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

Development Pipeline [Main table] (as of October 24, 2025)

| Development code<br>Origin | Generic name<br>Product name | Indication<br># Additional indication<br>(Combination drug) | Country/region | Projected submission | Mode of Action<br>Modality (Dosage form) | Partner |
|---|---|---|---|---|---|---|
| **Filed** | | | | | | |
| AF802/RG7853<br>in-house | alectinib<br>Alecensa | *ALK* fusion / rearrangement gene-positive unresectable advanced or recurrent solid tumors # | Japan | June 2025 | ALK inhibitor<br>Small molecule (oral) | – |
| RG7446<br>Roche | atezolizumab<br>Tecentriq | Unresectable thymic carcinoma # | Japan | May 2025 | Engineered anti-PD-L1 monoclonal antibody<br>Antibody (IV) | – |
| RG7828<br>Roche | mosunetuzumab<br>Lunsumio | Relapsed or refractory aggressive B-cell non-Hodgkin's lymphoma #<br>(Polivy) # | Japan | May 2025 | Anti-CD20/CD3 bispecific antibody<br>Antibody (SC) | Roche |
| RG435<br>Roche | bevacizumab<br>Avastin | Neurofibromatosis type 2 (NF2) # | Japan | August 2025 | Anti-VEGF humanized monoclonal antibody<br>Antibody (IV) | – |
| **Phase III** | | | | | | |
| AF802/RG7853<br>in-house | alectinib<br>Alecensa | Maintenance treatment of NSCLC (stage III) after chemoradiotherapy # | Global | – | ALK inhibitor<br>Small molecule (oral) | Roche |
| RG7446<br>Roche | atezolizumab<br>Tecentriq | NSCLC (perioperative) # | Japan | 2026 | Engineered anti-PD-L1 monoclonal antibody<br>Antibody (IV) | Roche |
| | | Muscle-invasive bladder cancer (adjuvant) # | Japan | 2026 | | Roche |
| | | HCC (intermediate stage) #<br>(Avastin) # | Japan | 2027 | | Roche |
| | | HCC (2nd Line) #<br>(lenvatinib or sorafenib) | Japan | – | | Roche |
| RG6171<br>Roche | giredestrant<br>– | Breast cancer (adjuvant) | Japan | 2027 | SERD (Selective Estrogen Receptor | Roche |

■Oncology ■Immunology ■Neuroscience ■Hematology ■Ophthalmology ■Other Diseases

| Development code<br>Origin | Generic name<br>Product name | Indication<br># Additional indication<br>(Combination drug) | Country/region | Projected submission | Mode of Action<br>Modality (Dosage form) | Partner |
|---|---|---|---|---|---|---|
| | | Breast cancer (1st Line)<br>(palbociclib) | Japan | 2026 | Degrader)<br>Small molecule (Oral) | Roche |
| | | Breast cancer (1st Line-3rd Line) (everolimus) | Japan | 2026 | | Roche |
| RG7828<br>Roche | mosunetuzumab<br>Lunsumio | Follicular lymphoma<br>(2nd Line) #<br>(lenalidomide) | Japan | 2026 | Anti-CD20/CD3 bispecific antibody<br>Antibody (IV) | Roche |
| | | Previously untreated follicular lymphoma # | Japan | 2028 and beyond | | Roche |
| RG6026<br>Roche | glofitamab<br>– | Previously untreated large B-cell lymphoma<br>(Polivy) | Japan | 2028 and beyond | Anti-CD20/CD3 bispecific antibody<br>Antibody (IV) | Roche |
| RG6330<br>Roche | divarasib<br>– | NSCLC (2nd Line) | Japan | 2027 | KRAS G12C inhibitor<br>Small molecule (Oral) | Roche |
| RG7159<br>GlycArt Biotechnology | obinutuzumab<br>Gazyva | Lupus nephritis # | Japan | 2026 | Glycoengineered type II anti-CD20 monoclonal Antibody<br>Antibody (IV) | Nippon shinyaku |
| | | Pediatric nephrotic syndrome # | Japan | 2026 | | Nippon shinyaku |
| | | Extra renal lupus # | Japan | 2027 | | Nippon shinyaku |
| RG6299/ASO factor B<br>Ionis Pharmaceuticals | sefaxersen<br>– | IgA nephropathy | Japan | 2028 and beyond | Antisense oligonucleotide targeting *complement factor B* mRNA<br>Nucleic acid (SC) | Roche |
| RG6631<br>Roche | afimkibart<br>– | Ulcerative colitis | Japan | 2027 | Anti-TL1A antibody<br>Antibody (-) | Roche |
| | | Crohn's disease | Japan | 2028 and beyond | | |
| SA237/RG6168<br>in-house | satralizumab<br>Enspryng | Myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD) # | Global | 2026 | pH-dependent binding humanized anti-IL-6 receptor monoclonal antibody | Roche |

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

| Development code<br>Origin | Generic name<br>Product name | Indication<br># Additional indication<br>(Combination drug) | Country/region | Projected submission | Mode of Action<br>Modality (Dosage form) | Partner |
|---|---|---|---|---|---|---|
| | | Autoimmune encephalitis (AIE) # | Global | 2027 | Antibody (SC) | Roche |
| RG6356/SRP-9001<br>Sarepta | delandistrogene moxeparvovec<br>Elevydis | Duchenne muscular dystrophy (DMD) (non-ambulatory) # | Japan | 2028 and beyond | Microdystrophin gene therapy<br>Gene therapy (IV) | Sarepta* |
| SKY59/RG6107<br>in-house | crovalimab<br>PiaSky | Atypical hemolytic uremic syndrome (aHUS) # | Global | 2026 | Anti-C5 recycling antibody<br>Antibody (SC) | Roche |
| ACE910/RG6013<br>In-house | emicizumab<br>Hemlibra | Type 3 von Willebrand disease # | Global | 2027 | Anti-coagulation factor IXa/X humanized bispecific monoclonal antibody<br>Antibody (SC) | Roche |
| SA237/RG6168<br>in-house | satralizumab<br>Enspryng | Thyroid eye disease (TED) # | Global | 2026 | pH-dependent binding humanized anti-IL-6 receptor monoclonal antibody<br>Antibody (SC) | Roche |
| RG6179<br>Roche | vamikibart<br>– | Noninfectious uveitic macular edema (UME) | Japan | 2026 | Anti-IL-6 monoclonal antibody<br>Antibody (vitreous injection) | Roche |
| RG7716<br>Roche | faricimab<br>Vabysmo | Non-proliferative diabetic retinopathy # | Japan | 2028 and beyond | Anti-VEGF/Anti-Ang-2 bispecific antibody<br>Antibody (vitreous injection) | – |
| **Phase II/III** | | | | | | |
| GYM329/<br>RG6237<br>in-house | emugrobart<br>– | Spinal muscular atrophy (Evrysdi) | Global | 2028 and beyond | Anti-latent myostatin sweeping antibody<br>Antibody (SC) | Roche |
| **Phase II** | | | | | | |

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

| Development code<br>Origin | Generic name<br>Product name | Indication<br># Additional indication<br>(Combination drug) | Country/region | Projected submission | Mode of Action<br>Modality (Dosage form) | Partner |
|---|---|---|---|---|---|---|
| RG6026<br>Roche | glofitamab<br>– | Relapsed or refractory diffuse large B-cell lymphoma | Japan | 2026 | Anti-CD20/CD3 bispecific antibody<br>Antibody (IV) | – |
| | | Relapsed or refractory mantle cell lymphoma | Japan | 2028 and beyond | | – |
| GYM329/<br>RG6237<br>in-house | emugrobart<br>– | Facioscapulohumeral muscular dystrophy (FSHD) | Global | 2028 and beyond | Anti-latent myostatin sweeping antibody<br>Antibody (SC) | Roche |
| SA237/RG6168<br>in-house | satralizumab<br>Enspryng | Duchenne muscular dystrophy (DMD) # | Global | 2028 and beyond | pH-dependent binding humanized anti-IL-6 receptor monoclonal antibody<br>Antibody (SC) | Roche |
| RG6042<br>Ionis Pharmaceuticals | tominersen<br>– | Huntington's disease | Japan | – | Antisense oligonucleotide targeting *HTT* mRNA<br>Nucleic acid (IV) | Roche |
| GYM329/RG6237<br>In-house | emugrobart<br>– | Obesity | Global | 2028 and beyond | Anti-latent myostatin sweeping antibody<br>Antibody (SC) | Roche |
| **Phase I/II** | | | | | | |
| RG6114<br>Roche | inavolisib<br>– | *PIK3CA*-mutated breast cancer<br>(palbociclib + fulvestrant) | Japan | – | PI3Kα inhibitor<br>Small molecule (Oral) | Roche |
| RG6330<br>Roche | divarasib<br>– | NSCLC (1st Line) | Japan | – | KRAS G12C inhibitor<br>Small molecule (Oral) | Roche |
| RG6102<br>MorphoSys | trontinemab<br>– | Alzheimer's disease | Japan | – | Anti-amyloid beta/TfR1 fusion protein<br>Antibody (IV) | Roche |
| NXT007/<br>RG6512<br>in-house | –<br>– | Hemophilia A | Global | 2028 and beyond | Anti-coagulation factor IXa/X bispecific antibody<br>Antibody (SC) | Roche |

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

| Development code<br>Origin | Generic name<br>Product name | Indication<br># Additional indication<br>(Combination drug) | Country/region | Projected submission | Mode of Action<br>Modality (Dosage form) | Partner |
|---|---|---|---|---|---|---|
| RG6321<br>Roche | ranibizumab (Port delivery system)<br>– | Neovascular age-related macular degeneration | Japan | 2026 | Humanized anti-VEGF monoclonal antibody Fragment Fab<br>Antibody (injection via implant) | – |
| | | Diabetic macular edema | Japan | 2026 | | – |
| RG6615<br>Alnylam Pharmaceuticals | zilebesiran<br>– | Hypertension | Japan | – | RNAi therapeutic targeting angiotensinogen (AGT)<br>RNAi (SC) | Alnylam Pharmaceuticals |
| **Phase I** | | | | | | |
| GC33<br>in-house | codrituzumab<br>– | HCC | Global | – | Anti-Glypican-3 humanized monoclonal antibody<br>Antibody (IV) | – |
| ALPS12<br>in-house | clesitamig<br>– | Solid tumors | Global | – | Anti-DLL3/CD3/CD137 trispecific antibody<br>Antibody (IV) | – |
| ROSE12<br>in-house | –<br>– | Solid tumors | Global | – | Anti-CTLA-4 Switch antibody<br>Antibody (IV) | – |
| MINT91<br>in-house | –<br>– | Solid tumors | Global | – | -<br>Small molecule (Oral) | – |
| AUBE00<br>In-house | –<br>– | Solid tumors | Global | – | Pan-KRAS inhibitor<br>Mid-size molecule (Oral) | – |
| RG7421<br>Exelixis | cobimetinib<br>– | Solid tumors | Japan | – | MEK inhibitor<br>Small molecule (Oral) | – |
| RG6160<br>Roche | cevostamab<br>– | Relapsed or refractory multiple myeloma | Japan | – | Anti-FcRH5/CD3 bispecific antibody<br>Antibody (IV) | – |
| DONQ52<br>in-house | –<br>– | Celiac disease | Global | – | Anti-HLA-DQ2.5/gluten peptides multispecific antibody | – |

■Oncology ■Immunology ■Neuroscience ■Hematology ■Ophthalmology ■Other Diseases

| Development code<br>Origin | Generic name<br>Product name | Indication<br># Additional indication<br>(Combination drug) | Country/region | Projected submission | Mode of Action<br>Modality (Dosage form) | Partner |
|---|---|---|---|---|---|---|
| | | | | | Antibody (SC) | |
| RAY121<br>in-house | –<br>– | Autoimmune disease | Global | – | Anti-C1s recycling antibody<br>Antibody (SC) | – |
| RG7935<br>Prothena | prasinezumab<br>– | Parkinson's disease | Japan | – | Anti-α-synuclein monoclonal antibody<br>Antibody (IV) | – |
| REVN24<br>in-house | –<br>– | Acute diseases | Global | – | –<br>Small molecule (IV) | – |
| BRY10<br>In-house | –<br>– | Chronic diseases | Global | – | –<br>Antibody (SC) | – |
| RAY121<br>in-house | –<br>– | – | Global | – | Anti-C1s recycling antibody<br>Antibody (-) | – |

**Development Discontinued**

| Development code<br>Origin | Generic name<br>Product name | Indication<br># Additional indication<br>(Combination drug) | Country/region | Development stage | Mode of Action<br>Modality (Dosage form) | Partner |
|---|---|---|---|---|---|---|
| RG6058<br>Roche | tiragolumab<br>– | NSCLC (stage III)<br>(Tecentriq) # | Japan | Phase III | Anti-TIGIT human monoclonal antibody<br>Antibody (IV) | Roche |
| RG6058<br>Roche | tiragolumab<br>– | HCC (1st Line)<br>(Tecentriq/Avastin) | Japan | Phase III | Anti-TIGIT human monoclonal antibody<br>Antibody (IV) | Roche |
| SKY59/RG6107<br>in-house | crovalimab<br>PiaSky | Sickle cell disease (SCD) # | Global (excluding Japan) | Phase II | Anti-C5 recycling antibody<br>Antibody (SC) | Roche |

In principle, completion of first dose is regarded as pipeline entry into each phase of clinical studies. * Sarepta manages the global study including Japan

## Changes from the last announcement on July 24, 2025

Oncology

- RG7446 Filed (Relapsed or refractory extranodal natural killer/T-cell lymphoma, nasal type) → Approved
- RG435 Filed (Neurofibromatosis type 2 (NF2))
- RG6026 Domestic Phase II（Relapsed or refractory diffuse large B-cell lymphoma: development started)
- RG6026 Domestic Phase II（Relapsed or refractory mantle cell lymphoma: development started)
- RG6330 Phase Ib/II (NSCLC (1st Line): development started)
- RG6058 Phase III (NSCLC (stage III) (combination with Tecentriq)) → Development discontinued
- RG6058 Phase III (HCC (1st Line) (combination with Tecentriq and Avastin)) → Development discontinued

Immunology

- CellCept Filed (Refractory nephrotic syndrome) → Approved
- RG6631 Phase III (Crohn's disease : development started)

Hematology

- SKY59/RG6107 Phase II (Sickle cell disease (SCD)) → Development discontinued

## R&D Activities

For the changes during the FY2025 (January 1 – September 30), please refer to page 4 of “CONSOLIDATED FINANCIAL STATEMENTS (IFRS) (Non-Audited) (for the nine months ended September 30, 2025).”

Changes from October 1, 2025 to October 24, 2025 are as follows:

Oncology

- We started Phase Ib/II study for a KRAS G12C inhibitor RG6330 for the treatment of NSCLC (1st Line) in October 2025.

## Development Pipeline [Attached table] (Major Chugai originated developments licensed out to 3rd parties excluding Roche)

| Development code<br>licensee/In-house | Generic name<br>Product name | Indication<br># Additional Indication<br>(combination) | Stage<br>Country/region | Mode of Action<br>Modality (Dosage form) | Licensee<br>(Granted rights ) |
|---|---|---|---|---|---|
| VS-6766/CKI27 | avutometinib<br>AVMAPKI | *KRAS*-mutated recurrent LGSOC<br>(defactinib) | Phase III<br>Overseas, U.S. | RAF/MEK clamp<br>Small molecule (Oral) | Verastem Oncology<br>(exclusive global license for the manufacturing, development and marketing) |
| | | | Phase II<br>Japan | | |
| | | *KRAS* G12C advanced NSCLC<br>(sotorasib±defactinib) | Phase I/II<br>Overseas, U.S. | | |
| | | mPDAC (1st line)<br>(defactinib+chemotherapy) | Phase I/II<br>U.S. | | |
| LY3502970/OWL833 | orforglipron<br>— | Type 2 diabetes | Phase III<br>Global | Oral non-peptidic GLP-1 receptor agonist<br>Small molecule (Oral) | Eli Lilly and Company<br>(worldwide development and commercialization rights) |
| | | Obesity | Phase III<br>Global | | |
| | | Obstructive sleep apnea | Phase III<br>Global | | |
| | | Hypertension | Phase III<br>Global | | |
| | | Osteoarthritis | Phase III<br>Global | | |
| AP306/EOS789 | —<br>— | Hyperphosphatemia | Phase II<br>China | Oral inhibitor of phosphate transporters<br>Small molecule (Oral) | Alebund<br>(exclusive global license for the manufacturing, development and marketing) |

**Progress made in R&D activities of major Chugai originated developments licensed out to 3rd party excluding Roche during the period from January 1, 2025 to October 24, 2025 was as follows.**

- In Europe, Galderma obtained regulatory approval for the anti-IL-31 receptor A humanized monoclonal antibody CIM331 (Product name in Europe: NEMLUVIO (nemolizumab)) for moderate-to-severe atopic dermatitis and prurigo nodularis in February 2025.
- In the U.S., Verastem obtained regulatory approval under the accelerated approval pathway for the RAF/MEK clamp VS-6766/CKI27 (Product name in the U.S.: AVMAPKI) for *KRAS*-mutated recurrent LGSOC (combination with defactinib) in May 2025.
- Eli Lilly and Company started a global Phase III study for the oral non-peptidic GLP-1 receptor agonist LY3502970/OWL833 for the treatment of hypertension in Q3 2025, and for the treatment of osteoarthritis in Q4 2025, respectively.
- PI3K Class I inhibitor "PA799" was granted exclusive worldwide rights for manufacturing, development, and commercialization to Menarini Group in November 2016, but all licensing rights were returned to Chugai in June 2025.

**Response to Requests from the MHLW Review Committee on Unapproved Drugs and Indications with High Medical Needs (As of October 24, 2025)**

| 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 |
| | CellCept | Refractory nephrotic syndrome (frequently relapsing or steroid-dependent nephrotic syndrome) | Approved in September 2025 |
| | 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) | NSCLC (periadjuvant) | Chemo ± Tecentriq | IMpower030 | Phase III | NCT03456063 |
| | Muscle-invasive bladder cancer (adjuvant) | Tecentriq vs. placebo | IMvigor011 | Phase III | NCT04660344 |

| Project | Expected indication | Study design | Study name | Stage | CT information |
|---|---|---|---|---|---|
| | HCC (intermediate stage) | Tecentriq + Avastin + TACE vs. TACE | TALENTACE | Phase III | NCT04803994 |
| | HCC [2nd line] | Tecentriq + lenvatinib or sorafenib vs. lenvatinib or sorafenib | IMbrave251 | Phase III | NCT04770896 |
| RG6171/SERD (giredestrant) | Breast cancer (adjuvant) | HR positive: RG6171 vs. endocrine therapy | lidERA | Phase III | NCT04961996 |
| | Breast cancer [1st line] | HR positive: RG6171 + palbocicilib vs. letrozole + palbocicilib | persevERA | Phase III | NCT04546009 |
| | Breast cancer [1st line-3rd line] | HR positive: RG6171 + everolimus vs. endocrine therapy+ everolimus | evERA | Phase III | NCT05306340 |
| RG7828 (Lunsumio) | Follicular lymphoma [2nd line] | Lunsumio + lenalidomide vs. Rituxan + lenalidomide | CELESTIMO | Phase III | NCT04712097 |
| | Relapsed or refractory aggressive B-cell non-Hodgkin's lymphoma | Lunsumio + Polivy vs. Rituxan + chemotherapy | SUNMO | Phase III | NCT05171647 |
| | 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 |
| RG6114 (inavolisib) | *PIK3CA*-mutated breast cancer | RG6114 + palbociclib + fulvestrant (single arm) | – | Phase I/II (domestic) | jRCT2031250161 |
| **Immunology** | | | | | |
| RG7159 (Gazyva) | Lupus nephritis | Standard of care treatment ± Gazyva | – | Phase III (domestic) | jRCT2011210059 |
| | Pediatric nephrotic syndrome | Gazyva vs. MMF | INShore | Phase III | NCT05627557 |
| | Extra renal lupus | Gazyva vs. Placebo | – | Phase III (domestic) | jRCT2071230031 |
| RG6299 (sefaxersen) | IgA nephropathy | RG6299 vs. Placebo | IMAGINATION | Phase III | NCT05797610 |
| RG6631 | Ulcerative colitis | RG6631 vs. Placebo | Ametrine-1 | Phase III | NCT06589986 |

| Project | Expected indication | Study design | Study name | Stage | CT information |
|---|---|---|---|---|---|
| (afimkibart) | 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 |
| GYM329/RG6237 (emugrobart) | Spinal muscular atrophy (SMA) | Evrysdi ± GYM329 | MANATEE | Phase II/III | NCT05115110 |
| RG6356/SRP-9001 (delandistrogene moxeparvovec) | Duchenne muscular dystrophy (DMD) (non-ambulatory) | RG6356 vs. Placebo | ENVISION | Phase III | NCT05881408 |
| **Hematology** | | | | | |
| SKY59/RG6107 (PiaSky) | Atypical hemolytic uremic syndrome (aHUS) | PiaSky (single arm) | COMMUTE-a | Phase III | NCT04861259 |
| | | | COMMUTE-p | Phase III | NCT04958265 |
| ACE910/RG6013 (Hemlibra) | von Willebrand disease | Hemlibra vs. On-demand therapy (standard of care treatment) | WILL-EMI | Phase III | NCT06998524 |
| **Ophthalmology** | | | | | |
| SA237/RG6168 (Enspryng) | Thyroid eye disease (TED) | Enspryng vs. Placebo | SatraGO-1/ SatraGO-2 | Phase III | NCT05987423 NCT06106828 |
| 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 |
| RG6321 (ranibizumab (Port delivery system)) | Neovascular age-related macular degeneration / Diabetic macular edema | RG6321 (single arm) | – | Phase I/II (domestic) | jRCT2071210073 |

## 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 September 30, 2025 | 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 | 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 | 100 | June, 2025 | jRCT2031250094 |
| **Immunology** | | | | | |
| DONQ52 | Celiac disease | Phase Ia/Ib | 56 | September, 2022 | NCT05425446 |
| | | Phase Ic | 56 | July, 2024 | ACTRN12624000316505 |
| RAY121 | Autoimmune disease | Phase Ib | 144 | August, 2024 | NCT06723106 |
| **Neuroscience** | | | | | |
| GYM329/RG6237 (emugrobart) | Facioscapulohumeral muscular dystrophy (FSHD) | Phase II | 48 | March, 2023 | NCT05548556 |
| SA237/RG6168 (Enspryng) | Duchenne muscular dystrophy (DMD) | Phase II | 50 | April, 2025 | NCT06450639 |
| **Hematology** | | | | | |
| NXT007/RG6512 | Hemophilia A | Phase I/II (domestic) | 124 | August, 2019 | jRCT2080224835 |
| | | Phase I (domestic) (only healthy adults) | 30 | May, 2022 | jRCT2031220050 |
| | | Phase I/II | 60 | October, 2023 | NCT05987449 |
| **Other diseases** | | | | | |
| REVN24 | Acute diseases | Phase I (domestic) (only healthy adults) | 210 | October, 2023 | jRCT2071230074 |
| BRY10 | Chronic diseases | Phase I | 72 | September, 2024 | jRCT2051240123 |

| Project | Expected indication | Stage | Enrollment* as of September 30, 2025 | Study start | CT information |
|---|---|---|---|---|---|
| | | (domestic) (only healthy adults) | | | |
| RAY121 | – | Phase I (only healthy adults) | 36 | March, 2025 | 2024-515151-38-00 |
| GYM329/RG6237 (emugrobart) | Obesity | Phase II | 234 | 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 October 24, 2025)

| Alterations | Cancer type | Relevant drugs |
|---|---|---|
| Activating *EGFR* alterations | NSCLC | afatinib maleate, erlotinib, gefitinib, osimertinib mesilate, dacomitinib hydrate |
| *EGFR* exon 20 T790M alteration | | osimertinib mesilate |
| *ALK* fusion genes | | alectinib, crizotinib, ceritinib, brigatinib |
| *ROS1* fusion genes | | entrectinib |
| *MET* exon 14 skipping alterations | | capmatinib hydrochloride hydrate |
| *BRAF* V600E and V600K alterations | Malignant melanoma | dabrafenib mesilate, trametinib dimethyl sulfoxide, vemurafenib, encorafenib, binimetinib |
| *ERBB2* copy number alterations (HER2 gene amplification positive) | Breast cancer | trastuzumab |
| *AKT1* alterations | | capivasertib |
| *PIK3CA* alterations | | |
| *PTEN* alterations | | |
| *KRAS/NRAS* wildtype | 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 genes | | entrectinib, larotrectinib sulfate, repotrectinib[1)] |
| *RET* fusion genes | | selpercatinib |
| *ALK* fusion genes | | alectinib |

| | | |
|---|---|---|
| *BRCA1/2* alterations | Ovarian cancer | olaparib |
| *BRCA1/2* alterations | Prostate cancer | olaparib, talazoparib tosilate |
| *FGFR2* fusion genes | Biliary tract cancer | pemigatinib |

* Underlined are the companion diagnostic features and relevant drugs currently under application for regulatory approval, [1)] Pending approval for additional indication by Bristol-Myers Squibb K.K.

## FoundationOne Liquid CDx Cancer Genomic Profile: companion diagnostic indications (as of October 24, 2025)

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