Development pipeline (as of October 22, 2021)

Development code	Origin Overseas name (Collaborator)	Indication # Additional indication	Stage (Date)	Generic name Product name Dosage form	Mode of Action
Oncology					
RG7596	Roche/Seagen Polivy	Relapsed or refractory diffuse large B-cell lymphoma (DLBCL)	Launched (21/05)	polatuzumab vedotin Polivy Injection	Anti-CD79b antibody-drug conjugate
		DLBCL #	Phase III		
RG7446	Roche Tecentriq	Non-small cell lung cancer (NSCLC) (adjuvant) #	Filed (21/07)	atezolizumab Tecentriq Injection	Engineered anti-PD-L1 monoclonal antibody
		NSCLC (neoadjuvant) #	Phase III		
		NSCLC (stage III) #	Phase III (in combination with RG6058)		
		Urothelial carcinoma #	Phase III		
		Muscle-invasive bladder cancer (adjuvant) #	Phase III		
		Renal cell carcinoma (adjuvant) #	Phase III		
	Roche Tecentriq (Takeda)	Renal cell carcinoma (2nd Line) #	Phase III (in combination with cabozantinib)		
	Roche Tecentriq	Early breast cancer #	Phase III		
		Ovarian cancer #	Phase III (in combination with RG435)		
		Hepatocellular carcinoma (HCC) (adjuvant) #	Phase III (in combination with RG435)		
		HCC (intermediate stage) #	Phase III (in combination with RG435)		

Development code	Origin Overseas name (Collaborator)	Indication # Additional indication	Stage (Date)	Generic name Product name Dosage form	Mode of Action
		Head and neck carcinoma (adjuvant) #	Phase III		
		Esophageal cancer #	Phase III (in combination with RG6058)		
		Pancreatic adenocarcinoma #	Phase I Morpheus platform (in combination with RG1569 or RG6058)		
RG435	Roche Avastin	HCC (adjuvant) #	Phase III (in combination with RG7446)	bevacizumab Avastin Injection	Anti-VEGF (Vascular Endothelial Growth Factor) humanized monoclonal antibody
		HCC (intermediate stage) #	Phase III (in combination with RG7446)		
		Small cell lung cancer (SCLC) #	Phase III (in combination with RG7446)		
RG7440	Roche/Array BioPharma	Prostate cancer	Phase III	ipatasertib Oral	AKT inhibitor
RG6264	Roche Phesgo	Breast cancer (Fixed-dose combination, subcutaneous injection)	Phase III	trastuzumab/pertuzumab Injection	Anti-HER2 humanized monoclonal antibody/ HER2 dimerization inhibitory humanized monoclonal antibody
AF802 / RG7853	In-house Alecensa (Roche)	NSCLC (adjuvant) #	Phase III	alectinib Alecensa Oral	ALK inhibitor
RG6058	Roche	SCLC	Phase III (in combination with RG7446)	tiragolumab Injection	Anti-TIGIT human monoclonal antibody
		NSCLC	Phase III (in combination with RG7446)		
		NSCLC (stage III)	Phase III (in combination with RG7446)		

Development code	Origin Overseas name (Collaborator)	Indication # Additional indication	Stage (Date)	Generic name Product name Dosage form	Mode of Action
		Esophageal cancer	Phase III (in combination with RG7446)		
RG6171	Roche	Breast cancer	Phase III	giredestrant Oral	SERD (Selective Estrogen Receptor Degrader)
		Breast cancer (adjuvant)	Phase III		
OBP-301	Oncolys BioPharma	Esophageal cancer	Phase II	Injection	Oncolytic type 5 adenovirus
		HCC	Phase I (in combination with RG7446 and RG435)		
GC33	In-house	HCC	Phase I	codrituzumab Injection	Anti-Glypican-3 humanized monoclonal antibody
ERY974	In-house	Solid tumors	Phase I	Injection	Anti-Glypican-3/CD3 bispecific antibody
RG7421	Roche/Exelixis Cotellic	Solid tumors	Phase I	cobimetinib Oral	MEK inhibitor
RG7802	Roche	Solid tumors	Phase I	cibisatamab Injection	Anti-CEA/CD3 bispecific antibody
RG7828	Roche	Hematologic tumors	Phase I	mosunetuzumab Injection	Anti-CD20/CD3 bispecific antibody
RG6026	Roche	Hematologic tumors	Phase I	glofitamab Injection	Anti-CD20/CD3 bispecific antibody
AMY109	In-house	Solid tumors	Phase I	Injection	–
STA551	In-house	Solid tumors	Phase I	Injection	Anti-CD137 agonistic Switch antibody

Development code	Origin Overseas name (Collaborator)	Indication # Additional indication	Stage (Date)	Generic name Product name Dosage form	Mode of Action
SPYK04	In-house	Solid tumors	Phase I	Oral	–
RG6194	Roche	Solid tumors	Phase I	Injection	Anti-HER2/CD3 bispecific antibody
SOF10/RG6440	In-house (Roche)	Solid tumors	Phase I	Injection	Anti-latent TGF-β1 monoclonal antibody
RG6396	Roche/ Blueprint medicine Gavreto	Solid tumors	Phase I	pralsetinib Oral	RET inhibitor
LUNA18	In-house	Solid tumors	Phase I	Oral	RAS inhibitor
Bone and Joint Diseases					
NRD101	In-house	Knee osteoarthritis / Shoulder periarthritis	Phase III (China)	purified sodium hyaluronate Suvenyl Injection	Sodium hyaluronate
Autoimmune Diseases					
RG7880	Roche	Inflammatory bowel disease	Phase I	efmarodocokin alfa Injection	Human IL-22 fusion protein
Neurology					
RG7916	Roche/PTC Therapeutics Evrysdi	Spinal muscular atrophy (SMA)	Launched (21/08)	risdiplam Evrysdi Oral	SMN2 splicing modifier
SA237 / RG6168	In-house Enspryng (Roche)	Neuromyelitis optica spectrum disorder (NMOSD)	Approved (21/06) EU	satralizumab Enspryng Injection	pH-dependent binding humanized anti-IL-6 receptor monoclonal antibody
		Generalized myasthenia gravis (gMG) #	Phase III		
RG1450	Roche/MorphoSys	Alzheimer's disease	Phase III	gantenerumab Injection	Anti-amyloid-beta human monoclonal antibody

Development code	Origin Overseas name (Collaborator)	Indication # Additional indication	Stage (Date)	Generic name Product name Dosage form	Mode of Action
RG6042	Roche/Ionis Pharmaceuticals	Huntington's disease	Phase III	tominersen Injection	Antisense oligonucleotide targeting *HTT* mRNA
RG7906	Roche	Schizophrenia	Phase II	ralmitaront Oral	Partial TAAR1 agonist
RG7935	Roche/Prothena	Parkinson's disease	Phase I	prasinezumab Injection	Anti-α-synuclein monoclonal antibody
GYM329 / RG6237	In-house (Roche)	Neuromuscular disease	Phase I	 Injection	Anti-latent myostatin sweeping antibody
RG6100	Roche/AC Immune	Alzheimer's disease	Phase I	semorinemab injection	Anti-tau humanized monoclonal antibody
RG6102	Roche/MorphoSys	Alzheimer's disease	Phase I	 Injection	Anti-amyloid beta/TfR1 fusion protein
Other diseases					
RG6413/RG6412	Roche/Regeneron Pharmaceuticals	COVID-19	Approved (21/07)	casirivimab and imdevimab Ronapreve Injection	SARS-CoV-2 neutralizing antibody cocktail
		prophylaxis and asymptomatic COVID-19 #	Filed (21/10)		
RG7716	Roche	Diabetic macular edema	Filed (21/06)	faricimab Injection	Anti-VEGF/Ang2 bispecific antibody
		Neovascular age related macular degeneration (nAMD)	Filed (21/06)		
		Retinal vein occlusion	Phase III		
MRA/RG1569	In-house Actemra/RoActemra(EU)	COVID-19 pneumonia #	Phase III	tocilizumab Actemra Injection	Humanized anti-human IL-6 receptor monoclonal antibody
ACE910 / RG6013	In-house Hemlibra	Acquired hemophilia A #	Phase III (Japan)	emicizumab Hemlibra Injection	Anti-coagulation factor IXa/X humanized bispecific monoclonal antibody

Development code	Origin Overseas name (Collaborator)	Indication # Additional indication	Stage (Date)	Generic name Product name Dosage form	Mode of Action
SKY59 / RG6107	In-house (Roche)	Paroxysmal nocturnal hemoglobinuria (PNH)	Phase III	crovalimab Injection	Anti-C5 recycling antibody
RG6422	Roche/Atea Pharmaceuticals	COVID-19	Phase III	 Oral	RNA polymerase inhibitor
NXT007	In-house	Hemophilia A	Phase I/II	 Injection	Anti-coagulation factor IXa/X bispecific antibody
PCO371	In-house	Hypoparathyroidism	Phase I	 Oral	PTH1 receptor agonist
AMY109	In-house	Endometriosis	Phase I	 Injection	–
RG7992	Roche	Non-alcoholic steatohepatitis	Phase I	 Injection	Anti-FGFR1/KLB bispecific antibody

In principle, completion of first dose is regarded as the start of clinical studies in each phase. * Roche conducted global Phase III studies of Actemra/RoActemra against COVID-19 pneumonia separately.

Changes from the last announcement on July 26, 2021

Oncology

- RG6171 Phase III (Breast cancer (Adjuvant): development started)
- LUNA18 Phase I (Solid tumors: development started)

Neurology

- RG7916 Approved (SMA) → Launched
- SA237/RG6168 Phase III (Generalized myasthenia gravis (gMG): development started)

Other diseases

- RG6413/RG6412 Filed (prophylaxis and asymptomatic COVID-19)

R&D Activities

For the changes during the FY2021 (January 1 – September 30), please refer to page 4 of “CONSOLIDATED FINANCIAL STATEMENTS (IFRS) (Non-Audited) (for the third quarter of the fiscal year 2021).”

Changes from October 1 to October 22, 2021 are as follows:

Oncology
- We started Phase I study for RAS inhibitor LUNA18 for the treatment of solid tumors in October 2021.

Neurology
- We started Phase III global study for pH-dependent binding humanized anti-IL-6 receptor monoclonal antibody SA237/RG6168 (Product name: Enspryng) for the treatment of generalized myasthenia gravis (gMG) in October 2021.

Other Diseases
- We filed SARS-CoV-2 neutralizing antibody cocktail RG6413/RG6107 (Product name: Ronapreve) for prophylaxis and treatment of asymptomatic COVID-19 in October 2021.

Major Chugai originated developments licensed out to 3rd party excluding Roche

Development code Chugai / partner	Indication	Stage	Generic name Product name Dosage form	Licensee (granted right)	Mode of Action
CKI27 / VS-6766	Ovarian cancer	Phase II (in combination with defactinib)	Oral	Verastem (exclusive global license for the manufacturing, development and marketing)	RAF/MEK inhibitor
	NSCLC				
CIM331	Atopic dermatitis	Filled (20/Q3) Japan	nemolizumab Injection	Maruho (rights for development and marketing in the skin disease area for the Japanese market)	Anti-IL-31 receptor A humanized monoclonal antibody
		Phase III (global)		Galderma (exclusive global license for the development and marketing excluding Japan and Taiwan)	
	Prurigo nodularis	Phase III (global)		Galderma (exclusive global license for the development and marketing excluding Japan and Taiwan)	
		Phase II/III (Japan)		Maruho (rights for development and marketing in the skin disease area for the Japanese market)	
OWL833 / LY3502970	Type 2 diabetes	Phase I	Oral	Eli Lilly and Company (worldwide development and commercialization rights)	Oral non-peptidic GLP-1 receptor agonist

Major clinical trials in oncology field

Treatment	Expected Indication	Study design	Study name	Stage	Planned filing year
RG7446 (Tecentriq)	NSCLC [1st line]	PD-L1 positive: Tecentriq ± RG6058	SKYSCRAPER-01	Phase III	2023
	NSCLC [stage III]	Tecentriq + RG6058 vs. durvalumab	SKYSCRAPER-03	Phase III	2024 and beyond
	NSCLC [2nd line]	Tecentriq + cabozantinib vs. docetaxel	CONTACT-01	Phase III	2023
	NSCLC (neoadjuvant)	Chemo ± Tecentriq	IMpower030	Phase III	2023
	NSCLC (adjuvant)	Tecentriq vs. best supportive care	IMpower010	Phase III	2021
	SCLC	Tecentriq + chemo ± Avastin	BEAT-SC	Phase III	2023
		Tecentriq + chemo ± RG6058	SKYSCRAPER-02	Phase III	2022
	Urothelial carcinoma (UC)	Tecentriq ± chemo vs. chemo	IMvigor130	Phase III	2022
	Muscle-invasive bladder cancer (adjuvant)	Tecentriq	IMvigor011	Phase III	2024 and beyond
	Renal cell carcinoma (adjuvant)	Tecentriq	IMmotion010	Phase III	2022
	Renal cell carcinoma [2nd line]	cabozantinib ± Tecentriq	CONTACT-03	Phase III	2023d
	Early breast cancer	TNBC (adjuvant): paclitaxel ± Tecentriq	IMpassion030	Phase III	2024 and beyond
		TNBC (neoadjuvant): nab-paclitaxel ± Tecentriq	IMpassion031	Phase III	
	Ovarian cancer	carboplatin + paclitaxel + Avastin ± Tecentriq	IMagyn050	Phase III	2022
	HCC (adjuvant)	Tecentriq + Avastin vs. active surveillance	IMbrave050	Phase III	2023
	HCC (intermediate stage)	Tecentriq + Avastin + TACE vs. TACE	TALENTACE	Phase III	2024 and beyond
	HCC [2nd line]	Tecentriq + lenvatinib or sorafenib vs. lenvatinib or sorafenib	IMbrave251	Phase III	2024 and beyond
	Head and neck carcinoma (adjuvant)	Tecentriq	IMvoke010	Phase III	2022
	Esophageal cancer	Tecentriq + RG6058 vs. Tecentriq vs. placebo	SKYSCRAPER-07	Phase III	2024 and beyond
	Pancreatic adenocarcinoma [1st line]	Tecentriq + Actemra vs. gemcitabine + nab-paclitaxel	Morpheus-PC	Phase I	-
		Tecentriq + RG6058 vs. gemcitabine + nab-paclitaxel			-
RG7440 (ipatasertib)	Prostate cancer	castration-resistant: abiraterone ± RG7440	IPATential150	Phase III	2022
RG7596 (polatuzumab vedotin)	DLBCL	Rituxan + Chemo ± RG7596	POLARIX	Phase III	2021
RG6264	Breast cancer	RG6264 (SC) + chemo vs. Herceptin (IV) + Perjeta (IV) + chemo	FeDeriCa	Phase III	2021
AF802 (Alecensa)	NSCLC (adjuvant)	*ALK* fusion-positive: Alecensa vs. chemo	ALINA	Phase III	2023
RG6171 / SERD	Breast cancer	HR positive: RG6171 + palbocicilib ± Letrozole	persevERA	Phase III	2024 and beyond
	Breast cancer (adjuvant)	HR positive: RG6171 vs. endocrine therapy	lidERA	Phase III	2024 and beyond
OBP-301	Esophageal cancer	OBP-301 + radiotherapy	-	Phase II*	2024 and beyond

FoudationOne CDx Cancer Genomic Profile: companion diagnostic indications (as of October 22, 2021)

Alterations	Cancer type	Relevant drugs
Activated *EGFR* gene alterations	NSCLC	afatinib dimaleate, erlotinib hydrochloride, gefitinib, osimertinib mesylate
EGFR exon 20 T790M alterations		osimertinib mesylate
ALK fusion genes		alectinib hydrochloride, crizotinib, ceritinib
ROS1 fusion genes		entrectinib
MET exon 14 skipping alterations		capmatinib hydrochloride hydrate
BRAF V600E and V600K alterations	Malignant melanoma	dabrafenib mesylate, trametinib dimethyl sulfoxide, vemurafenib
ERBB2 copy number alterations (HER2 gene amplification positive)	Breast cancer	trastuzumab (genetical recombination)
KRAS/NRAS wild-type	Colorectal cancer	cetuximab (genetical recombination), panitumumab (genetical recombination)
Microsatellite instability-high		nivolumab (genetical recombination)
Microsatellite instability-high	Solid tumors	pembrolizumab (genetical recombination)
Tumor mutational burden-high		pembrolizumab (genetical recombination)
NTRK1/2/3 fusion gene		entrectinib, larotrectinib sulfate
BRCA1/2 alterations	Ovarian cancer	olaparib
BRCA1/2 alterations	Prostate cancer	olaparib
FGFR2 fusion genes	Biliary Tract Cancer	pemigatinib

* Underlined are the companion diagnostic features and relevant drugs currently under application for regulatory approval

FoudationOne Liquid CDx Cancer Genomic Profile: companion diagnostic indications (as of October 22 2021)

Alterations	Cancer type	Relevant drugs
Activated *EGFR* gene alterations	NSCLC	afatinib dimaleate, erlotinib hydrochloride, gefitinib, osimertinib mesylate
EGFR exon 20 T790M alterations		osimertinib mesylate
ALK fusion genes		alectinib hydrochloride, crizotinib, ceritinib
ROS1 fusion genes		entrectinib
NTRK1/2/3 fusion gene	Solid tumors	entrectinib
BRCA1/2 alterations	Prostate cancer	olaparib