

Oncology

Origin	Product Name	Major Indication	Basic Information
In-house	Alecensa® ALK inhibitor Generic name: alectinib Launch in Japan: September 2014	<ul style="list-style-type: none"> ➤ ALK fusion gene-positive unresectable, advanced, or recurrent 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	<ul style="list-style-type: none"> ➤ Unresectable, advanced, or recurrent colorectal cancer ➤ Unresectable, advanced, or recurrent NSCLC ➤ Inoperable or recurrent breast cancer ➤ Malignant glioma ➤ Ovarian cancer ➤ Advanced or recurrent 	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.

Chugai Main Products

as of April 24, 2024

Origin	Product Name	Major Indication	Basic Information
		cervical cancer ➤ Unresectable HCC	
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 molecular targeted 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	➤ HER2-overexpressing breast cancer ➤ HER2-overexpressing,	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-

Chugai Main Products

as of April 24, 2024

Origin	Product Name	Major Indication	Basic Information
	<p>Generic name: trastuzumab Launch in Japan: June 2001</p>	<p>advanced/recurrent gastric cancer not amenable to curable resection</p> <ul style="list-style-type: none"> ➤ Advanced or recurrent HER2-positive colorectal cancer that has progressed following cancer chemotherapy and is not amenable to curative resection 	<p>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 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.</p>
Roche	<p>Kadcyla® Anti-HER2 antibody-tubulin polymerization inhibitor conjugate Generic name: trastuzumab emtansine Launch in Japan: April 2014</p>	<ul style="list-style-type: none"> ➤ HER2-positive inoperable or recurrent breast cancer ➤ HER2-positive postoperative breast cancer 	<p>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.</p>
Roche	<p>Perjeta® Anti-HER2 humanized</p>	<ul style="list-style-type: none"> ➤ HER2-positive inoperable or recurrent breast 	<p>Perjeta is a humanized monoclonal antibody and is the first molecular targeted therapy that inhibits the dimerization of</p>

Origin	Product Name	Major Indication	Basic Information
	monoclonal antibody Generic name: pertuzumab Launch in Japan: September 2013	cancer <ul style="list-style-type: none"> ➤ 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 	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: November 2023	<ul style="list-style-type: none"> ➤ 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.

Origin	Product Name	Major Indication	Basic Information
Roche	Polivy [®] Antimicrotubule binding anti-CD79b monoclonal antibody Generic name: polatuzumab vedotin Launch in Japan: May 2021	<ul style="list-style-type: none"> ➤ 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	<ul style="list-style-type: none"> ➤ Unresectable, advanced, or recurrent nonsquamous non-small cell lung cancer (NSCLC) ➤ Adjuvant treatment of PD-L1-positive non-small cell lung cancer (NSCLC) ➤ Chemotherapy-naïve people with unresectable, advanced, or recurrent nonsquamous NSCLC ➤ Extensive-stage small cell lung cancer (SCLC) ➤ PD-L1-positive inoperable or recurrent 	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.

Chugai Main Products

as of April 24, 2024

Origin	Product Name	Major Indication	Basic Information
		triple-negative breast cancer (TNBC) ➤ Unresectable hepatocellular carcinoma (HCC)	

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	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.

Chugai Main Products

as of April 24, 2024

Origin	Product Name	Major Indication	Basic Information
		pancreas transplants	
In-house	<p>Edirol® Osteoporosis agent (Active vitamin D₃ derivative) Generic name: eldecalcitol Launch in Japan: April 2011 Launch in China: July 2022</p>	<p>➤ Osteoporosis</p>	<p>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 vertebral fractures.</p>
In-house	<p>Enspryng® pH-dependent binding humanized anti-IL-6 receptor monoclonal antibody Generic name: satralizumab Launch in Japan: August 2020</p>	<p>➤ Prevention of relapses of neuromyelitis optica spectrum disorder (NMOSD)</p>	<p>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</p>

Chugai Main Products

as of April 24, 2024

Origin	Product Name	Major Indication	Basic Information
			December 2018. Enspryng is approved in over 70 countries worldwide, including Japan, U.S. and European Union.
Roche	Evrysdi® Spinal muscular atrophy agent Generic name: risdiplam Launch in Japan: August 2021	<ul style="list-style-type: none"> ➤ 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 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	<ul style="list-style-type: none"> ➤ 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

Chugai Main Products

as of April 24, 2024

Origin	Product Name	Major Indication	Basic Information
			<p>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 110 countries worldwide.</p>
Roche	<p>Mircera® Long-acting erythropoiesis-stimulating agent Generic name: epoetin beta pegol Launch in Japan: July 2011</p>	<ul style="list-style-type: none"> ➤ Renal anemia 	<p>Mircera is a drug that raises the stability of epoetin beta in the bloodstream through pegylation. It is a type of renal anemia 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.</p>
Roche	<p>Ronapreve® anti-SARS-CoV-2 monoclonal antibody Generic name: casirivimab/imdevimab Launch in Japan: July 2021</p>	<ul style="list-style-type: none"> ➤ SARS-CoV-2 infection ➤ Prevention of symptomatic SARS-CoV-2 infection 	<p>Ronapreve was designed specifically by Regeneron to block the infectivity of SARS-CoV-2, the virus that causes COVID-19. The two 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.</p>
Roche	<p>Tamiflu® Anti-influenza agent Generic name: oseltamivir Launch in Japan: February 2001</p>	<ul style="list-style-type: none"> ➤ Treatment and prevention of influenza type A or B virus infection 	<p>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.</p>

Chugai Main Products

as of April 24, 2024

Origin	Product Name	Major Indication	Basic Information
Roche	Vabysmo® Anti VEGF/anti Ang-2 bispecific antibody Generic name: faricimab Launch in Japan: May 2022	<ul style="list-style-type: none"> ➤ 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.