Chugai Main Products

as of April 24, 2025

Oncology

Origin	Product Name	Major Indication	Basic Information
In-house	Alecensa® ALK inhibitor Generic name: alectinib Launch in Japan: September 2014	➢ *ALK* fusion gene-positive unresectable, advanced, or recurrent non-small cell lung cancer (NSCLC) ➢ Adjuvant therapy for *ALK* fusion gene-positive NSCLC	Alecensa, an oral, small molecule targeted molecular therapy created by Chugai, inhibits the activity of the tyrosine kinase anaplastic lymphoma kinase (ALK) with EML4-ALK (*ALK*) fusion gene expressed in about 2 to 5 percent of NSCLC. In addition to being the first product from Chugai research to be granted breakthrough therapy designation by the U.S. FDA as a secondline treatment in 2013, Alecensa received the same designation as a first-line treatment in 2016, and it is contributing to the treatment of patients around the world. Alecensa is marketed all over the world including Europe and the United States by Roche.
Roche	Avastin® Anti-VEGF humanized monoclonal antibody (Generic name: bevacizumab) Launch in Japan: June 2007	➢ Unresectable, advanced, or recurrent colorectal cancer ➢ Unresectable, advanced, or recurrent NSCLC ➢ Inoperable or recurrent breast cancer ➢ Malignant glioma ➢ Ovarian cancer ➢ Advanced or recurrent cervical cancer ➢ Unresectable HCC	Avastin is a humanized monoclonal antibody targeting vascular endothelial growth factor (VEGF). It is the first therapeutic agent in the world that inhibits angiogenesis, which is the growth of the network of blood vessels that supply nutrients and oxygen to the cancer. Unlike conventional anticancer agents that act directly on cancer cells, Avastin acts on the cancer microenvironment.

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Roche	FoundationOne® CDx Cancer Genomic Profile Launch in Japan: June 2019 FoundationOne® Liquid CDx Cancer Genomic Profile Launch in Japan: August 2021	–	FoundationOne CDx Cancer Genomic Profile (F1CDx), developed by U.S.-based Foundation Medicine, Inc., is a nextgeneration sequencing-based diagnostic device. It detects substitutions, insertion and deletion alterations, and copy number alterations in 324 genes and select gene rearrangements, as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB). The program is available as a companion diagnostic for multiple moleculartargeted drugs approved in Japan. FoundationOne Liquid CDx Cancer Genomic Profile is a liquid biopsy test for solid tumors using blood samples. It detects alterations of 324 genes from tumor DNA circulating in blood (ctDNA). It can be used in cases where tumor tissue is difficult to sample. The product is expected to bring further advances in PHC, including by allowing tissue samples and blood samples to be used selectively at different stages of treatment.
Roche	Herceptin® Anti-HER2 humanized monoclonal antibody Generic name: trastuzumab Launch in Japan: June 2001	➢ HER2-overexpressing breast cancer ➢ HER2-overexpressing, advanced/recurrent gastric cancer not amenable to curable resection ➢ Advanced or recurrent HER2-	Herceptin is a humanized monoclonal antibody that targets human epidermal growth factor receptor type 2 (HER2),8 which contributes to tumor cell growth. The earliest PHC-based anticancer agent, Herceptin has built a solid reputation as an essential treatment for HER2-positive breast cancer since its launch in 2001. Overexpression of HER2 is found in about 15 to 20 percent of breast cancers. Such cancer is diagnosed as HER2-positive. HER2-positive breast cancer

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		positive colorectal cancer that has progressed following cancer chemotherapy and is not amenable to curative resection	progresses rapidly, and has been associated with a poor prognosis. However, treatment outcomes have improved significantly with the emergence of Herceptin and other medicines that target HER2.
Roche	Kadcyla® Anti-HER2 antibody-tubulin polymerization inhibitor conjugate Generic name: trastuzumab emtansine Launch in Japan: April 2014	➢ HER2-positive inoperable or recurrent breast cancer ➢ HER2-positive postoperative breast cancer	Kadcyla is an antibody-drug conjugate of the anti-HER2 humanized monoclonal antibody trastuzumab (product name: Herceptin) and the potent chemotherapeutic agent DM1, joined together with a stable linker.
Roche	Lunsumio® Anti-CD20/CD3 humanized bispecific antibody Generic name: mosunetuzumab Launch in Japan: March 2025	➢ Relapsed or refractory follicular lymphoma who have received two or more prior standard therapies	Lunsumio is a CD20/CD3 T cell-engaging bispecific antibody designed to target CD20 on B cells and CD3 on T cells. Lunsumio is expected to activate the immune system through cytotoxic T cells and have antitumor effects on CD20 expressing tumor cells. Furthermore, Lunsumio is a fixed-duration treatment based on the patient's response to therapy, and is expected to reduce the burden of treatment on patients.

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Roche	Perjeta® Anti-HER2 humanized monoclonal antibody Generic name: pertuzumab Launch in Japan: September 2013	➢ HER2-positive inoperable or recurrent breast cancer ➢ Neoadjuvant and adjuvant therapy for HER2-positive breast cancer ➢ Advanced or recurrent HER2-positive colorectal cancer that has progressed following cancer chemotherapy and is not amenable to curative resection	Perjeta is a humanized monoclonal antibody and is the first molecular targeted therapy that inhibits the dimerization of HER2. The combination of Perjeta and Herceptin, which also targets HER2, provides a more comprehensive blockade of HER signaling pathways associated with the proliferation of tumor cells.
Roche	Phesgo® Anti-HER2 humanized monoclonal antibody/hyaluronandegradation enzyme combination Generic name: pertuzumab, trastuzumab and vorhyaluronidase alfa Launch in Japan:	➢ HER2-positive breast cancer ➢ Advanced or recurrent HER2-positive colorectal cancer that has progressed following cancer chemotherapy and is not amenable to curative resection	Phesgo, subcutaneous fixed-dose combination without preparation contains the same monoclonal antibodies as Perjeta and Herceptin, and also a vorhyaluronidase alfa (genetical recombination) combined in a single vial. It takes over eight minutes for a loading dose of Phesgo and over five minutes for the subsequent doses. Reduction of administration time is expected to contribute to patients' daily life.

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Origin	Product Name	Major Indication	Basic Information
	November 2023		
Roche	Polivy® Antimicrotubule binding anti-CD79b monoclonal antibody Generic name: polatuzumab vedotin Launch in Japan: May 2021	➢ Diffuse large B-cell lymphoma	Polivy is an antibody-drug conjugate of an anti-CD79b monoclonal antibody and the microtubule inhibitor MMAE, joined together with a linker. In-licensed from Roche, the conjugate is designed to deliver MMAE directly into B cells via CD79b, which is expressed on B cells, so that the inhibitor can act.
Roche	Tecentriq® Anti-PD-L1 humanized monoclonal antibody Generic name: atezolizumab Launch in Japan: April 2018	➢ Unresectable, advanced, or recurrent NSCLC ➢ Adjuvant treatment of PD-L1-positive NSCLC ➢ Extensive-stage small cell lung cancer (SCLC) ➢ PD-L1-positive, hormone receptor-negative and HER2-negative inoperable or recurrent breast cancer ➢ Unresectable hepatocellular carcinoma (HCC)	Tecentriq is an engineered anti-PD-L1 monoclonal antibody inlicensed from Roche. One way that tumor cells evade the immune system is by expressing a protein called programmed death-ligand (PD-L1) on their surface, which is believed to shield them from immune system attacks by binding to T cells. Tecentriq restores and maintains the immune response of T cells by binding to PD-L1, and is expected to demonstrate efficacy against cancer cells. Its mode of action differs from conventional treatments that attack cancer cells directly. Since it takes advantage of the patient’s own immune response, it is also promising for use in combination with existing drugs and for various cancer types.

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Specialty (excl. Oncology)

Origin	Product Name	Major Indication	Basic Information
In-house	Actemra® Humanized anti-human IL-6 receptor monoclonal antibody Generic name: tocilizumab Launch in Japan: June 2005	➢ Rheumatoid arthritis ➢ Castleman's disease ➢ Adult Still's disease ➢ SARS-CoV-2 pneumonia (limited to patients requiring oxygen intervention)	Actemra, created by Chugai and the first therapeutic antibody originating in Japan, blocks the activity of IL-6, a type of cytokine. There are two types of formulation; an intravenous infusion formulation and a subcutaneous formulation with the aim of improving convenience. In addition, Actemra is marketed all over the world including Europe and the United States by Roche.
Roche	CellCept® Immunosuppressant Generic name: mycophenolate mofetil Launch in Japan: November 1999	➢ Refractory rejections after kidney transplant ➢ Suppression of rejections after the following organ transplants: kidney, heart, liver, lung and pancreas transplants	CellCept is used to treat refractory rejection after kidney transplants and to prevent rejection after kidney, heart, liver, lung, and pancreas transplants. The need for transplantation medication has been rising in Japan, driven by advances in transplantation therapy.
In-house	Edirol® Osteoporosis agent (Active vitamin D_3 derivative) Generic name: eldecalcitol	➢ Osteoporosis	Edirol, a vitamin D3 preparation born out of Chugai's many years of research in vitamin D, is an agent that improves bone metabolism in addition to calcium metabolism. In the 2015 osteoporosis prevention and treatment guidelines, Edirol received a Grade A recommendation, the only one for an active vitamin D3 derivative, for its effectiveness in increasing bone density and preventing

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Origin	Product Name	Major Indication	Basic Information
	Launch in Japan: April 2011 Launch in China: July 2022		vertebral fractures.
In-house	Enspryng® pH-dependent binding humanized anti-IL-6 receptor monoclonal antibody Generic name: satralizumab Launch in Japan: August 2020	➢ Prevention of relapses of neuromyelitis optica spectrum disorder (NMOSD)	Enspryng is a next-generation therapeutic antibody that has shown success in blocking IL-6 receptors with a longer duration of action. Chugai created Enspryng by applying its novel antibody engineering technology (Recycling Antibody® technology) that enables a single antibody molecule to block the target antigen repeatedly. As a result, a prolonged serum half-life has been demonstrated in clinical trials, which will make a lower dosing frequency possible. Because IL-6 promotes the production of the anti-AQP4 antibodies that are the primary cause of NMOSD, this drug is expected to improve (reduce recurrence of) the symptoms of these diseases as it inhibits the production of those antibodies by blocking the IL-6 signal. In the United States, it received breakthrough therapy designation for the treatment of NMOSD from the U.S. FDA in December 2018. Enspryng is approved in over 90 countries worldwide, including Japan, U.S. and European Union.
Roche	Evrysdi® Spinal muscular atrophy agent	➢ Spinal muscular atrophy	Evrysdi is an SMN2 splicing modifier that increases generation of a protein derived from the SMN2 gene. This protein is nearly identical to the protein made from the SMN1 gene, which is not functional in

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	Generic name: risdiplam Launch in Japan: August 2021		SMA patients. Evrysdi shows promise in improving neural and muscular function. Reduction in burden is expected by oral administration.
In-house	Hemlibra® Anti-coagulation factor IXa/X humanized bispecific monoclonal antibody Generic name: emicizumab Launched in Japan: May 2018	➢ Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in patients with congenital factor VIII deficiency ➢ Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in patients with acquired hemophilia A	Hemlibra is a bispecific antibody that employs Chugai's innovative antibody engineering technologies. Like factor VIII, which is low or missing in hemophilia A, Hemlibra simultaneously binds to factor IXa and factor X, stimulating the activation of factor X by activated factor IX and promoting normal blood coagulation for hemostasis. Unaffected by inhibitors, Hemlibra can prevent bleeding with subcutaneous injections once a week, once every two weeks, or once every four weeks, and is promising as a drug that can change the existing system of treatment. Another key feature is that Chugai's proprietary technology ART-Ig® is applied to Hemlibra, enabling industrial production of bispecific antibodies. The drug received breakthrough therapy designation from the U.S. FDA in September 2015 for its potential to prevent bleeding in hemophilia patients with inhibitors, and in April 2018 for its potential to prevent bleeding in patients without inhibitors. Hemlibra is approved in over 120 countries worldwide.
Roche	Mircera® Long-acting	➢ Renal anemia	Mircera is a drug that raises the stability of epoetin beta in the bloodstream through pegylation. It is a type of renal anemia

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Origin	Product Name	Major Indication	Basic Information
	erythropoiesis-stimulating agent Generic name: epoetin beta pegol Launch in Japan: July 2011		treatment with the longest serum half-life among ESAs, enabling stable and sustained control of anemia. It stimulates erythropoiesis through a different interaction with the EPO receptor on burst-forming unit erythroid (BFU-E) cells in the bone marrow.
In-house	PiaSky® pH-dependent binding humanized anti-complement (C5) monoclonal antibody Generic name: crovalimab Launch in Japan: May 2024	➢ Paroxysmal nocturnal hemoglobinuria	PiaSky is an anti-C5 recycling antibody created with Chugai's Recycling Antibody® technology. Recycling antibodies are designed to achieve pH-dependent antigen binding so that a single antibody molecule can bind with the antigen multiple times, enabling a longer efficacy compared with a conventional antibody. Crovalimab is designed to target C5, a key component of the complement system, and is expected to control complement activity. It is also expected to reduce the treatment burden for patients and their caregivers through subcutaneous administration. Since crovalimab binds to complement C5 at a different site from existing antibody drugs, it can be an effective treatment option for patients with a specific C5 gene mutation reported in Asia (appears in approximately 3.2% of Japanese patients with PNH), to which existing antibody drugs do not bind.
Roche	Ronapreve® anti-SARS-CoV-2	➢ SARS-CoV-2 infection ➢ Prevention of symptomatic	Ronapreve was designed specifically by Regeneron to block the infectivity of SARS-CoV-2, the virus that causes COVID-19. The two

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Origin	Product Name	Major Indication	Basic Information
	monoclonal antibody Generic name: casirivimab/imdevimab Launch in Japan: July 2021	SARS-CoV-2 infection	potent, virus-neutralizing antibodies that form casirivimab and imdevimab are believed to bind non-competitively to the critical receptor binding domain of the virus's spike protein.
Roche	Tamiflu® Anti-influenza agent Generic name: oseltamivir Launch in Japan: February 2001	➢ Treatment and prevention of influenza type A or B virus infection	Tamiflu is an oral anti-influenza agent that is effective against both type A and type B infections. It inhibits viral replication by blocking the action of neuraminidase, an enzyme essential for the multiplication of the influenza virus.
Roche	Vabysmo® Anti VEGF/anti Ang-2 bispecific antibody Generic name: faricimab Launch in Japan: May 2022	➢ Age-related macular degeneration associated with subfoveal choroidal neovascularization ➢ Diabetic macular edema ➢ Macular edema associated with retinal vein occlusion	Vabysmo is the first bispecific antibody in the field of ophthalmology designed to inhibit two disease pathways involved in many retinal diseases by blocking the actions of vascular endothelial growth factor-A (VEGF-A) and angiopoietin-2 (Ang-2). Intraocular injection achieves durability of up to 16-week dosing interval and is expected to reduce the treatment burden on patients.