## **Q2 Topics (1/2)**



As of July 24, 2025

Launched	Evrysdi	Addition of dosage form (tablet)	May 2025 (Japan)
	AVMAPKI <sup>TM*</sup>	Adult patients with KRAS-mutated recurrent low-grade serous ovarian cancer who have received prior systemic therapy (combination with FAK inhibitor FAKZYNJA <sup>TM</sup> (defactinib tablet))	May 2025 (U.S.)
Approved	Elevidys	Duchenne muscular dystrophy (ambulatory) (gene therapy product)	May 2025 (Japan)
	PiaSky	Paroxysmal nocturnal hemoglobinuria	May 2025 (Taiwan)
	Vabysmo	Angioid streaks (additional indication)	May 2025 (Japan)
	Lunsumio + Polivy	Relapsed or refractory aggressive B-cell non-Hodgkin's lymphoma (additional indication)	May 2025 (Japan)
Filed	Tecentriq	Unresectable thymic carcinoma (additional indication)	May 2025 (Japan)
	Alecensa	ALK fusion / rearrangement gene-positive unresectable advanced or recurrent solid tumors (additional indication)	June 2025 (Japan)
	GYM329	Obesity (Phase II)	May 2025
	Vabysmo	Non-proliferative diabetic retinopathy (domestic Phase III)	May 2025
nitiation of Study	Hemlibra	von Willebrand disease (Phase III)	June 2025
	AUBE00	Solid tumors (pan-KRAS inhibitor / mid-size molecule / oral) (Phase I)	June 2025
	RG6114/inavolisib	PIK3CA-mutated breast cancer (domestic Phase I/II)	July 2025

Orange: in-house projects (development in global) Blue: In-licensed from Roche (development and distribution in Japan) \*Conducted by Verastem Oncology, a global licensee

## CHUGAI Roche Roche Group

## **Q2 Topics (2/2)**

As of July 24, 2025

Doodout	Tecentriq + Avastin	Phase III TALENTACE study (unresectable hepatocellular carcinoma) : Met one of the primary endpoints (TACE PFS)	May 2025	
Readout	AVMAPKI <sup>TM</sup> *	Phase II RAMP 205 study (pancreatic ductal adenocarcinoma): Positive results for safety and efficacy	May 2025	
Conclusion of Agreement	Joint Research and License Agreement  Development of novel therapies for age-related diseases with Gero			
Damayad fyan	tiragolumab	Esophageal cancer (SKYSCRAPER-07 study): Discontinuation of development		
Removed from Pipeline	Five early-stage in- house products	Discontinuation of in-house development: LUNA18, SAIL66, SOF10, STA551, AMY109		
	AVMAPKI <sup>TM</sup> *	Phase II RAMP 205 study (pancreatic ductal adenocarcinoma (1st-line treatment), in combination with standard of care)	June 2025	
	NEMLUVIO®**	Phase III ARCADIA long-term extension study (atopic dermatitis, 2-year data)	June 2025	
Medical	NEMLUVIO®**	Phase III OLYMPIA long-term extension study (prurigo nodularis, 2-year data)	June 2025	
Conference	NXT007	Phase I/II NXTAGE study (hemophilia A)	June 2025	
	orforglipron***	Phase III ACHIEVE-1 study (type 2 diabetes)	June 2025	
	Lunsumio + Polivy	Phase III SUNMO study (relapsed or refractory aggressive B-cell non-Hodgkin's lymphoma)	June 2025	
Open Innovation	Investment by Chugai Venture Fund, LLC****	- Stylus Medicine - Two U.Sbased companies	April 2025 May and July 2025	

Orange: in-house projects (development in global) Blue: In-licensed from Roche (development and distribution in Japan) TACE: transarterial chemoembolization, PFS: progression-free survival \*Conducted by Verastem Oncology, a global licensee \*\*Conducted by Galderma, an overseas licensee \*\*\* Conducted by Eli Lilly and Company, a global licensee \*\*\*\* Conducted by Eli Lilly and Company, a global licensee \*\*\*\* Conducted by Eli Lilly and Company, a global licensee \*\*\*\*\* Conducted by Eli Lilly and Company, a global licensee \*\*\*\*\* Conducted by Eli Lilly and Company, a global licensee \*\*\*\*\* Conducted by Eli Lilly and Company, a global licensee \*\*\*\*\*



## 2025: Key R&D Milestones

As of July 24, 2025

	Product	Indication / Study name	Progress			
Projects to be	<u>Elevydis</u>	Duchenne muscular dystrophy (ambulatory)	<u>Approved</u>			
Approved	Vabysmo	<b>Vabysmo</b> angioid streaks				
	PiaSky	COMMUTE-a study*: atypical hemolytic uremic syndrome (aHUS)				
	Lunsumio + Polivy	SUNMO study: r/r aggressive B-cell non-Hodgkin's lymphoma	Achieved PE			
<b>50/5!</b>	Lunsumio	CELESTIMO study: follicular lymphoma (2nd line)				
P3/Pivotal	giredestrant	persevERA study: HR positive breast cancer (1st line)				
Readouts	evERA study: HR positive breast cancer (1st line to 3rd lin					
	vamikibart	SANDCAT study: noninfectious uvetic macular edema (UME)				
	GAZYVA	INShore study: pediatric nephrotic syndrome				
	GYM329 + Evrysdi	MANATEE study: spinal muscular atrophy (SMA)				
	GYM329	MANOEUVRE study: facioscapulohumeral muscular dystrophy (FSHD)				
P2 Readouts	NXT007	hemophilia A	PoC confirmed / Decision to proceed to Phase III**			
P1/2 Readout	trontinemab	Brainshuttle™ AD study: Alzheimer's disease	Decision to proceed to Phase III			
Initiation of study	GYM329	obesity (Phase II study) <u>Study</u>				

Orange: in-house projects (development in global) Blue: In-licensed from Roche (development and distribution in Japan) \*Adult/Adolescent patients, \*\*Three phase 3 studies scheduled to initiate in 2026 (vs. FVIII products, vs. Hemlibra, and pediatric patients) r/r: relapsed or refractory, PE: primary endpoint, HR: hormone receptor, PoC: Proof of Concept

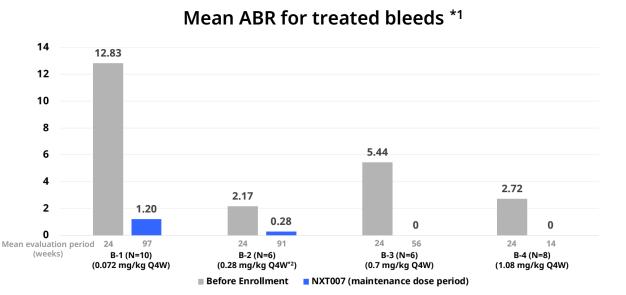
Underlined: Changes since April 24, 2025



## NXT007: P1/2 Study for Severe Hemophilia A Without Inhibitors

- First clinical data of NXT007 in people with hemophilia A. Hemlibra-naïve people enrolled
- In the high dose cohorts (B-3, B-4), plasma concentrations reached the predicted normal range of FVIII– equivalent activity, with no treated bleeds observed. NXT007 was well tolerated, based on data up to date
- Three Phase III studies to be initiated in 2026, including H2H with Hemlibra. In addition to efficacy, safety including ADA (anti drug antibody) will be further evaluated

### **Efficacy (ABR : Annualized Bleeding Rate)**



<sup>\*1</sup> Bleeding information before study was collected from 24 weeks before the study in a retrospective manner. ABR was calculated by annualizing the number of bleeding episodes observed during the evaluation period \*2 Dosing regimen was switched from 0.14 mg/kg Q2W to 0.28 mg/kg Q4W to reflect study protocol amendment

### **Saftey**

- No dose-dependent increases in AEs were observed. No serious adverse events related to NXT007, or thromboembolic events were observed
- ADA was observed in 22 out of 30 patients; the number of ADA positive patients at the final observation before the data cutoff was 10. ADA impacting PK was observed in 2 patients. No ADA cross-reacting with emicizumab was observed

	<b>B-1</b> (N=10)	<b>B-2</b> (N=6)	<b>B-3</b> (N=6)	<b>B-4</b> (N=8)	Total (N=30)
ADA post-baseline incidence *3	7	6	4	5	22
ADA impacting PK	1	0	1	0	2
ADA cross-reacting with emicizumab	0	0	0	0	0

<sup>\*3</sup> No patients were ADA positive at baseline.

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## **AUBE00 (Pan-KRAS Inhibitor)**

Second clinical-stage project applying mid-size molecule technology. Phase 1 trial initiated for solid tumors.

Expecting superior efficacy compared to the pan-RAS inhibitor LUNA18, resulting from a wide therapeutic

window based on KRAS-selective inhibitory activity.

#### Characteristics of AUBE00

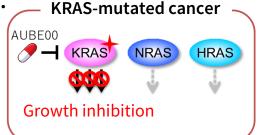
- Expected to deliver anti-tumor effects and favorable safety profiles through selective inhibitory activity against KRAS-GDP
- Anticipated to target a wide range of KRAS genetic mutations. No such drugs have been approved yet, representing high unmet medical needs

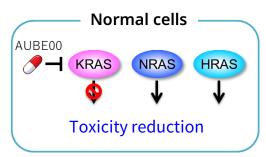
#### What is KRAS?

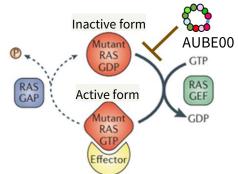
 One of the most frequently mutated oncogenes that contribute to tumor development and progression

### Characteristics of mid-sized molecule technology

- Cyclic peptides containing non-natural amino acids
- Expected to improve binding affinity by interacting with broad interfaces of target proteins
- Possess high membrane permeability and metabolic stability, making oral administration feasible

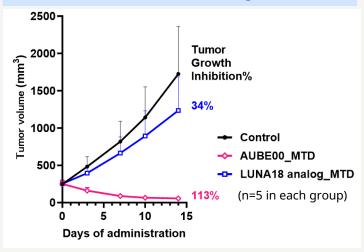






Anti-tumor effects in a xenograft mouse model inoculated with a human KRASmutated non-small cell lung cancer (Source: Internal data)

AUBE00 demonstrated robust tumor regression in a xenograft model that was insensitive to a LUNA18 analog



#### Tumor growth inhibition (%):

This represents the tumor inhibition effect against tumor growth in the control group. 100% indicates tumor growth has completely stopped, while values exceeding 100% indicate tumor shrinkage

MTD (Maximal tolerable dose)



## **ROSE12: Anti-CTLA-4 Switch Antibody**

ROSE12 is expected to have a wide therapeutic window, and its phase 1 trial for solid tumors is currently underway

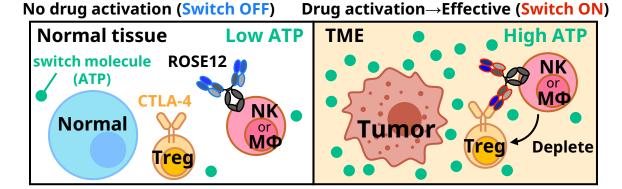
NK: natural killer MΦ: macrophage TMF: tumor microenvironment

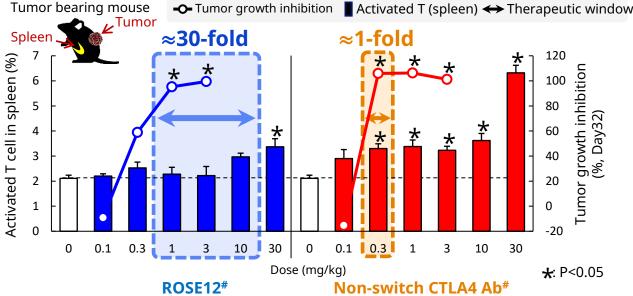
### ROSE12:

- Selectively depletes immunosuppressive regulatory T cells (Tregs) in tumors and increases activated T cells, demonstrating anti-tumor effects while reducing systemic side effects
- Shows anti-tumor effects without increasing activated
   T cells in normal tissues in non-clinical studies
- A phase 1 clinical trial for patients with locally advanced or metastatic solid tumors as monotherapy and in combination with Tecentriq is ongoing in Japan and the U.S. (NCT05907980)

### CTLA-4:

- Membrane protein highly expressed on Treg which has strong immunosuppressive function
- ROSE12 binds to Treg via CTLA-4 only in the presence of the switch molecule (extracellular ATP)





25



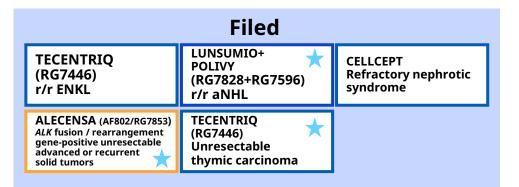
## **Portfolio of Each Modality**

				AS 01 July 24, 2023
Drug Discovery	Pre-clinical development	Clinical		Launched
Antibody drugs, cellular and g	ene therapy products	NXT007 DONQ52 RAY121 GC33 ALPS12 ROSE12	Enspryng (MOGAD, AIE, TED/P3 DMD/P2) PiaSky (aHUS/P3, SCD/P2) GYM329 (SMA/P2/3, FSHD/P2, Obesity/P2	Actemra Hemlibra Enspryng PiaSky
26		BRY10	Developments licensed out	Mitchga (JPN) NEMLUVIO (U.S./EU)
Small molecule drugs		REVN24	Alecensa (Maintenance treatment of NSCLC(stage III) after chemoradiotherapy/P3)	Alecensa Edirol Oxarol
>9		MINT91	Orforglipron (T2D, Obesity, Osleep apnea/P3 AP306 (Hyperphosp hatemia/P2)  AVMAPKI (NSCLC, mPDAC)	Deberza AVMAPKI
Mid-size molecule drugs		AUBE00		



## **Projected Submissions (Phase II & Later Programs and Products)**

As of July 24, 2025



In-house In-licensed (Roche)

aHUS: atypical hemolytic uremic syndrome r/r aNHL: relapsed or refractory aggressive B-cell non-Hodgkin's lymphoma DMD: Duchenne muscular dystrophy

r/r ENKL: relapsed or refractory extranodal natural killer/T-cell lymphoma, nasal type FSHD: facioscapulohumeral muscular dystrophy

HCC: hepatocellular carcinoma LBCL: large B-cell lymphoma

👚 new entry

MIBC: muscle-invasive bladder cancer MOGAD: myelin oligodendrocyte glycoprotein antibody-associated disease NSCLC: non-small cell lung cancer

nAMD: neovascular age-related macular degeneration

SCD: sickle cell disease SMA: spinal muscular atrophy

**GAZYVA** (RG7159) Extra renal lupus

ELEVYDIS(RG6356) DMD (non-ambulatory)

afimkibart (RG6631) **Ulcerative colitis** 

(RG6330) **2L NSCLC** 

giredestrant **Breast cancer (adj)** 

(SA237/RG6168) encephalitis

2027

**ENSPRYNG** 

NXT007/RG6512 Hemophilia A

GYM329/RG6237 Obesity

GYM329/RG6237 **FSHD** 

GYM329/RG6237 + EVRYSDI

**VABYSMO** (RG7716)

Non-proliferative diabetic retinopathy

LUNSUMIO (RG7828) **Previously untreated** Follicular lymphoma

sefaxersen (RG6299) IgA nephropathy

glofitamab (RG6026) **Previously untreated** 

LBCL + Polivy **PIASKY** 

(SKY59/RG6107) SCD (Global (excluding Japan))

TECENTRIQ+AVASTIN (RG7446+RG435) HCC (intermediate stage)

**TECENTRIQ** (RG7446) MIBC (adj)

tiragolumab+ TECENTRIO (RG6058+RG7446) NSCLC (Stage III) tiragolumab(RG6058) 1L HCC **TECENTRIQ+AVASTIN** 

**ENSPRYNG** (SA237/RG6168) Thyroid eye disease

PIASKY (SKY59/RG6107) aHUS

**ENSPRYNG** (SA237/RG6168) MOGAD

ranibizumab(PDS) (RG6321)

**nAMD** 

vamikibart (RG6179) **UME** 

giredestrant (RG6171) **1L-3L Breast cancer** 

giredestrant (RG6171) 1L Breast cancer

**GAZYVA** (RG7159) **Lupus nephritis** 

GAZYVA(RG7159)

**Pediatric nephrotic** 

syndrome

LUNSUMIO (RG7828) 2L Follicular lymphoma

**TECENTRIO** (RG7446) **NSCLC** (perioperative)

ranibizumab(PDS) (RG6321) DME

(SA237/RG6168) **DMD** 

NME Line extension

divarasib

(RG6171)

**ENSPRYNG** Autoimmune

2025 2026 2028 and beyond

## CHUGAI

## Projects under Development (1/2)

As of July 24, 2025

	Phas	se I	Phase II	Phase	III	Filed
Cancer	GC33 / codrituzumab - HCC ALPS12 / clesitamig - Solid tumors ROSE12 - Solid tumors MINT91 - Solid tumors AUBE00 - Solid tumors	RG7421 / cobimetinib - Solid tumors RG6026 / glofitamab - Hematologic tumors RG6160 / cevostamab - r/r MM	RG6114 / inavolisib - PIK3CA- mutated breast cancer (PI/II) ★	AF802 (RG7853) / Alecensa - NSCLC (stage III)*  RG7446 / Tecentriq - NSCLC (perioperative) - MIBC (adjuvant) - HCC (2L)  RG7446 / Tecentriq +RG435 / Avastin - HCC (intermediate stage)  RG6058 / tiragolumab +RG7446 / Tecentriq - NSCLC (stage III)  RG6058 / tiragolumab+RG7446 / Tecentriq+RG435 / Avastin - HCC (1L)	RG6171 /giredestrant  - BC (adjuvant)  - BC (1L)  - BC (1L-3 L)  RG7828 / Lunsumio  - Follicular lymphoma (2L)  - Previously untreated follicular lymphoma  RG6026 / glofitamab  +RG7596 / Polivy  - Previously untreated large B-cell lymphoma  RG6330 / divarasib  - NSCLC (2L)	AF802 (RG7853) / Alecensa - ALK fusion / rearrangement gene-positive unresectable advanced or recurrent solid tumors★ RG7446 / Tecentriq - r/r ENKL - Unresectable thymic carcinoma★ RG7828 / Lunsumio +RG7596 / Polivy - r/r aNHL ★
Immunology	DONQ52 - Celiac disease RAY121 - Autoimmune disease			RG7159 / Gazyva - Lupus nephritis - Pediatric nephrotic syndrome - Extra renal lupus	RG6299 / sefaxersen -IgA nephropathy RG6631 / afimkibart - Ulcerative colitis	CellCept - Refractory nephrotic syndrome

Orange: in-house projects (development in global) Blue: In-licensed from Roche (development and distribution in Japan

In principle, completion of first dose is regarded as pipeline entry into each phase of clinical studies. \*maintenance therapy after chemoradiation aNHL: aggressive B-cell non-Hodgkin's lymphoma, BC: breast cancer, ENKL: refractory extranodal natural killer/T-cell lymphoma, nasal type, HCC: hepatocellular carcinoma, MIBC: muscle-invasive bladder cancer, MM: multiple myeloma, NSCLC: non-small cell lung cancer, r/r: relapsed or refractory

<sup>★:</sup> Projects with advances in stages since April 24, 2025



## Projects under Development (2/2)

As of July 24, 2025

	Pha	ise I	Phase II	P	hase III	Filed
Neurology	RG7935 / prasinezumab - Parkinson's disease RG6102/trontinemab -Alzheimer's disease (PI/II)		GYM329 (RG6237) / emugrobart - SMA (combination with Evrysdi) (PII/III) - FSHD SA237 (RG6168) / Enspryng - DMD RG6042 / tominersen - Huntington's disease	SA237 (RG6168) / Enspryng - MOGAD - AIE	RG6356 / Elevydis - DMD* (non- ambulatory)	
Hematology			SKY59 (RG6107) / PiaSky(Global (excluding Japan)) - SCD NXT007 (RG6512) - Hemophilia A (PI/II)	SKY59 (RG6107) / PiaSky - aHUS ACE910 (RG6013) / Hemlibra - von Willebrand disease*		
Ophthal mology	RG6321 / PDS - nAMD (PI/II) - DME (PI/II)			SA237 (RG6168) / Enspryng - TED	RG6179 / vamikibart - UME RG7716 / Vabysmo - Non-proliferative diabetic retinopathy★	
Other	REVN24 - Acute diseases BRY10 - Chronic diseases	RAY121 - (Not disclosed) RG6615 / zilebesiran - Hypertension (PI/II)	GYM329 (RG6237) / emugrobart - Obesity★			

Orange: in-house projects (development in global) Blue: In-licensed from Roche (development and distribution in Japan)

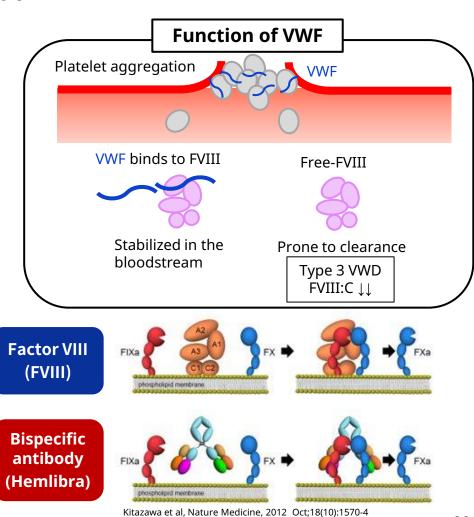
In principle, completion of first dose is regarded as pipeline entry into each phase of clinical studies

★: Projects with advances in stages since April 24, 2025 \*Sarepta manages the global study, including Japan.



# Advance Hemlibra into Global PhIII Development for von Willebrand Disease (VWD)

- Hemlibra is expected to prevent bleeds for people with Type 3 VWD due to its mode of action
- von Willebrand factor (VWF) is a plasma protein that mediates platelet adhesion and aggregation at sites of vascular injury and also binds and stabilizes the blood clotting factor VIII (FVIII) in the circulation
- VWD is an inherited bleeding disorder caused by quantitative deficiency, dysfunction, or absence of VWF (Type 1, 2, and 3 respectively), characterized mainly by mucosa-associated bleeding (e.g. nose bleeds, oral-cavity bleeds, easy bruising) and heavy menstrual periods
- FVIII mimetic function of Hemlibra is expected to prevent the bleeds for people with Type 3 VWD, who can experience bleeding in joints and muscle due to reduction in FVIII activity caused by VWF absence.
  - Current replacement therapy with VWF has several issues: i.v. infusion,
     frequent injection due to short half life, development of alloantibody



Oldenburg J, et al, N Engl J Med. 2017



## **Small Molecule Drug Discovery: Portfolio**

As of July 24, 2025

#### In-house molecule



















Chronic disease >7
Cancer >1





Alecensa
(Maintenance treatment of NSCLC(stage III) after chemoradiotherapy /P3)



Alecensa (NSCLC, NSCLC adjuvant)



Edirol (Osteoporosis)



Oxarol (Psoriasis)

Developments licensed out to 3rd parties excl. Roche



AP306 (Hyperpho sphatemia /P2)





Deberza (T2D)



AVMAPKI (NSCLC, mPDAC/P1/2)



AVMAPKI (LGSOC)

**Drug Discovery** 

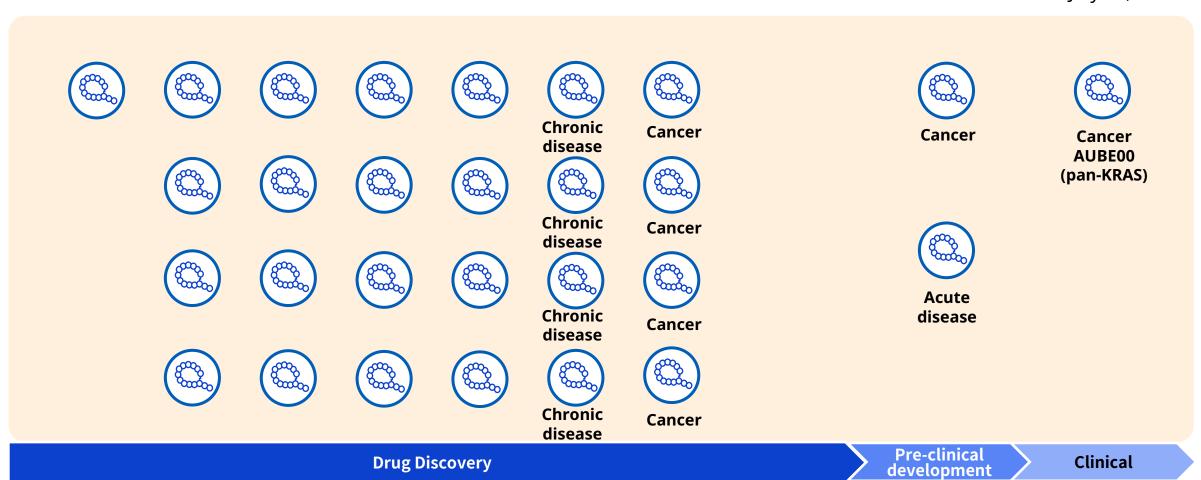
Pre-clinical development

Clinical

Launched



## Mid-Size Molecule Drug Discovery: Portfolio

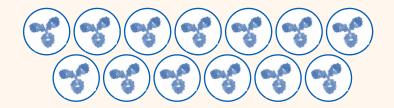




## **Antibody Drug, Cellular and Gene Therapy: Portfolio**

As of July 24, 2025

### **Established technologies**

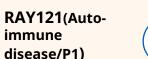




Infectious disease



NXT007 (Hemophilia A/P1/2)





GC33 (Cancer/P1)



BRY10 (Chronic disease/P1)



PiaSky (aHUS/P3, SCD/P2)

**GYM329** 

(SMA/P2/3, FSHD/P2,

Obesity/P2)

Enspryng

(MOGAD, AIE,

TED/P3. DMD/P2)



arthritis etc.) Hemlibra (Hemophilia A

(Rheumatoid



Enspryng (NMOSD)

etc.)

Actemra



PiaSky (PNH)

Developments licensed out to 3rd parties excl. Roche



Mitchga (Atopic dermatitis/JPN)

NEMLUVIO (Atopic dermatitis, PN (U.S./EU))

### **New technologies**





DONQ52 (Celiac/P1)



ALPS12 (Cancer/P1)



ROSE12 (Cancer/P1)

**Drug Discovery** 

Pre-clinical development

Clinical

Launched



# Advances in Major Chugai Originated Projects Out-Licensed to 3rd Parties (1/2)

As of July 24, 2025

Generic name/ Development code	Mode of Action	Licensee	Granted rights to licensee	Indication	Stage	Progress	
			Exclusive global	KRAS-mutated recurrent low-grade serous ovarian cancer (LGSOC)  Advanced KRAS G12C mutant non-small cell lung cancer (NSCLC)	KRAS-mutated recurrent low-grade serous ovarian	Overseas/US: P3 US: Approved ★	<ul> <li>U.S. FDA BTD (recurrent LGSOC in combination with defactinib)</li> <li>U.S. orphan drug designation (avutometinib in combination with defactinib in recurrent LGSOC)</li> <li>RAMP301 trial (P3) ongoing globally</li> <li>Obtained approval in May 2025 under the accelerated approval pathway in the U.S. for the treatment of adult patients with KRAS-mutated recurrent LGSOC who have received prior systemic therapy, in combination with defactinib ★</li> </ul>
avutometinib	RAF/MEK	Verastem Oncology	license for the manufacturing,		Japan: P2	RAMP201J trial (P2 in combination with defactinib) ongoing	
/VS-6766	clamp		development and marketing		Overseas/ U.S. : P1/2	<ul> <li>RAMP 203 trial (P1/2 in combination with sotorasib with or without defactinib) ongoing globally</li> <li>U.S. FDA fast track designation of avutometinib in combination with sotorasib</li> <li>U.S. FDA fast track designation for the combination of avutometinib plus defactinib with sotorasib</li> </ul>	
				First-line metastatic pancreatic ductal adenocarcinoma (mPDAC)	US: P1/2	RAMP 205 trial (P1/2 evaluating avutometinib and defactinib in combination with gemcitabine and nab-paclitaxel) ongoing	

★: Changes since April 24, 2025



# Advances in Major Chugai Originated Projects Out-Licensed to 3rd Parties (2/2)

Generic name/ Development code	Mode of Action	Licensee	Granted rights to licensee	Indication	Stage	Progress
	Anti-IL-31 receptor A		Exclusive global license for the	Atopic dermatitis	Overseas: Approved (US/EU)	<ul> <li>Obtained U.S. FDA approval in Dec 2024</li> <li>Obtained EMA approval in Feb 2025</li> </ul>
nemolizumab	humanized monoclonal antibody	Galderma	development and marketing excluding Japan	Prurigo nodularis	Overseas: Approved (US/EU)	<ul> <li>Obtained U.S. FDA approval in Aug 2024</li> <li>Obtained EMA approval in Feb 2025</li> </ul>
	· I i i land	Eli Lillv	commercialization	Type 2 diabetes	Global: P3	<ul> <li>Phase 3 (ACHIEVE-1): orforglipron demonstrated HbA1c reduction by an average of 1.3% to 1.6% and a 7.9% weight reduction at the highest dose at 40 weeks. A safety profile was consistent with injectable GLP-1 medicines</li> </ul>
orforglipron /LY3502970		and		Obesity	Global: P3	<ul> <li>Phase 2 study: orforglipron demonstrated up to a 14.7% weight reduction at 36 weeks. The results were published in the New England Journal of Medicine*</li> </ul>
				Obstructive sleep apnea	Global: P3	Initiated a phase 3 study in Q4 2024
-/AP306	of phosphate   Alebund	Exclusive global license for the manufacturing,	Hyperphospha	China: P2	<ul> <li>In a phase 2 study, AP306 showed a clinically significant reduction in serum phosphorus levels at the end of treatment compared to baseline</li> </ul>	
(EOS789)	transporters		development and marketing	temia		<ul> <li>AP306 is granted China Breakthrough Therapy Designation for the treatment of hyperphosphatemia in patients with chronic kidney disease</li> </ul>

<sup>\*</sup> Sean W, et al. Daily Oral GLP-1 Receptor Agonist Orforglipron for Adults with Obesity. NEJM 2023.



## FoundationOne CDx Cancer Genomic Profile -Companion diagnostic indications-

Alterations	Cancer type	Relevant drugs
Activating <i>EGFR</i> alterations		afatinib maleate, erlotinib hydrochloride, gefitinib, osimertinib mesilate, dacomitinib hydrate
EGFR exon 20 T790M alteration	Non-small cell	osimertinib mesilate
ALK fusion genes	lung cancer (NSCLC)	alectinib hydrochloride, crizotinib, ceritinib, brigatinib
ROS1 fusion genes	(143626)	Entrectinib
MET exon 14 skipping alterations		capmatinib hydrochloride hydrate
BRAF V600E and V600K alterations	Malignant melanoma	dabrafenib mesylate, trametinib dimethyl sulfoxide, vemurafenib, encorafenib, binimetinib
<i>ERBB2</i> 2 copy number alterations (HER2 gene amplification positive)		trastuzumab (genetical recombination)
AKT1 alterations	ВС	capivasertib
PIK3CA alterations		
PTEN alterations		
KRAS/NRAS wild type	CDC	cetuximab (genetical recombination), panitumumab (genetical recombination)
Microsatellite Instability-High	CRC	nivolumab (genetical recombination)
Microsatellite Instability-High		pembrolizumab (genetical recombination)
Tumor Mutational Burden-High		pembrolizumab (genetical recombination)
NTRK1/2/3 fusion genes	Solid tumors	entrectinib, larotrectinib sulfate, <u>repotrectinib</u>
RET fusion genes		selpercatinib
BRCA1/2 alterations	Ovarian cancer	olaparib
BRCA1/2 alterations	Prostate cancer	olaparib, talazoparib tosilate
FGFR2 fusion genes	Biliary tract cancer	pemigatinib



## FoundationOne Liquid CDx Cancer Genomic Profile

-Companion diagnostic indications-

Alterations	Cancer type	Relevant drugs	
Activating <i>EGFR</i> alterations		afatinib maleate, erlotinib hydrochloride, gefitinib, osimertinib mesilate	
EGFR exon 20 T790M alteration	Non-small cell- lung cancer (NSCLC)	osimertinib mesilate	
ALK fusion genes		alectinib hydrochloride, crizotinib, ceritinib	
ROS1 fusion genes		entrectinib	
MET exon14 skipping alterations		capmatinib hydrochloride hydrate	
NTRK1/2/3 fusion genes	Solid tumors	entrectinib	
BRCA1/2 alterations	Prostate cancer	olaparib	