmology					
Anti-Tie2 agonist (RG6351)	DME	II	~285	FPI Q1 2025	NCT06850922
OpRegen (RG6501)[2]	Geographic atrophy	II	60	FPI Q1 2023	NCT05626114
Other					
LepB inhibitor (RG6436)	Complicated urinary tract infection	I	104	FPI Q2 2024	ISRCTN18049481

Partner: [1]Kiniksa Pharmaceuticals, [2]Lineage Cell Therapeutics

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