Oncology **Immunology** **Neuroscience** **Hematology** **Ophthalmology** **Other Diseases**

Development Pipeline [Main table] (as of June 30, 2026)

Development code Licensor	Generic name Product name	Indication # Additional indication (Combination drug)	Country/region	Projected submission	Mode of Action Modality (Dosage form)	Partner
Filed						
RG7446 Roche	atezolizumab Tecentriq	Adjuvant therapy for MRD-positive bladder cancer #	Japan	January 2026	Engineered anti-PD-L1 monoclonal antibody Antibody (IV)	Roche
		Maintenance therapy following definitive chemoradiotherapy in locally advanced esophageal cancer #	Japan	June 2026		Roche
RG6171 Roche	giredestrant –	Breast cancer (adjuvant)	Japan	May 2026	SERD (Selective Estrogen Receptor Degrader) Small molecule (Oral)	Roche
		Unresectable or recurrent breast cancer	Japan	May 2026		Roche
RG7159 Roche	obinutuzumab Gazyva	Idiopathic nephrotic syndrome #	Japan	May 2026	Humanized anti-CD20 monoclonal antibody Antibody (IV)	Nippon shinyaku
– Travere Therapeutics	sparsentan –	IgA nephropathy	Japan	June 2026	Dual endothelin /angiotensin II receptor antagonist Small molecule (Oral)	–
SA237/RG6168 in-house	satralizumab Enspryng	Thyroid eye disease (TED) #	U.S.	June 2026	pH-dependent binding humanized anti-IL-6 receptor monoclonal antibody Antibody (SC)	Roche
RG6321 Roche	ranibizumab (Port Delivery Platform with ranibizumab) –	Neovascular age-related macular degeneration	Japan	June 2026	Humanized anti-VEGF monoclonal antibody fragment (Fab) Antibody (injection via implant)	–
		Diabetic macular edema	Japan	June 2026		–
Phase III						
AF802/RG7853 in-house	alectinib Alecensa	Maintenance treatment of NSCLC (stage III) after chemoradiotherapy #	Global	–	ALK inhibitor Small molecule (oral)	Roche

Oncology **Immunology** **Neuroscience** **Hematology** **Ophthalmology** **Other Diseases**

Development code Licensor	Generic name Product name	Indication # Additional indication (Combination drug)	Country/region	Projected submission	Mode of Action Modality (Dosage form)	Partner
RG7446 Roche	atezolizumab Tecentriq	HCC (intermediate stage) # (Avastin) #	Japan	2027	Engineered anti-PD-L1 monoclonal antibody Antibody (IV)	Roche
RG7828 Roche	mosunetuzumab Lunsumio	Follicular lymphoma (2nd Line) # (lenalidomide)	Japan	2026	Anti-CD20/CD3 bispecific antibody Antibody (IV)	Roche
		Previously untreated follicular lymphoma #	Japan	2029 and beyond		Roche
RG6026 Roche	glofitamab –	Previously untreated large B-cell lymphoma (Polivy)	Japan	2028	Anti-CD20/CD3 bispecific antibody Antibody (IV)	Roche
RG6330 Roche	divarasib –	NSCLC (2nd Line)	Japan	2026	KRAS G12C inhibitor Small molecule (Oral)	Roche
		NSCLC (1st Line)	Japan	2029 and beyond		Roche
RG6114 Roche	inavolisib –	*PIK3CA*-mutated, HER2-positive breast cancer (1st Line) (Phesgo)	Japan	2028	PI3Kα inhibitor Small molecule (oral)	Roche
		PIK3CA-mutated breast cancer (endocrine-sensitive) (1st Line) (CDK4/6 inhibitor + letrozole)	Japan	2029 and beyond		Roche
RG7159 Roche	obinutuzumab Gazyva	Lupus nephritis #	Japan	2026	Humanized anti-CD20 monoclonal antibody Antibody (IV)	Nippon shinyaku
		Extrarenal lupus #	Japan	2027		Nippon shinyaku
RG6299/ASO factor B Roche	sefaxersen –	IgA nephropathy	Japan	2029 and beyond	Antisense oligonucleotide targeting *complement factor B* mRNA Nucleic acid (SC)	Roche

Oncology **Immunology** **Neuroscience** **Hematology** **Ophthalmology** **Other Diseases**

Development code Licensor	Generic name Product name	Indication # Additional indication (Combination drug)	Country/region	Projected submission	Mode of Action Modality (Dosage form)	Partner
RG6631 Roche	afimkibart –	Ulcerative colitis	Japan	2027	Anti-TL1A antibody Antibody (-)	Roche
		Crohn's disease	Japan	2029 and beyond		Roche
SA237/RG6168 in-house	satralizumab Enspryng	Myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD) #	Global	2026	pH-dependent binding humanized anti-IL-6 receptor monoclonal antibody Antibody (SC)	Roche
		Autoimmune encephalitis (AIE) #	Global	2027		Roche
RG6102 Roche	trontinemab –	Alzheimer's disease	Japan	2029 and beyond	Anti-amyloid beta/TfR1 fusion protein Antibody (IV)	Roche
RG6356/SRP-9001 Roche	delandistrogene moxeparvovec Elevidys	Duchenne muscular dystrophy (DMD) (non-ambulatory) #	Japan	2029 and beyond	Microdystrophin gene therapy Gene therapy (IV)	Sarepta*
SKY59/RG6107 in-house	crovalimab PiaSky	Atypical hemolytic uremic syndrome (aHUS) #	Global	2026	Anti-C5 recycling antibody Antibody (SC)	Roche
ACE910/RG6013 In-house	emicizumab Hemlibra	Type 3 von Willebrand disease #	Global	2027	Anti-coagulation factor IXa/X humanized bispecific monoclonal antibody Antibody (SC)	Roche
NXT007/RG6512 in-house	zemocimig –	Hemophilia A	Global	2028	Anti-coagulation factor IXa/X bispecific antibody Antibody (SC)	Roche
SA237/RG6168 in-house	satralizumab Enspryng	Thyroid eye disease (TED) #	Global (excl. U.S.)	2026	pH-dependent binding humanized anti-IL-6 receptor monoclonal antibody Antibody (SC)	Roche

Oncology **Immunology** **Neuroscience** **Hematology** **Ophthalmology** **Other Diseases**

Development code Licensor	Generic name Product name	Indication # Additional indication (Combination drug)	Country/region	Projected submission	Mode of Action Modality (Dosage form)	Partner
RG6179 Roche	vamikibart –	Noninfectious uveitic macular edema (UME)	Japan	2026	Anti-IL-6 monoclonal antibody Antibody (vitreous injection)	Roche
RG7716 Roche	faricimab Vabysmo	Non-proliferative diabetic retinopathy (NPDR) #	Japan	2028	Anti-VEGF/Anti-Ang-2 bispecific antibody Antibody (vitreous injection)	–
RG6615 Roche	zilebesiran –	Hypertension	Japan	2029 and beyond	RNAi therapeutic targeting angiotensinogen (AGT) RNAi (SC)	Alnylam Pharmaceuticals
RG6640 Roche	enicepatide –	Obesity	Japan	2029 and beyond	Long-acting GLP-1/GIP receptor agonist Peptide (SC)	Roche
Phase II						
RG6026 Roche	glofitamab –	Relapsed or refractory diffuse large B-cell lymphoma	Japan	2026	Anti-CD20/CD3 bispecific antibody Antibody (IV)	–
		Relapsed or refractory mantle cell lymphoma	Japan	2028		–
DONQ52 in-house	– –	Celiac disease	Global	2029 and beyond	Anti-HLA-DQ2.5/gluten peptides multispecific antibody Antibody (SC)	–
RG6042 Roche	tominersen –	Huntington's disease**	Japan	–	Antisense oligonucleotide targeting *HTT* mRNA Nucleic acid (IV)	Roche
GYM329/RG6237 In-house	emugrobart –	Obesity	Global	2029 and beyond	Anti-latent myostatin sweeping antibody Antibody (SC)	Roche
Phase I/II						

Oncology **Immunology** **Neuroscience** **Hematology** **Ophthalmology** **Other Diseases**

Development code Licensor	Generic name Product name	Indication # Additional indication (Combination drug)	Country/region	Projected submission	Mode of Action Modality (Dosage form)	Partner
RG6114 Roche	inavolisib –	*PIK3CA*-mutated breast cancer (endocrine-resistant) (palbociclib + fulvestrant)	Japan	2027	PI3Kα inhibitor Small molecule (Oral)	Roche
Phase I						
GC33 in-house	codrituzumab –	HCC	Global	–	Anti-Glypican-3 humanized monoclonal antibody Antibody (IV)	–
ALPS12 in-house	clesitamig –	Solid tumors	Global	–	Anti-DLL3/CD3/CD137 trispecific antibody Antibody (IV)	–
ROSE12 in-house	– –	Solid tumors	Global	–	Anti-CTLA-4 Switch antibody Antibody (IV)	–
MINT91 in-house	– –	Solid tumors	Global	–	- Small molecule (Oral)	–
AUBE00 In-house	– –	Solid tumors	Global	–	Pan-KRAS inhibitor Macrocyclic peptide (Oral)	–
RG7421 Roche	cobimetinib –	Solid tumors	Japan	–	MEK inhibitor Small molecule (Oral)	–
RG6160 Roche	cevostamab –	Relapsed or refractory multiple myeloma	Japan	–	Anti-FcRH5/CD3 bispecific antibody Antibody (IV)	–
RAY121 in-house	– –	Autoimmune disease	Global	–	Anti-C1s recycling antibody Antibody (SC)	–
RG7935 Roche	prasinezumab –	Parkinson's disease	Japan	–	Anti-α-synuclein monoclonal antibody Antibody (IV)	–
REVN24 in-house	– –	Postoperative complications after cardiac surgery	Global	–	– Small molecule (IV)	–

Oncology **Immunology** **Neuroscience** **Hematology** **Ophthalmology** **Other Diseases**

Development code Licensor	Generic name Product name	Indication # Additional indication (Combination drug)	Country/region	Projected submission	Mode of Action Modality (Dosage form)	Partner
RAY121 in-house	– –	–	Global	–	Anti-C1s recycling antibody Antibody (-)	–
Development Discontinued						
RG6171 Roche	giredestrant –	Breast cancer (1st Line) (palbociclib)	Japan	Phase III	SERD (Selective Estrogen Receptor Degrader) Small molecule (Oral)	Roche

In principle, completion of first dose is regarded as pipeline entry into each phase of clinical studies. The treatment lines and target segments described in the indication section are based on the currently ongoing clinical trials and do not represent the final wording on the package insert.

*Sarepta manages the global study including Japan **Removed from the pipeline at the FY2026.12 Q2 Financial Results announcement

Changes from the last announcement on March 31, 2026

Oncology

- AF802/RG7853 Filed (Advanced or recurrent *ALK* fusion gene-positive solid tumors) → Approved
- RG435 Filed (Neurofibromatosis type 2) → Approved
- RG7446 Filed (Maintenance therapy following definitive chemoradiotherapy in locally advanced esophageal cancer)
- RG6171 Phase III (Breast cancer (adjuvant)) → Filed
- RG6171 Phase III (Unresectable or recurrent breast cancer) → Filed
- RG6171 Phase III (Breast cancer (1st Line) (combination with palbociclib)) → Development discontinued

Immunology

- RG7159 Phase III (Idiopathic nephrotic syndrome) → Filed
- sparsentan Phase III (IgA nephropathy) → Filed
- DONQ52 Phase I (Celiac disease) → Phase II

Hematology

- NXT007/ RG6512 Phase I/ II (Hemophilia A) → Phase III

Ophthalmology

- SA237/RG6168 Phase III (Thyroid eye disease (TED)) (U.S.) → Filed
- RG6321 Phase I/ II (Neovascular age-related macular degeneration) → Filed
- RG6321 Phase I/ II (Diabetic macular edema) → Filed

Other Diseases

- RG6640 Phase III (Obesity: development started)

Development Pipeline [Attached table]

(Major Chugai originated projects licensed out to 3rd parties excluding Roche) (as of June 30, 2026)

Development code licensee/In-house	Generic name Product name	Indication (combination)	Stage Country/region	Mode of Action Modality (Dosage form)	Licensee (Granted rights)
VS-6766/CKI27	avutometinib AVMAPKI	Recurrent low-grade serous ovarian cancer (LGSOC) (defactinib)	Phase III Global	RAF/MEK clamp Small molecule (Oral)	Verastem Oncology (exclusive global license for the manufacturing, development and marketing)
		Metastatic pancreatic ductal adenocarcinoma (mPDAC) (1st line) (defactinib+chemotherapy)	Phase I/II U.S.		
– /CIM331	nemolizumab NEMLUVIO	Chronic pruritus of unknown origin (CPUO)	Phase II Overseas	Anti-IL-31 receptor A humanized monoclonal antibody Antibody (SC)	Galderma (exclusive global license for the development and marketing excluding Japan)
		Systemic sclerosis (SSc)	Phase II Overseas		
LY3502970/OWL833	orforglipron Foundayo	Type 2 diabetes	Phase III Global Filed EU	Oral non-peptidic GLP-1 receptor agonist Small molecule (Oral)	Eli Lilly and Company (worldwide development and commercialization rights)
		Obesity	Phase III Global Filed EU, Japan		

		Obstructive sleep apnea	Phase III Global		
		Hypertension	Phase III Global		
		Osteoarthritis	Phase III Global		
		Stress urinary incontinence	Phase III Global		
		Investigation of the effect of orforglipron on the incidence of major adverse cardiovascular events*	Phase III Global		
		Peripheral arterial disease	Phase III Global		
AP306/EOS789	— —	Hyperphosphatemia	Phase IIb China/U.S.	Oral inhibitor of phosphate transporters Small molecule (Oral)	Alebund Pharmaceuticals (exclusive global license for the manufacturing, development and marketing)

The treatment lines and target segments described in the indication section are based on the currently ongoing clinical trials and do not represent the final wording on the package insert.

*In Participants with established atherosclerotic cardiovascular disease and/or chronic kidney disease

Progress made in R&D activities of major Chugai originated projects licensed out to 3rd party excluding Roche during the period from January 1, 2026 to June 30, 2026 was as follows.

- Eli Lilly and Company started a global Phase III study for the oral non-peptidic GLP-1 receptor agonist LY3502970/OWL833 (orforglipron) for the treatment of peripheral arterial disease in Q1 2026. In addition, it has filed for approval to the European Medicines Agency for the treatment of type 2 diabetes and obesity in Q1 2026, and obtained approval for adults with obesity, or overweight with weight-related medical problems in the U.S. in Q2 2026.
- AP306/EOS789, an oral inhibitor of phosphate transporters, started a global Phase IIb study for the treatment of hyperphosphatemia in China and the U.S. in Q2 2026.
- Galderma started a global Phase II study for the anti-IL-31 receptor A humanized monoclonal antibody CIM331 (Overseas product name: NEMLUVIO) for the treatment of systemic sclerosis in Q2 2026.

Response to Requests from the MHLW Review Committee on Unapproved Drugs and Indications with High Medical Needs (As of June 30, 2026)

Development Request	Product	Indication	Development Status
Fourth development request	Xeloda*	Neuroendocrine tumor	Submitted company opinion and waiting for evaluation by committee
	Avastin	Cerebral edema induced by radiation necrosis	Submitted company opinion and waiting for evaluation by committee
	Mircera	Anemia associated with chronic kidney disease (CKD) in pediatric patients 3 months of age and older	Submitted company opinion and waiting for evaluation by committee

*Transferred the marketing authorization holder to CHEPLAPHARM K.K. as of February 1, 2024

Major Clinical Trials

Project	Expected indication	Study design	Study name	Stage	CT information
Oncology					
AF802/RG7853 (Alecensa)	Maintenance treatment of NSCLC (stage III) after chemoradiotherapy	*ALK* fusion-positive: Alecensa vs. durvalumab	HORIZON01	Phase III	NCT05170204
RG7446 (Tecentriq)	HCC (intermediate stage)	Tecentriq + Avastin + TACE vs. TACE	TALENTACE	Phase III	NCT04712643
RG7828 (Lunsumio)	Follicular lymphoma [2nd line]	Lunsumio + lenalidomide vs. Rituxan + lenalidomide	CELESTIMO	Phase III	NCT04712097
	Previously untreated follicular lymphoma	Lunsumio + lenalidomide vs. Rituxan + chemotherapy	–	Phase III (domestic)	jRCT2011240017
RG6026 (glofitamab)	Previously untreated large B-cell lymphoma	RG6026 + Polivy + Rituxan + chemotherapy vs. Polivy + Rituxan + chemotherapy	SKYGLO	Phase III	NCT06047080
	Relapsed or refractory diffuse large B-cell lymphoma	RG6026 + gemcitabine + oxaliplatin (GemOx) (single arm)	–	Phase II (domestic)	jRCT2051250036
	Relapsed or refractory mantle cell lymphoma	RG6026 (single arm)			
RG6330 (divarasib)	NSCLC [2nd line]	RG6330 vs. sotorasib or adagrasib	Krascendo 1	Phase III	NCT06497556
	NSCLC [1st line]	RG6330 + pembrolizumab vs. pembrolizumab +chemotherapy	Krascendo 2	Phase III	NCT06793215
RG6114 (inavolisib)	*PIK3CA*-mutated, HER2-positive breast cancer (1st Line)	RG6114 + Phesgo vs Placebo + Phesgo	INAVO122	Phase III	NCT05894239

Project	Expected indication	Study design	Study name	Stage	CT information
	PIK3CA-mutated breast cancer (endocrine-sensitive) (1st Line)	RG6114 + CDK4/6 Inhibitor + letrozole vs Placebo + CDK4/6 Inhibitor + letrozole	INAVO123	Phase III	NCT06790693
	PIK3CA-mutated breast cancer (endocrine-resistant)	RG6114 + palbociclib + fulvestrant (single arm)	–	Phase I/II (domestic)	jRCT2031250161
Immunology					
RG7159 (Gazyva)	Lupus nephritis	Standard of care treatment ± Gazyva	–	Phase III (domestic)	jRCT2011210059
	Extra renal lupus	Gazyva vs. Placebo	–	Phase III (domestic)	jRCT2071230031
RG6299 (sefaxersen)	IgA nephropathy	RG6299 vs. Placebo	IMAGINATION	Phase III	NCT05797610
RG6631 (afimkibart)	Ulcerative colitis	RG6631 vs. Placebo	Ametrine-1	Phase III	NCT06589986
	Crohn's disease	RG6631 vs. Placebo	SIBERITE-1	Phase III	NCT06819878
Neuroscience					
SA237/RG6168 (Enspryng)	Myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD)	Enspryng vs. Placebo	METEOROID	Phase III	NCT05271409
	Autoimmune encephalitis (AIE)	Enspryng vs. Placebo	CIELO	Phase III	NCT05503264
RG6356 (Elevidys)	Duchenne muscular dystrophy (DMD) (non-ambulatory)	Elevidys vs. Placebo	ENVISION	Phase III	NCT05881408
RG6102 (trontinemab)	Alzheimer's disease	RG6102 vs. Placebo	TRONTIER 1/ TRONTIER 2	Phase III	NCT07169578 NCT07170150
Hematology					
SKY59/RG6107 (PiaSky)	Atypical hemolytic uremic syndrome (aHUS)	PiaSky (single arm)	COMMUTE-a	Phase III	NCT04861259
		PiaSky (single arm)	COMMUTE-p	Phase III	NCT04958265
ACE910/RG6013 (Hemlibra)	Type 3 von Willebrand disease	Hemlibra vs. On-demand therapy (standard of care treatment)	WILL-EMI	Phase III	NCT06998524
NXT007/RG6512 (zemocimig)	Hemophilia A	zemocimig vs. Human coagulation factor VIII products	ZEBRHA 1	Phase III	NCT07416526
		zemocimig vs. Hemlibra	ZEBRHA 2	Phase III	NCT07416604

Project	Expected indication	Study design	Study name	Stage	CT information
Ophthalmology					
RG6179 (vamikibart)	Noninfectious uveitic macular edema	RG6179 vs. sham	Sandcat	Phase III	NCT05642325
RG7716 (Vabysmo)	Non-proliferative diabetic retinopathy	RG7716 vs. sham	AZUSA	Phase III (domestic)	jRCT2071250009
Other diseases					
RG6615 (zilebesiran)	Hypertension	RG6615 vs. Placebo	ZENITH	Phase III	NCT07181109
RG6640 (enicepatide)	Obesity	RG6640 vs. Placebo	Enith1/ Enith2	Phase III	NCT07351045 NCT07351058

The treatment lines and target segments described in the indication section are based on the currently ongoing clinical trials and do not represent the final wording on the package insert.

Clinical Trials of In-House Developed Projects

Excluding projects listed in Major Clinical Trials among the projects listed in the development pipeline. Only clinical trials led by Chugai or Roche are listed.

Project	Expected indication	Stage	Enrollment* as of June 30, 2026	Study start	CT information
Oncology					
GC33	HCC	Phase I	27	November, 2008	NCT00746317
		Phase I	42	October, 2009	NCT00976170
		Phase I (domestic)	18	October, 2010	jRCT2080221218
		Phase II	185	May, 2012	NCT01507168
		Phase I	27	August, 2016	jRCT2080223270
ALPS12 (clesitamig)	Solid tumors	Phase I	122	October, 2025	NCT07107490
ROSE12	Solid tumors	Phase Ia/Ib	219	June, 2023	NCT05907980
MINT91	Solid tumors	Phase I	122	April, 2025	jRCT2031240713
AUBE00	Solid tumors	Phase I	130	June, 2025	jRCT2031250094
Immunology					
DONQ52	Celiac disease	Phase II	92	April, 2026	NCT07239336
RAY121	Autoimmune disease	Phase Ib	144	August, 2024	NCT06723106

Project	Expected indication	Stage	Enrollment* as of June 30, 2026	Study start	CT information
Other diseases					
REVN24	Postoperative complications after cardiac surgery	Phase I (domestic) (only healthy adults)	210	October, 2023	jRCT2071230074
RAY121	–	Phase I (only healthy adults)	36	March, 2025	2024-515151-38-00
GYM329/RG6237 (emugrobart)	Obesity	Phase II	285	May, 2025	NCT06965413

* The number of enrollments is listed based on public information and generally refers to estimations or actual results.

FoundationOne CDx Cancer Genomic Profile: companion diagnostic indications (as of June 30, 2026)

Alterations	Cancer type	Relevant drugs
Activating *EGFR* alterations	NSCLC	afatinib, erlotinib, gefitinib, osimertinib, dacomitinib†
EGFR exon 20 T790M alteration		osimertinib
ALK fusion genes		alectinib, crizotinib, ceritinib, brigatinib, lorlatinib
ROS1 fusion genes		entrectinib
MET exon 14 skipping alterations		capmatinib
BRAF V600E and V600K alterations	Malignant melanoma	dabrafenib, trametinib, vemurafenib, encorafenib, binimetinib
BRAF V600 alterations and *BRAF* fusion genes	Glioma	tovorafenib
ERBB2 copy number alterations (HER2 gene amplification positive)	Breast cancer	trastuzumab
AKT1 alterations		capivasertib
PIK3CA alterations		
PTEN alterations		
KRAS/NRAS wildtype	Colorectal cancer	cetuximab, panitumumab
Microsatellite instability-high		nivolumab

Microsatellite instability-high	Solid tumors	pembrolizumab
Tumor mutational burden-high		pembrolizumab
NTRK1/2/3 fusion genes		entrectinib, larotrectinib, repotrectinib
RET fusion genes		selpercatinib
ALK fusion genes		alectinib
BRCA1/2 alterations	Ovarian cancer	olaparib
BRCA1/2 alterations	Prostate cancer	olaparib, talazoparib†
FGFR2 fusion genes	Biliary tract cancer	pemigatinib

Underlined are the companion diagnostic features and relevant drugs currently under application for regulatory approval, or in the process of completing approval related procedures.

† Relevant drugs for which procedures for removal are underway.

FoundationOne Liquid CDx Cancer Genomic Profile: companion diagnostic indications (as of June 30, 2026)

Alterations	Cancer type	Relevant drugs
Activating *EGFR* alterations	NSCLC	afatinib, erlotinib, gefitinib, osimertinib
EGFR exon 20 T790M alteration		osimertinib
ALK fusion genes		alectinib, crizotinib, ceritinib
ROS1 fusion genes		entrectinib
MET exon 14 skipping alterations		capmatinib
NTRK1/2/3 fusion genes	Solid tumors	entrectinib
BRCA1/2 alterations	Prostate cancer	olaparib