SPECIAL Report

New Drugs Listed in 2022

A Synopsis of the Key Drugs Listed in 2022 – their positioning and how they are going to impact the market landscape.

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INDEX

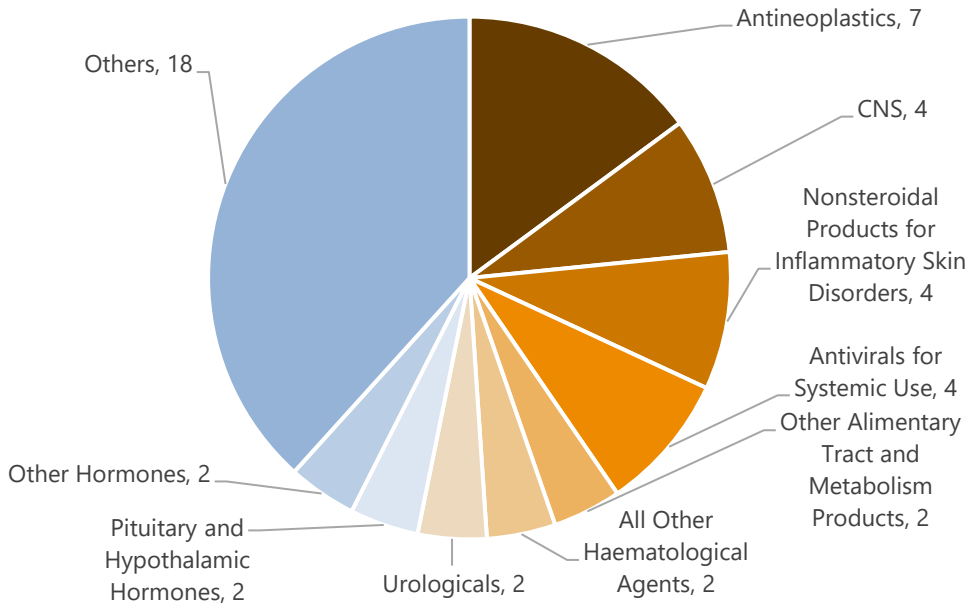
SPECIAL Report

2023.4

Overview of New Drugs[*1] Listed in 2022

In 2022, a total of 47 new drug entities were listed in Japan. This count was little larger than the count of new drugs listed a year ago in the 2021 (45 new drugs), however the combined peak sales estimate for 2022 was slightly lower (¥360 Billion vs. ¥366 Billion).

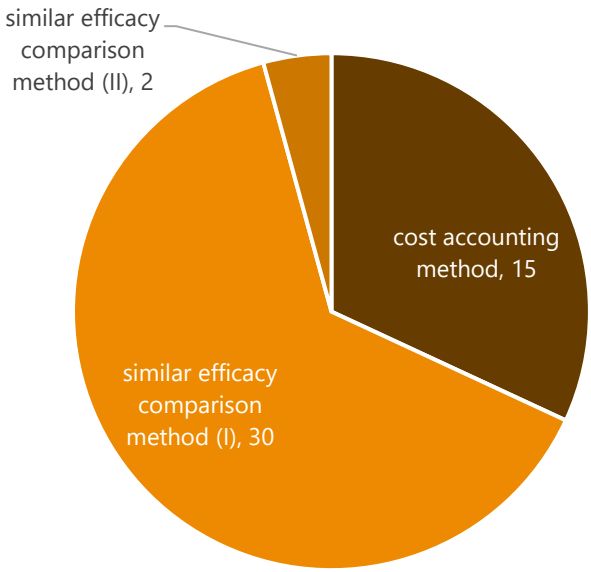
Oncology continues to be the largest contributor for new drugs flow and a total of 7 new drugs from oncology were listed. It was followed by 4 each from CNS, Nonsteroidal Products for Inflammatory Skin Disorders, and Antivirals for Systemic Use (Figure 1).



Source: MHLW, Encise Research Center

Figure 1. New Drugs Listing in 2022 by Therapeutic Category

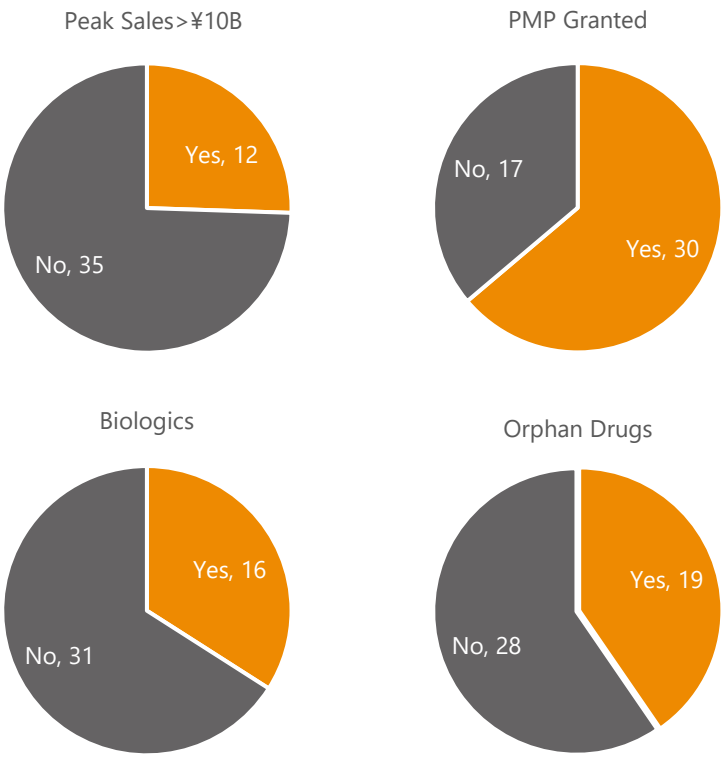
On pricing method front – maximum 30 drugs were priced by 'similar efficacy comparison method (I)', followed by 15 from the 'cost accounting method' (Figure 2).



Source: MHLW, Encise Research Center

Figure 2. New Drugs Listing by Price Method

Out of these 47 newly listed drug entities, 12 are expected to have over ¥10 Billion of peak sales potential and 30 have received 'price-maintenance premium'. Out of these 47, 16 are biologics and 19 are listed under orphan drug status. (Figure 3 to 6).



Source: MHLW, Encise Research Center

Figure 3 to 6.

New Drugs Listings by Different Categories

A more comprehensive overview of new drugs listing in past 10 years is provided under the appendix of this report (figure 7 to figure 12).

*1...The report includes all 'ethical drugs' approved as drugs containing new active ingredients and 'human cell therapy and gene therapy products' categories specified by the MHLW.

Amvuttra – The 2nd generation treatment for TTR-FAP

Drug Profile - Amvuttra					
Modality	Nucleic Acid	Molecule	Vutrisiran Sodium	Brand	Amvuttra
Launch Month	November 2022	Form	Injection	Strength	25mg/0.5mL/syringe
Therapeutic Classes[*2] (2nd level)	Other CNS Drugs	Mechanism of Action (MOA)	Inhibition of transthyretin (TTR) production mediated by RNAi		
Therapeutic Classes[*2] (3rd level)	All Other CNS Drugs				
Indication	Transthyretin-type familial amyloid polyneuropathy (designated as an orphan drug)				
Manufecturer	Alnylam Japan	Marketer	Alnylam Japan	Originator/s	Alnylam Pharmaceuticals
Price Maintenance Premium (PMP)	Applied	Unit Price (at the time of first listing)	¥7,810,923	Peak Sales (Predicted[*3])	¥11.7 Billion
Total Sales of the Therapeutic Category (All Other CNS Drugs)[*4]					¥153 Billion
Contribution of the Brands in the Category (All Other CNS Drugs)[*4]					60%
Hospital (≥100 beds) Sales Ratio in the Category (All Other CNS Drugs)[*4]					81%

[*2]…Encise's Anatomical Therapeutic Chemical Classification
[*3]…according to the Ministry of Health, Labour and Welfare (MHLW)
[*4]…therapeutic category sales based on ATC 3 level in year 03/2023

Source: Encise Research Center, MHLW disclosures

Amvuttra is a treatment of transthyretin-mediated familial amyloid polyneuropathy (TTR-FAP), also known as hereditary transthyretin-mediated (hATTR) amyloidosis, and carries an Orphan drug designation. It is considered a second generation treatment for the indication as Alynylam already markets Onpattro (patisiran), which is considered first generation TTR-FAP treatment. It was (launched in 2019 and given intravenously once every three weeks. While the second-generation Amvuttra is administered subcutaneously just once every three months.
Both are currently also being investigated in global clinical trials for their label expansions into transthyretin-mediated amyloidosis with cardiomyopathy (ATTR-CM), which is estimated to be some 10 times more common than hATTR amyloidosis.

MOA: Amvuttra belongs to RNAi therapeutics. It is a double-stranded small interfering RNA (siRNA) that targets mutant and wild-type transthyretin (TTR) messenger RNA (mRNA).

Transthyretin-mediated familial amyloid polyneuropathy (TTR-FAP): TTR-FAP is an inherited, progressively debilitating, and often fatal disease caused by mutations in the TTR gene. It causes abnormal amyloid proteins to accumulate and damage body organs and tissue, such as the peripheral nerves and heart, resulting in intractable peripheral sensory neuropathy, autonomic neuropathy, and/or cardiomyopathy, as well as other disease manifestations. The median survival is 4.7 years following diagnosis.

Comparative Landscape: Onpattro was the first drug approved by the US Food and Drug Administration (FDA) for the treatment of hATTR amyloidosis in August 2018 and it generated global sales of US$474,737 in 2021. In Japan it was launched in September 2019 and generated ¥7.5 Billion in FY 2021. As per Alnylam, over 2,000 patients were already on treatment of Onpattro in 2021. Alynylam thinks that many patients would eventually choose Amvuttra for its dosing advantage though the switch rate said to be unclear at this point. It is expected to hit peak sales of ¥11.7 billion in the 10th year on the market, treating 376 patients in Japan.
Pfizer's Vyndaqel has been approved in Japan for the use in suppressing the progression of peripheral neuropathy in TTR-FAP since 2013. In 2019, Vyndaqel also gained the world's first approval for ATTR-CM (under a sakigake-designated indication).

Global Status: Amvuttra was approved by the US FDA in June 2022 and received the marketing authorisation from the European Union in September 2022.

Bimzelx - For 'completely clear skin' in psoriasis

Drug Profile - Bimzelx					
Modality	Biologics (mAb)	Molecule	Bimekizumab	Brand	Bimzelx
Launch Month	April 2022	Form	Injection	Strength	160mg/mL/kit, 160mg/mL/syringe
Therapeutic Classes[*2] (2nd level)	Nonsteroidal Products for Inflammatory Skin Disorders	Mechanism of Action (MOA)	Interleukin (IL)-17A and IL-17F inhibitor		
Therapeutic Classes[*2] (3rd level)	Systemic Antipsoriasis Products				
Indication	The following diseases with inadequate response to existing treatment: psoriasis vulgaris, pustular psoriasis, psoriatic erythroderma				
Manufecturer	UCB Japan	Marketer	UCB Japan	Originator/s	UCB
Price Maintenance Premium (PMP)	Applied	Unit Price (at the time of first listing)	¥156,820, ¥156,587	Peak Sales (Predicted[*3])	¥12.0 Billion
Total Sales of the Therapeutic Category (Systemic Antipsoriasis Products)[*4]					¥14 Billion
Contribution of the Brands in the Category (Systemic Antipsoriasis Products)[*4]					86%
Hospital (≥100 beds) Sales Ratio in the Category (Systemic Antipsoriasis Products)[*4]					100%

[*2]...Encise's Anatomical Therapeutic Chemical Classification
[*3]...according to the Ministry of Health, Labour and Welfare (MHLW)
[*4]...therapeutic category sales based on ATC 3 level in year 03/2023

Source: Encise Research Center, MHLW disclosures

Bimzelx was launched for the indication of plaque psoriasis, pustular psoriasis, and psoriatic erythroderma in patients who show insufficient responses to existing therapies.

MOA: Bimzelx is humanized monoclonal Immunoglobulin (Ig) G1 antibody. It selectively inhibits both interleukin (IL)-17A and IL-17F - both proinflammatory cytokines linked to a variety of inflammatory diseases, and hence and is expected to suppress inflammatory conditions to a greater degree than inhibitors of IL-17A alone. It is the first antibody that simultaneously binds to IL-17A and IL-17F.

Psoriasis: Psoriasis is an immune-mediated disease that causes inflammation in the body and typically characterized by the visible signs of inflammation such as raised plaques and scales on the skin. The overactive immune system speeds up skin cell growth in psoriasis patients. Symptoms often start between ages 15 and 25, but it can start at any age. Men, women, and children of all skin colors can get psoriasis. Depending of the location of appearance, psoriasis is classified in many types:

Plaque psoriasis is the most common type, affecting up to 80-90 percent of psoriasis patients. It is characterised as raised patches of inflamed, itchy, and painful skin with scales and it can happen at any area of body. Pustular psoriasis affects about 3 percent psoriasis patients. Symptoms may include pustules (white, pus-filled, painful bumps) that may be surrounded by inflamed or reddened/discolored skin. Psoriatic erythroderma is rare, affecting about two percent of psoriasis patients. This type of psoriasis can cause intense redness or discoloration and shedding of skin layers in large sheets. It often affects nearly the whole body and can be life-threatening. An estimated 430,000 people suffer from psoriasis in Japan.

Therapy Paradigm and Competitive Landscape: The treatment approach for psoriasis generally involves different types of treatments which are often used in combination. This includes the use of a variety of topical treatments (e.g., creams and ointments for emollient effect), phototherapy (exposure of ultraviolet light), and the drugs for systemic use. However, among biologics, IL-17 inhibitors are the first-line treatment for patients who suffer primarily from cutaneous symptoms.

Bimzelx is likely to compete with existing biologics especially the IL-17 inhibitors. Bimzelx was priced using the comparator-method (I) by referring to Cosentyx (secukinumab), which is a IL-17A inhibitor and hence one of the closest competitor, and posted a total sales of ¥8.5 Billion in FY 2021. However, it will also directly compete other biologics approved for psoriasis.

In global comparative PIII/IIIb trails, Bimzelx was compared directly against ustekinumab (an IL-12 inhibitor), adalimumab (a tumor necrosis factor- alpha (TNF-α) inhibitor), and secukinumab where it met all the primary and secondary endpoints. Patients on Bimzelx demonstrated superior skin clearance at week 16, compared to those on placebo, existing biologics (as measured by at least a 90% improvement from base line in the Psoriasis Area and Severity Index (PASI 90) and Investigator's Global Assessment (IGA) response of clear or almost clear skin (IGA 0/1). Due to this encouraging results, UCB management have referred Bimzelx as a drug which can result in completely 'clear skin' in psoriasis patients. As per UCB, Bimzelx is expected to treat some 10,000 patients in Japan.

Pricing & Peak Sales Potential: Bimzelx was priced using the comparator-method (I) by referring to Cosentyx. Bimzelx earned the premium for usefulness II (5%) and its peak sales are expected to be ¥12 billion in the ninth year on the market. It is into the H1 category of CEA products.
In January 2023, it was also filed for additional indications of psoriatic arthritis (PsA), ankylosing spondylitis (AS), and non-radiographic axial spondyloarthritis (nr-axSpA). The filing was backed on the data from two PIII trials, dubbed BE OPTIMAL and BE COMPLETE. In these studies, the drug achieved the primary endpoint and all key secondary endpoints, demonstrating a clinically meaningful improvement versus placebo in joint and skin conditions. Such label expansions in future will further increase the peak sales potential of Bimzelx.

Global Status: It was approved in Europe in August 2021 under the Bimzelx brand. It is not approved in the US and the UCB has resubmitted its biologic licence application (BLA) to the US Food and Drug Administration (FDA) in December 2022.

Kerendia – For CKD with DT2

Drug Profile - Kerendia					
Modality	Small Molecule	Molecule	Finerenone	Brand	Kerendia
Launch Month	June 2022	Form	Tablet	Strength	10mg/tablet, 20mg/tablet
Therapeutic Classes[*2] (2nd level)	Drugs Used in Diabetes	Mechanism of Action (MOA)	Mineralocorticoid receptor (MR) antagonist		
Therapeutic Classes[*2] (3rd level)	Other Drugs Used in Diabetes				
Indication	Chronic kidney disease associated with type 2 diabetes excluding patients with end-stage renal failure or on dialysis				
Manufecturer	Bayer Yakuhin	Marketer	Bayer Yakuhin	Originator/s	Bayer HealthCare Pharmaceuticals
Price Maintenance Premium (PMP)	Not applied	Unit Price (at the time of first listing)	¥149.1, ¥213.1	Peak Sales (Predicted[*3])	¥26.4 Billion
Total Sales of the Therapeutic Category (Other Drugs Used in Diabetes)[*4]					¥4 Billion
Contribution of the Brands in the Category (Other Drugs Used in Diabetes)[*4]					26%
Hospital (≥100 beds) Sales Ratio in the Category (Other Drugs Used in Diabetes)[*4]					62%

[*2]…Encise's Anatomical Therapeutic Chemical Classification
[*3]…according to the Ministry of Health, Labour and Welfare (MHLW)
[*4]…therapeutic category sales based on ATC 3 level in year 03/2023

Source: Encise Research Center, MHLW disclosures

Kerendia was approved for the treatment of chronic kidney disease (CKD) associated with type 2 diabetes (DT2), excluding patients with end-stage renal failure and those on dialysis. The active ingrediatent finerenone is also being developed for the treatment for Heart Failure (heart failure with midrange ejection fraction (HFmrEF) and heart failure with preserved ejection fraction (HFpEF)) by Bayer, where it is currently under global Ph III trials.
The Peak sales for Kerendia are projected at ¥26.4 billion in the ninth year on the market, according to the MHLW.

MOA & Potential: Kerendia is a non-steroidal mineralocorticoid receptor (MR) antagonist. This is a new mode of action designed to suppress the overactivation of MRs, which are the main cause of renal and cardiovascular complications. Kerendia is the only non-steroidal mineralocorticoid receptor (MR) antagonist indicated for CKD associated with DT2.

Chronic Kidney Disease (CKD) in Type 2 Diabetes (DT2): CKD is a common and potentially deadly condition which is widely underrecognized. CKD progresses silently and unpredictably, with many symptoms not appearing until the disease is well-advanced. Estimated about 40 percent of DT2 patients accompany CKD. It is estimated that CKD affects more than 190 million people with DT2 worldwide. Despite guideline-directed therapies, patients with CKD and DT2 are at high risk of CKD progression and cardiovascular (CV) events. CKD in DT2 is the main cause of end stage kidney disease, which requires dialysis or a kidney transplant to stay alive. Patients with CKD with DT2 are three times more likely to die from a CV-related cause than those with DT2 alone.

Treatment Parading and Competitive Landscape: In very recent times, the sodium glucose cotransporter-2 (SGLT-2) inhibitors with very convincing clinical data have emerged in the forefront of the treatment line for CKD with DT2.

Forxiga (dapagliflozin) was initially approved for diabetes and later added a chronic heart failure (CHF) and CKD indications. It was first SGLT2 inhibitor drug approved in Japan for the indication of CKD. Later in June, 2022, Canaglu (canagliflozin) was also approved for additional indication of CKD associated with DT2type 2 diabetes (patients with end-stage renal failure and those on dialysis are excluded). SGLT-2 inhibitor Jardiance (Empagliflozin) is also under the development for CKD indication and its marketing company Nippon Boehringer Ingelheim believes that Jardiance would gain top position following its CKD indication is granted.

While from a different mode of action, Kerendia is likely to directly complete with SGLT-2 inhibitors and it will be very interesting to see how it positions itself and captures the market.

Global Status: Kerendia was approved by the US Food and Drug Administration (FDA) in July 2021, by the European Commission in February 2022, and the Chinese National Medical Products Administration (NMPA) in June 2022.

Lagevrio – The first NHI listed oral antiviral for COVID-19

Drug Profile - Lagevrio					
Modality	Small Molecule	Molecule	Molnupiravir	Brand	Lagevrio
Launch Month	December 2021	Form	Capsule	Strength	200mg/capsule
Therapeutic Classes[*2] (2nd level)	Antivirals for Systemic Use	Mechanism of Action (MOA)	Inhibition of synthesis of nucleic acid (RNA)		
Therapeutic Classes[*2] (3rd level)	Antivirals, Other				
Indication	SARS-CoV-2 infection				
Manufecturer	MSD	Marketer	MSD	Originator/s	Emory University, Georgia State University
Price Maintenance Premium (PMP)	Applied	Unit Price (at the time of first listing)	¥2,357.8	Peak Sales (Predicted[*3])	¥13.8 Billion
Total Sales of the Therapeutic Category (Antivirals, Other)[*4]					¥40 Billion
Contribution of the Brands in the Category (Antivirals, Other)[*4]					36%
Hospital (≥100 beds) Sales Ratio in the Category (Antivirals, Other)[*4]					68%

[*2]…Encise's Anatomical Therapeutic Chemical Classification
[*3]…according to the Ministry of Health, Labour and Welfare (MHLW)
[*4]…therapeutic category sales based on ATC 3 level in year 03/2023

Source: Encise Research Center, MHLW disclosures

Lagevrio was the first oral antiviral drug for the treatment of coronavirus disease 2019 (COVID-19) to be available in Japan. It had received a special approval in December 2021 and was initially sold to the Japanese government and allocated to healthcare providers via a designated channel due to limited supplies. It joined the NHI price list in August 2022 and became available under general distribution from September.

MOA: Lagevrio belongs to the polymerase inhibitors class of antivirals. Specifically, it is a prodrug of the synthetic nucleoside derivative N4-hydroxycytidine and exerts its antiviral action by introducing copying errors during viral RNA replication.

Competitive Landscape: Paxlovid and Xocova were the next to be approved (in February and November on 2022 respectively), but they were not available in routine channel until after their NHI listing in March 2023. Until then, they were available only to the institutions via government purchase. After their NHI listing, the competition for oral-antivirals for COVID-19 is likely to be intensified.

Both Paxlovid and Xocova are allowed for the 12 years and older while Lagevrio use in restricted in adults only. Xocova can also be used in patients without risk factors for severe disease and thus has a different target population than Paxlovid and Lagevrio, which target high-risk patients. Among these three candidates, Lagevrio is a polymerase inhibitor while the other two are protease inhibitors

Table. Oral Antivirals for COVID-19 in Japan[*5]

Brand Name	Lagevrio	Paxlovid	Xocova
Molecule	Molnupiravir	Nirmatrelvir+Ritonavir	Ensitrelvir
MOA	Polymerase Inhibitor	Protease Inhibitor	Protease Inhibitor
Special Approval	December 2021	February 2022	November 2022
In Regular Channel Since	September 2022	March 2023	March 2023
NHI Listing	Yes	Yes	Yes
Key Sponsor/s	MSD	Pfizer	Shionogi
Peak Sales Est. at time of Listing[*6]	¥13.8 billion (In the first year on market)	¥28.1 billion (In the 6th year)	¥19.2 billion (In the second year)

[*5]...Encise's Anatomical Therapeutic Chemical Classification
[*6]...according to the Ministry of Health, Labour and Welfare (MHLW)

Global Status: The US Food and Drug Administration (FDA) has granted an Emergency Use Authorisation (EUA) to Lagevrio for the treatment of mild-to-moderate COVID-19 in adults with positive results of direct SARS-CoV-2 viral testing who are at high risk for progressing to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate.

Lyfnua – The first NHI approved drug for the Chronic Cough

Drug Profile - Lyfnua					
Modality	Small Molecule	Molecule	Gefapixant citrate	Brand	Lyfnua
Launch Month	April 2022	Form	Tablet	Strength	45mg/tablet
Therapeutic Classes[*2] (2nd level)	Cough and Cold Preparations	Mechanism of Action (MOA)	P2X3 receptor antagonist		
Therapeutic Classes[*2] (3rd level)	Antitussives				
Indication	Refractory chronic cough				
Manufecturer	MSD	Marketer	Kyorin Pharmaceutical	Originator/s	Roche
Price Maintenance Premium (PMP)	Not applied	Unit Price (at the time of first listing)	¥203.2	Peak Sales (Predicted[*3])	¥16.0 Billion
Total Sales of the Therapeutic Category (Antitussives)[*4]					¥9 Billion
Contribution of the Brands in the Category (Antitussives)[*4]					19%
Hospital (≥100 beds) Sales Ratio in the Category (Antitussives)[*4]					86%

[*2]…Encise's Anatomical Therapeutic Chemical Classification
[*3]…according to the Ministry of Health, Labour and Welfare (MHLW)
[*4]…therapeutic category sales based on ATC 3 level in year 03/2023

Source: Encise Research Center, MHLW disclosures

Lyfnua is an oral selective P2X3 receptor antagonist for the treatment of “refractory chronic cough”. There is currently no treatment available that carries this indication, and Japan was the first major market to approve the drug. Kyorin has obtained the distribution rights from MSD which has a strong franchise for respiratory products including expectorants.

MOA: Lyfnua is designed to block the binding of extracellular adenosine triphosphate (ATP) and P2X3 receptors (purinoceptor 3) found on C nerve fibers in the airway. A cough is caused by the binding of extracellular ATP to P2X3 receptors, which can be sensed as a signal of potential damage. Lyfnua inhibits this binding to reduce sensory nerve activation, thereby suppressing cough.

Pricing & Peak Sales Potential: Lyfnua was priced by the cost-based method, with no premium granted. MSD had filed appeals two times to make it eligible for the price maintenance premium (PMP), but its bid was dismissed in both instances. MSD has appealed to the MHLW committees that since Lyfnua has a new mechanism of action and it is the only drug indicated for refractory chronic cough, it meets the criteria for obtaining a launch premium for utility (II) and post-launch PMP.
As the peak sales forecast is ¥16 billion (10th year on the market) according to the Ministry of Health, Labour and Welfare (MHLW), Lyfnua was placed into the H1 category of cost-effectiveness analysis (CEA) products.

Chronic Cough: A chronic cough is defined as a cough that lasts for at least eight weeks. Its prevalence rate estimated at 1-12% in countries around the world. Some people develop refractory chronic cough that persists even after underlying diseases such as asthma and acid reflux are treated, while others suffer lingering cough with no organic cause identified in thorough screening.

Competitive Landscape: There is no treatment available that carries an indication of refractory or unexplained chronic cough. For chronic cough, general expectorants and OTC medicines are used so far. However, there some other companies which are developing P2X3 receptor antagonists. These include Bellus and Shionogi. Shionogi's sivopixant (S-600918) is an oral P2X3 receptor antagonist, and it is currently under global Ph II trials for refractory or unexplained chronic cough and Japan Ph I for neuropathic pain.

Global Status: In the US, the Food and Drug Administration (FDA) has not approved the drug and has issued a complete response letter (CRL) to Merck. Merck said that the FDA has requested some additional information related to the cough counting system used to track efficacy in Ph III, and there was no issue related to the safety. Merck also announced that it plans to conduct "additional analyses" and submit its response by the first half or 2023. The European approval of the drug is also pending.

Ostabalo – The third player in the hPTHrP derivative market for osteoporosis

Drug Profile - Ostabalo					
Modality	Small Molecule	Molecule	Abaloparatide Acetate	Brand	Ostabalo
Launch Month	January 2023	Form	Injection	Strength	1.5mg/0.75mL/syringe
Therapeutic Classes[*2] (2nd level)	Other Hormones	Mechanism of Action (MOA)	Stimulation of bone formation		
Therapeutic Classes[*2] (3rd level)	Parathyroid Hormones and Analogues				
Indication	Osteoporosis with high risk of bone fractures				
Manufecturer	Teijin Pharma	Marketer	Teijin Pharma	Originator/s	3M Drug Delivery Systems, Biomeasure, Ipsen
Price Maintenance Premium (PMP)	Not applied	Unit Price (at the time of first listing)	¥16,128	Peak Sales (Predicted[*3])	¥20.7 Billion
Total Sales of the Therapeutic Category (Parathyroid Hormones and Analogues)[*4]					¥67 Billion
Contribution of the Brands in the Category (Parathyroid Hormones and Analogues)[*4]					31%
Hospital (≥100 beds) Sales Ratio in the Category (Parathyroid Hormones and Analogues)[*4]					48%

[*2]…Encise's Anatomical Therapeutic Chemical Classification
[*3]…according to the Ministry of Health, Labour and Welfare (MHLW)
[*4]…therapeutic category sales based on ATC 3 level in year 03/2023

Source: Encise Research Center, MHLW disclosures

Ostabalo is a self-administered drug, injected subcutaneously once daily, for the treatment of patients with osteoporosis at a high risk of fractures. Ostabalo was initially approved in March 2021 for its 28-day formulation, but the sponsor Teijin decided to skip its NHI listing because the 28-day formulation was inappropriate to meet Japan's two-week prescription restriction for newly approved medicines. Later in November 2022, the 14-day formulation was approved.

MOA: Ostabalo is a derivative of the human parathyroid hormone (PTH)-related peptide (hPTHrP) and is expected to promote bone formation by selectively stimulating RG-type PTH type 1 receptors involved in bone metabolism, with a predominant effect on bone formation over bone resorption.

Osteoporosis: In osteoporosis, the bones gradually become porous and consequently weaker and increasingly brittle. The process of bone metabolism (bone remodelling) is closely regulated by the hormones and other chemicals which is disrupted in the disease. It is largely an age-related disease but genetic factors, nutritional deficiency since childhood and puberty, lack of exercise, and unhealthy lifestyle also affect bone quality and strength. According to the guidelines for the prevention and treatment of osteoporosis 2015, it was estimated that the number of osteoporosis patients in Japan was 12.8 million (3 million men, and 9.8 million women), which was about 10% of the population. This prevalence rate is very high compared to the US and European countries.

Treatment Paradigm: The drug regimen for osteoporosis includes selective estrogen receptor modulators (SERMs), bisphosphonates, PTH, and antibodies. The SERMs and bisphosphonates are considered as the initial candidates for maintaining and improving the bone mineral density (BMD). They inhibit the bone loss, but do not induce new bone formation. As the disease progresses and patients are at high risk of fractures, the need of advanced medical intervention is sought. The next stage of medication involves anti-receptor activator of nuclear factor-κB ligand (RANKL) monoclonal antibody (mAb), PTH and their derivatives which help making new bones but also break it down.

Competitive Landscape: PTH and derivatives currently form over 27% of the osteoporosis market. Forteo and Teribone were only two players in the PTHrP derivatives market until the entry of Osteblo. However, the PTH Landscape has been changing rapidly as both the Forteo and Teribone have gone off patent and generics (GEs) have entered.
Mochida had launched a biosimilar (BS) version of Forteo in November 2019, which posted ¥6.3 billion (14% YoY) in 2022, achieving 35% market share by value. Since April 2021, Kaken started to copromote Mochida's BS version. Kaken has a strong track record in the field of orthopedics as it sells its joint function improving agent Artz (sodium hyaluronate), and this co-promotion is likely to further increase BS penetration in the market.

The first GE for Teribone was listed in June 2022 for Sawai Pharma, after legal battles between originator Asahi Kasei and Sawai. To protect its sales from GE versions, Asahi Kasei's has launched a twice-weekly self-injectable Teribone auto-injector in December 2019, which is drawing switches from its original once-weekly SC version. The auto-injector is estimated to accounts for nearly 60% of Teribone in use, and Sawai does not has this version on its GE offering.
As per data submitted to the Ministry of Health, Labour and Welfare (MHLW), Ostabalo is expected to achieve peak sales of ¥20.7 billion in the 10th year on the market.

Global Status: The US Food and Drug Administration (FDA) has approved abaloparatide (under brand name Tymlos) in December 2022 for the treatment for osteoporosis in men at high risk for fracture. It also received the marketing authorization from European Union around the same time.

Pivlaz – For the prevention of vasospasm after aSAH

Drug Profile - Pivlaz					
Modality	Small Molecule	Molecule	Clazosentan sodium	Brand	Pivlaz
Launch Month	April 2022	Form	Injection	Strength	150mg/6mL/vial
Therapeutic Classes[*2] (2nd level)	Cerebral and Peripheral Vasotherapeutics	Mechanism of Action (MOA)	Endothelin receptor antagonism		
Therapeutic Classes[*2] (3rd level)	Cerebral and Peripheral Vasotherapeutics				
Indication	Prevention of cerebral vasospasm, vasospasm-related cerebral infarction and cerebral ischemic symptoms after aneurysmal subarachnoid hemorrhage				
Manufecturer	Idorsia Pharmaceuticals Japan	Marketer	Idorsia Pharmaceuticals Japan	Originator/s	Roche
Price Maintenance Premium (PMP)	Applied	Unit Price (at the time of first listing)	¥80,596	Peak Sales (Predicted[*3])	¥13.8 Billion
Total Sales of the Therapeutic Category (Cerebral and Peripheral Vasotherapeutics)[*4]					¥14 Billion
Contribution of the Brands in the Category (Cerebral and Peripheral Vasotherapeutics)[*4]					71%
Hospital (≥100 beds) Sales Ratio in the Category (Cerebral and Peripheral Vasotherapeutics)[*4]					66%

[*2]…Encise's Anatomical Therapeutic Chemical Classification
[*3]…according to the Ministry of Health, Labour and Welfare (MHLW)
[*4]…therapeutic category sales based on ATC 3 level in year 03/2023

Source: Encise Research Center, MHLW disclosures

Pivlaz is approved for the prevention of cerebral vasospasms, vasospasm-related cerebral infarction, and cerebral ischemic symptoms after aneurysmal subarachnoid hemorrhage (aSAH). Idorsia is also aiming for label extensions for Pivlaz in the future.
Pivlaz was approved in Japan ahead of rest of the world and it is Idorsia's first product to be launched. Idorsia was created as a spin-off from Actelion Pharmaceuticals when it was integrated into Johnson & Johnson in 2017.

MOA: As an 'endothelin receptor antagonist', Pivlaz is designed to selectively inhibit endothelin A (ETA) receptors, thereby targeting the root cause of cerebral vasospasms. In a Japan PIII trial, the drug has demonstrated a significant reduction in cerebral vasospasm-related symptoms and all-cause death.

Aneurysmal Subarachnoid Hemorrhage (aSAH): aSAH is classified as a type of stroke. aSAH is a condition involving sudden bleeding occurring in the subarachnoid space (at the surface of the brain) and could be life-threatening. The incidence of SAH is estimated to be between six and nine per 100,000 people worldwide. In Japan, the incidence is approximately two times higher compared to other countries.

Treatment Paradigm and Competitive Landscape: Pivlaz is the first drug that treats the condition via ETA receptors. The cerebral vasospasm is typically treated with hemodynamic therapy – which involves inducing high blood pressure while keeping a healthy amount of fluid in the body's circulatory system in the patient in an attempt to force a blood supply to the brain region affected by the vasospasm. If this is not effective, some invasive methods such as balloon angioplasty may be performed. For those vessels not accessible to angioplasty, local injection of a vasodilator into the affected vessels is sometimes attempted, however this is also an invasive procedure.
In terms of prevention, the calcium channel blocker nimodipine is sometimes used for reducing the consequences of low blood supply to the brain in people who have had aSAH.

Pricing & Peak Sales Potential: Pivlaz became one of the first drug to get imposed to the so-called "zero premium coefficient" rule introduced in the FY2022 drug pricing reform, which is applied to products with low-cost disclosure ratios.
The product was priced using the cost-based method and received the premium for usefulness II (5%). However, as it faced the zero premium coefficient rule, the 5% reward was not reflected in its final price. Pivlaz is expected to peak at ¥13.8 billion in its eighth year on the market, according to the Ministry of Health, Labour and Welfare (MHLW) and it will be subject to the cost-effectiveness analysis (CEA) scheme under the H1 category.

Global Status: Pivlaz is currently only available in Japan.

Sotyktu – A first in class TYK2 inhibitor for psoriasis

Drug Profile - Sotyktu					
Modality	Small Molecule	Molecule	Deucravacitinib	Brand	Sotyktu
Launch Month	November 2022	Form	Tablet	Strength	6mg/tablet
Therapeutic Classes[*2] (2nd level)	Nonsteroidal Products for Inflammatory Skin Disorders	Mechanism of Action (MOA)	Tyrosine kinase 2 (TYK-2) inhibitor		
Therapeutic Classes[*2] (3rd level)	Systemic Antipsoriasis Products				
Indication	The following diseases inadequately responding to existing treatments: psoriasis vulgaris, pustular psoriasis, psoriatic erythroderma				
Manufacturer	Bristol-Myers Squibb	Marketer	Bristol-Myers Squibb	Originator/s	Bristol-Myers Squibb
Price Maintenance Premium (PMP)	Applied	Unit Price (at the time of first listing)	¥2,770.9	Peak Sales (Predicted[*3])	¥22.5 Billion
Total Sales of the Therapeutic Category (Systemic Antipsoriasis Products)[*4]					¥14 Billion
Contribution of the Brands in the Category (Systemic Antipsoriasis Products)[*4]					86%
Hospital (≥100 beds) Sales Ratio in the Category (Systemic Antipsoriasis Products)[*4]					100%

[*2]…Encise's Anatomical Therapeutic Chemical Classification
[*3]…according to the Ministry of Health, Labour and Welfare (MHLW)
[*4]…therapeutic category sales based on ATC 3 level in year 03/2023

Source: Encise Research Center, MHLW disclosures

Sotyktu was approved for the treatment of psoriasis vulgaris, pustular psoriasis, and erythrodermic psoriasis which are inadequately controlled with existing treatments. Due to its paediatric development, Sotyktu is also granted two-year extension for the re-examination period (data protection period), which is extended until September 2032.

MOA: Sotyktu is an oral, selective tyrosine kinase 2 (TYK2) inhibitor, which is a member of the Janus kinase (JAK) family of enzymes. TYK2 plays a role in transmitting extracellular stimulatory signals into cells. It is the first medicine to selectively block TYK2-mediated signalling pathways by binding to the pseudokinase domain of TYK2.

Psoriasis: Psoriasis is an immune-mediated disease that causes inflammation in the body and typically characterized by the visible signs of inflammation such as raised plaques and scales on the skin. The overactive immune system speeds up skin cell growth in psoriasis patients. Symptoms often start between ages 15 and 25, but it can start at any age. Men, women, and children of all skin colors can get psoriasis. Depending of the location of appearance, psoriasis is classified in many types:
Plaque psoriasis is the most common type, affecting up to 80-90 percent of psoriasis patients. It is characterised as raised patches of inflamed, itchy, and painful skin with scales and it can happen at any area of body. Pustular psoriasis affects about 3 percent psoriasis patients. Symptoms may include pustules (white, pus-filled, painful bumps) that may be surrounded by inflamed or reddened/discolored skin. Psoriatic erythroderma is rare, affecting about two percent of psoriasis patients. This type of psoriasis can cause intense redness or discoloration and shedding of skin layers in large sheets. It often affects nearly the whole body and can be life-threatening. An estimated 430,000 people suffer from psoriasis in Japan.

Treatment Paradigm and Competitive Landscape: The treatment approach for psoriasis generally involves different types of treatments which are often used in combination. This includes the use of a variety of topical treatments (e.g., creams and ointments for emollient effect), phototherapy (exposure of ultraviolet light), and the drugs for systemic use.
In recent years, a number of biologics have been introduced for the treatment for psoriasis and all of them are all injectable. Sotyktu is likely to position itself as a drug candidate which has clinical efficacy comparable to biologics but has a better safety profile with oral convenience. During its global clinical trials in moderate-to-severe psoriasis, Sotyktu demonstrated superior efficacy to apremilast (a PDE4 inhibitor, sold in Japan as Otezla from Amgen and posted ¥14.2 Billion in FY 2021). Sotyktu is expected to generate a peak sale of ¥22.5 billion in the 10th year on the market, according to the Ministry of Health, Labour and Welfare (MHLW)'s document.

Global Status: The US Food and Drug Administration (FDA) approved Sotyktu in September 2022 for adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. In Europe, it received a marketing authorisation valid throughout the EU in March 2023.

Tezspire – The 2nd biologic for severe asthma from AstraZeneca

Drug Profile - Tezspire					
Modality	Biologics (mAb)	Molecule	Tezepelumab (genetical recombination)	Brand	Tezspire
Launch Month	November 2022	Form	Injection	Strength	210mg/1.91mL/syringe
Therapeutic Classes[*2] (2nd level)	Anti-asthma and COPD Products	Mechanism of Action (MOA)	Thymic stromal lymphopoietin (TSLP) blocker		
Therapeutic Classes[*2] (3rd level)	All Other Anti-asthma and COPD Products				
Indication	Bronchial asthma (limited to patients with severe or refractory disease in whom asthma symptoms cannot be controlled with existing treatment)				
Manufacturer	AstraZeneca	Marketer	AstraZeneca	Originator/s	Amgen
Price Maintenance Premium (PMP)	Applied	Unit Price (at the time of first listing)	¥176,253	Peak Sales (Predicted[*3])	¥14.5 Billion
Total Sales of the Therapeutic Category (All Other Anti-asthma and COPD Products)[*4]					¥10 Billion
Contribution of the Brands in the Category (All Other Anti-asthma and COPD Products)[*4]					63%
Hospital (≥100 beds) Sales Ratio in the Category (All Other Anti-asthma and COPD Products)[*4]					98%

[*2]…Encise's Anatomical Therapeutic Chemical Classification
[*3]…according to the Ministry of Health, Labour and Welfare (MHLW)
[*4]…therapeutic category sales based on ATC 3 level in year 03/2023

Source: Encise Research Center, MHLW disclosures

Tezspire was launched for the treatment of severe or refractory bronchial asthma that cannot be controlled with existing therapies. It is also being developed for the treatment of chronic rhinosinusitis with nasal polyps in Japan, where currently it is under PIII trials.

In the AstraZeneca's respiratory franchise, Tezspire follows the rollout of Fasenra (benralizumab) for severe asthma in 2018 and chronic obstructive pulmonary disease (COPD) agents Breztri (budesonide + glycopyrronium + formoterol fumarate) and Bevespi (glycopyrronium + formoterol fumarate) in 2019. No other company has two biologics (Fasenra and Tezspire) for severe asthma.

It was approved primarily based on the data from the global PIII NAVIGATOR trial, which included Japan. The study covered adults (aged 18-80) and adolescents (aged 12-17) with severe uncontrolled asthma who were receiving standard of care (SoC, medium- or high-dose inhaled corticosteroids (ICSs) plus at least one additional controller medication), with more than 1,000 subjects enrolled in total. In the study, Tezspire added to SoC demonstrated a statistically significant and clinically meaningful 56% reduction in the annualized asthma exacerbation rate (AAER) over 52 weeks in the overall population, versus placebo plus SoC.

MOA: Tezspire is a first-in-class monoclonal antibody that targets an epithelial cytokine called thymic stromal lymphopoietin (TSLP), thereby acting at the top of the inflammatory cascade.

Asthma: Asthma is considered as an allergic disease, characterized by airway hyperresponsiveness. It commonly begins during childhood and it is a reversible airflow obstruction. As per the patient survey conducted by the Ministry of Health, Labour and Welfare in 2020, there were estimated 1.8 million patients with bronchial asthma in Japan.

Treatment Paradigm: Asthma treatment varies with its stage and generally involves combination therapies. ICSs have been long considered as standard care. The use of long-acting β2-agonist (LABA), long-acting muscarinic antagonist (LAMA), alone or in combination is added with the disease progression. Use of short-acting beta2-agonist (SABA) is generally applied for rescue therapy associated with an increased risk of exacerbations. The Biologics are generally used when the asthma is not controlled by the existing therapies.

Competitive Landscape: After the entry of Tezspire, there are now five biologics (antibodies) are available in the market. The existing four were Dupixent, Fasenra, Xolair, and Nucala. Generally, they are used in patients with symptoms not adequately controlled with a high-dose ICS (and in combinations with other controllers), and offer little difference in their target patients, dosing schedule etc. Most of the biologics target eosinophils by different mechanisms, which is considered as a trigger to asthma. All these biologics posted a total of ¥109.7 billion (23% YoY) in 2022 (including their sales from all approved indications). They are one of the fastest growing segments in recent years (3-Years compound annual growth rate (CAGR) 31%).

Global Status: In the US, Tezspire was approved on the priority review pathway in December 2021 for the add-on maintenance treatment of adult and paediatric patients aged 12 years and older with severe asthma. Globally, it is also being developed for COPD.

Vabysmo – The first bispecific antibody for eyes

Drug Profile - Vabysmo					
Modality	Biologics (mAb)	Molecule	Faricimab (genetical recombination)	Brand	Vabysmo
Launch Month	May 2022	Form	Injection	Strength	6mg/0.05mL/vial
Therapeutic Classes[*2] (2nd level)	Ophthalmologicals	Mechanism of Action (MOA)	Inhibition of vascular endothelial growth factor A (VEGF-A) and angiopoietin-2 (Ang-2)		
Therapeutic Classes[*2] (3rd level)	Ocular Antineovascularisation Products				
Indication	Age-related macular degeneration Diabetic macular edema associated with subfoveal choroidal neovascularization				
Manufecturer	Chugai Pharmaceutical	Marketer	Chugai Pharmaceutical	Originator/s	Roche
Price Maintenance Premium (PMP)	Not applied	Unit Price (at the time of first listing)	¥163,894	Peak Sales (Predicted[*3])	¥32 Billion
Total Sales of the Therapeutic Category (Ocular Antineovascularisation Products)[*4]					¥122 Billion
Contribution of the Brands in the Category (Ocular Antineovascularisation Products)[*4]					59%
Hospital (≥100 beds) Sales Ratio in the Category (Ocular Antineovascularisation Products)[*4]					85%

[*2]…Encise's Anatomical Therapeutic Chemical Classification
[*3]…according to the Ministry of Health, Labour and Welfare (MHLW)
[*4]…therapeutic category sales based on ATC 3 level in year 03/2023

Source: Encise Research Center, MHLW disclosures

Vabysmo is approved for the treatment of neovascular age-related macular degeneration (nAMD) and diabetic macular edema (DME), which are major causes of blindness and vision loss in adults. It is the first ophthalmology product for Chugai and its launch marks the Roche group's full-scale foray into the ophthalmology market. It is a high potential drugs with the peak sales is projected to be ¥ 32 billion in the 10th year on the market.

MOA: Vabysmo is an anti-vascular endothelial growth factor A (VEGF-A)/anti- angiopoietin-2 (Ang-2) bispecific antibody. it blocks VEGF-A and Ang-2, two pathways that contribute to a number of retinal conditions. VEGF-A and Ang-2 contribute to vision loss by destabilizing the vascular structure, causing new leaky blood vessels and increasing inflammation. By blocking both pathways, the drug stabilizes blood vessels, which could result in better vision outcomes for a longer amount of time in patients with retinal conditions.

Neovascular age-related macular degeneration (nAMD) and diabetic macular edema (DME):
AMD is a condition that affects the part of the eye that provides sharp, central vision needed for activities like reading, driving, and is a leading cause of vision loss in people over the age of 60. nAMD (or 'wet' AMD) is an advanced form of the disease that can cause rapid and severe vision loss. It develops when new and abnormal blood vessels grow uncontrolled under the macula (the central area of the retina responsible for the sharp vision needed for reading and driving), causing swelling, bleeding and/or fibrosis. Worldwide, around 20 million and in Japan estimated about 880,000 people are living with nAMD.
DME is a vision-threatening complication of diabetic retinopathy (DR), which occurs when damage to blood vessels and the formation of new blood vessels causes blood and/or fluid to leak into the retina and cause swelling (particularly in the macula). Estimated around 21 million people globally and 710,000 people in Japan are affected from DME. Both nAMD and DME patients are expected to grow with the increase in aging population and the prevalence of diabetes.

Competitive Landscape: nAMD and DME markets have recently seen the entry of a number of big players. These markets are expanding and the R&D activity is high in this arena. VEGF inhibitors (or anti- VEGF) have been dominating this market. The first anti-VEGF medication for AMD was Macugen (pegaptanib) which was non-biologic and was knocked-out after the entry of more effective and dose convenient biologic anti- VEGF drugs.
Lucentis was the first biologics launched in 2009. It is administered with an interval of at least 1 month between doses and approved for several indications. It posted ¥24.6 Billion (-6.8% YoY) in FY 03/2022. Its sales are falling after the launch of biosimilars (Senju pharma, marketed by Takeda) and availability of newer drugs (like Eylea and Beovu etc.)
Eylea was the second biologic and has been dominating the market since its launch in November 2012 (FY 03/2022 sales ¥86.5 Billion, 9.5% YoY). Beovu, was the latest VEGF-inhibitor before Vabysmo. It carried the highest forecasted Peak-sales potential among all drugs approved in 2020 (¥29.4 Billion). Launched in May 2020, it posted ¥4.4 Billion in FY 2022. Compared to Eylea, it offers longer dosing Interval and non-Inferior efficacy, which positioned it as a high potential drug candidate.

Both Lucentis and Eylea carry a wide indication base, which include DME and Macular Edema following Retinal Vein Occlusion (MEfRVO) apart from nAMD. While Beovu was only approved for nAMD and DME. Vabysmo should be positioned to compete against all these major players in nAMD, DME space. In a global PIII trial, it was given at an interval of up to four months and it demonstrated non-inferiority to Eylea administered every two months. This dosing internal benefit is expected to reduce patient's burdens associated with hospital visits and treatment.

Global Status: The US Food and Drug Administration (FDA) had approved Vabysmo in January 2022. It received marketing authorisation valid throughout the European Union in September 2022.

Voxzogo – The first and only therapy in children with achondroplasia

Drug Profile - Voxzogo					
Modality	Biologics (not mAb)	Molecule	Vosoritide (genetical recombination)	Brand	Voxzogo
Launch Month	August 2022	Form	Injection	Strength	0.4mg/vial (solution for dissolution supplied), 0.56mg/vial (solution for dissolution supplied), 1.2mg/vial (solution for dissolution supplied)
Therapeutic Classes[*2] (2nd level)	Other Drugs for Disorders of the Musculo-skeletal System	Mechanism of Action (MOA)	C-type natriuretic peptide analogue		
Therapeutic Classes[*2] (3rd level)	All Other Musculoskeletal Products				
Indication	Chondrodysplasia without epiphyseal line closure (designated as an orphan drug)				
Manufecturer	Biomarin Pharmaceutical Japan	Marketer	Biomarin Pharmaceutical Japan	Originator/s	BioMarin Pharmaceutical
Price Maintenance Premium (PMP)	Applied	Unit Price (at the time of first listing)	¥121,034, ¥124,241, ¥124,994	Peak Sales (Predicted[*3])	¥23.2 Billion
Total Sales of the Therapeutic Category (All Other Musculoskeletal Products)[*4]					¥94 Billion
Contribution of the Brands in the Category (All Other Musculoskeletal Products)[*4]					59%
Hospital (≥100 beds) Sales Ratio in the Category (All Other Musculoskeletal Products)[*4]					71%

[*2]…Encise's Anatomical Therapeutic Chemical Classification
[*3]…according to the Ministry of Health, Labour and Welfare (MHLW)
[*4]…therapeutic category sales based on ATC 3 level in year 03/2023

Source: Encise Research Center, MHLW disclosures

Voxzogo is an analog of C-type natriuretic peptide (CNP) approved to increase linear growth in children with achondroplasia without epiphyseal closure. It is the first and only therapy for achondroplasia in children.

Voxzogo received a 5% utility premium for its new mechanism of action and a 10% marketability premium for its orphan designation. However, it faced a 'zero premium coefficient rule', which is applied to products priced by the cost-based method with low ratios of cost disclosures (below 50%). According to the MHLW, Voxzogo is expected to generate a peak sale at ¥23.2 billion in the fifth year, with 515 patients to be treated. Despite its large peak sales potential, it will not be subject to cost-effectiveness assessments due to its orphan status.

MOA: It down-regulates fibroblast growth factor receptor type 3 (FGFR3) signalling to promote endochondral ossification in paediatric patients.

Achondroplasia: Achondroplasia is a rare genetic bone growth disorder and the most common form of disproportionate short stature, occurring in about one in every 20,000 births. It is caused by a change in the FGFR3 gene, which impairs the growth of bone in the cartilage of the growth plate. Achondroplasia is characterized by distinctive features including disproportionate short stature, curvature of the spine and an enlarged head (macrocephaly). These characteristics may lead to various health challenges including reduced breathing for short periods of time (apnea), upper airway obstruction, obesity, hearing loss, dental problems etc.
Achondroplasia can be diagnosed before birth through fetal ultrasound. DNA testing can also be used to identify a change in FGFR3 to confirm clinical diagnosis. The condition may also be diagnosed after birth through a physical exam.

Treatment Paradigm: Individuals with achondroplasia face several health challenges. A child with achondroplasia may begin to see certain specialists at different times throughout life. Options to manage the achondroplasia to alleviate clinical complications may include surgical procedures, orthopaedic and orthodontist managements etc. Achondroplasia, however doesn't affect cognitive health.
Currently two main types of therapies are under investigation – CNP Analogues and The Decoy[*7] Method. CNP is a hormone that plays an important role in bone growth. It activates the NPRB receptors, (natriuretic peptide receptor B), reducing the effects of the overactive FGFR3 receptors. While decoys are designed to block the molecules that normally activate the FGFR3 receptors.

Competitive Landscape: Voxzogo is the first medical treatment for Achondroplasia however some new drugs are under development. Infigratinib (BGJ398) from BridgeBio is one such candidate, currently under Ph II development. It is an orally administered, ATP-competitive, FGFR1-3 tyrosine kinase inhibitor. However, Voxzogo is unlikely to see any competition for next four-five years.

Global Status: Voxzogo was approved in the European Union in August 2021 and in the US in November 2021.

[*7]...A decoy is a specially engineered protein particle that mimics the 3D structure of some other particle (such as receptor) of interest. Due to such structural similarity, they are often used to achieve a certain desired biochemical effect in absence or shortage of some other particles or molecules (which otherwise would have exerted that effect).

Vyvgart – An Orphan Drug with MultiBillion US$ Global Potential in immunity arena

Drug Profile - Vyvgart					
Modality	Biologics (not mAb)	Molecule	Efgartigimod alfa (genetical recombination)	Brand	Vyvgart
Launch Month	May 2022	Form	Injection	Strength	400mg/20mL/vial
Therapeutic Classes[*2] (2nd level)	Immunosuppressants	Mechanism of Action (MOA)	Neonatal Fc receptor (FcRn) blocker		
Therapeutic Classes[*2] (3rd level)	Other Immunosuppressants				
Indication	Generalized myasthenia gravis (limited to cases in which treatment with steroids or non-steroidal immunosuppressive agents is inadequate) (designated as an orphan drug)				
Manufecturer	argenx	Marketer	argenx	Originator/s	arGEN-X
Price Maintenance Premium (PMP)	Applied	Unit Price (at the time of first listing)	¥421,455	Peak Sales (Predicted[*3])	¥37.7 Billion
Total Sales of the Therapeutic Category (Other Immunosuppressants)[*4]					¥199 Billion
Contribution of the Brands in the Category (Other Immunosuppressants)[*4]					51%
Hospital (≥100 beds) Sales Ratio in the Category (Other Immunosuppressants)[*4]					72%

[*2]…Encise's Anatomical Therapeutic Chemical Classification
[*3]…according to the Ministry of Health, Labour and Welfare (MHLW)
[*4]…therapeutic category sales based on ATC 3 level in year 03/2023

Source: Encise Research Center, MHLW disclosures

Vyvgart is the first product for argenx, which was founded in 2008. Vyvgart was approved for the treatment of generalized myasthenia gravis (gMG) and has an orphan drug designation. Vyvgart is currently approved for use via intravenous injection for patients with gMG who do not have sufficient responses to steroids or non-steroidal immunosuppressive therapies.

MOA: Vyvgart is a neonatal Fc receptor (FcRn) blocker. By binding and blocking the FcRn, it promotes the breakdown of pathogenic immunoglobulin G (IgG) antibodies and thereby expected to improve neuromuscular transmission.

Myasthenia Gravis (MG): MG is a rare and chronic autoimmune disease where IgG autoantibodies disrupt communication between nerves and muscles, causing debilitating and potentially life-threatening muscle weakness.

MG can affect any voluntary muscle, including those controlling eye movements, facial expression, speaking and swallowing, and arms and legs. In more life-threatening cases, MG can affect muscles responsible for breathing. When it affects a different part of the body at the same time it is called Generalized Myasthenia Gravis (gMG) and is a sever condition of the disease.

According to the national epidemiological survey conducted by Japan Intractable Disease Information Center in 2018, the number of patients was 29,210 and 23.1 people in every 100,000 have MG. The overall median age of onset was age 59, age 60 for men, and age 58 for women. MG occurs in all ethnic groups throughout the world, and in both genders.

Treatment Paradigm: MG is treated with medications, surgery and other therapies – alone or in combination. Typically, two types of medications used to treat MG – anticholinesterases (which temporarily relieves the symptoms) and immunosuppressants (which attacks the disease at its source). By suppressing the body's immune system, immunosuppressants stop the body from damaging the neuromuscular junction in the first place. However, these treatments can have serious side effects.

Many of the patients need to undergo thymectomy (surgical removal of the thymus gland, which is found to be abnormal in about half of individuals with MG and considered to play an important role in MG). Intravenous Immune Globulin (IVIG) therapy (to temporarily modify the immune system), and Plasmapheresis (or 'plasma exchange', to removes antibodies) are also performed to some patients.

Comitative Landscape: Rozanolixizumab, another FcRn inhibitor, was filed in Japan by UCB in February 2023 for gMG. It was granted a priority review status following orphan drug designation in Japan.

Pricing & Potential: With MG alone, Vyvgart is projected to generate peak sales of ¥37.7 billion in Japan in its 10th year on the market. However, as it is under development for several other indications, it carries much higher market potential. argenx is targeting ~25 indications by 2025. Some analysts have estimate that it carries a US$5-10 billion in global peak sales potential from all indications.

Global Status: In the US, it was approved in December 2021 for the treatment of adults with gMG who are anti-acetylcholine receptor (AChR) antibody positive. And it received a marketing authorisation valid throughout the EU in August 2022.

Profile of new drugs in 2022, excluding the drugs which are described above

Viagra

Drug Profile - Viagra					
Modality	Small Molecule	Molecule	Sildenafil citrate	Brand	Viagra
Launch Month	March 1999[*8]	Form	Tablet, Film	Strength	25mg/tablet, 50mg/tablet, 25mg/film, 50mg/film
Therapeutic Classes[*2] (2nd level)	Urologicals	Mechanism of Action (MOA)	Phosphodiesterase 5 (PDE5) inhibitor		
Therapeutic Classes[*2] (3rd level)	Erectile Dysfunction Products				
Indication	Erectile dysfunction (patients without the ability to achieve and maintain an erection sufficient for satisfactory sexual activity)				
Manufacturer	Viatris Japan	Marketer	Viatris Japan	Originator/s	Pfizer
Price Maintenance Premium (PMP)	Not applied	Unit Price (at the time of first listing)	¥959.6, ¥1,380, ¥991.6, ¥1,424.1	Peak Sales (Predicted[*3])	¥0.02 Billion
Total Sales of the Therapeutic Category (Erectile Dysfunction Products)[*4]					¥4 Billion
Contribution of the Brands in the Category (Erectile Dysfunction Products)[*4]					5%
Hospital (≥100 beds) Sales Ratio in the Category (Erectile Dysfunction Products)[*4]					87%

Cialis

Drug Profile - Cialis					
Modality	Small Molecule	Molecule	Tadalafil	Brand	Cialis
Launch Month	September 2007[*9]	Form	Tablet	Strength	5mg/tablet, 10mg/tablet, 20mg/tablet
Therapeutic Classes[*2] (2nd level)	Urologicals	Mechanism of Action (MOA)	Phosphodiesterase 5 (PDE5) inhibitor		
Therapeutic Classes[*2] (3rd level)	Erectile Dysfunction Products				
Indication	Erectile dysfunction (patients without the ability to achieve and maintain an erection sufficient for satisfactory sexual activity)				
Manufacturer	Nippon Shinyaku	Marketer	Nippon Shinyaku	Originator/s	GlaxoSmithKline, ICOS
Price Maintenance Premium (PMP)	Not applied	Unit Price (at the time of first listing)	¥1,343.8, ¥1,454.6, ¥1,529.9	Peak Sales (Predicted[*3])	¥0.03 Billion
Total Sales of the Therapeutic Category (Erectile Dysfunction Products)[*4]					¥4 Billion
Contribution of the Brands in the Category (Erectile Dysfunction Products)[*4]					5%
Hospital (≥100 beds) Sales Ratio in the Category (Erectile Dysfunction Products)[*4]					87%

[*2]...Encise's Anatomical Therapeutic Chemical Classification
[*3]...according to the Ministry of Health, Labour and Welfare (MHLW)
[*4]...therapeutic category sales based on ATC 3 level in year 03/2023
[*8]...The drug was launched in March 1999 and listed in April 2022. It is only covered by insurance for use in the treatment of infertility.
[*9]...The drug was launched in September 2007 and listed in April 2022. It is only covered by insurance for use in the treatment of infertility.

Source: Encise Research Center, MHLW disclosures

Rekovelle

Drug Profile - Rekovelle					
Modality	Biologics (not mAb)	Molecule	Follitropin delta (genetical recombination)	Brand	Rekovelle
Launch Month	October 2021[*10]	Form	Injection	Strength	12μg/0.36mL/syringe, 36μg/1.08mL/syringe, 72μg/2.16mL/syringe
Therapeutic Classes[*2] (2nd level)	Sex Hormones and Products with Similar Desired Effects, Systemic Action Only	Mechanism of Action (MOA)	Follicle stimulating hormone action		
Therapeutic Classes[*2] (3rd level)	Gonadotrophins, Including Other Ovulation Stimulants				
Indication	Controlled ovarian stimulation in assisted reproductive technology				
Manufacturer	Ferring Pharmaceuticals	Marketer	Ferring Pharmaceuticals	Originator/s	Ferring Pharmaceuticals
Price Maintenance Premium (PMP)	Not applied	Unit Price (at the time of first listing)	¥15,103, ¥36,394, ¥63,390	Peak Sales (Predicted[*3])	¥3.1 Billion
Total Sales of the Therapeutic Category (Gonadotrophins, Including Other Ovulation Stimulants)[*4]					¥13 Billion
Contribution of the Brands in the Category (Gonadotrophins, Including Other Ovulation Stimulants)[*4]					15%
Hospital (≥100 beds) Sales Ratio in the Category (Gonadotrophins, Including Other Ovulation Stimulants)[*4]					80%

Ganirest

Drug Profile - Ganirest					
Modality	Small Molecule	Molecule	Ganirelix acetate	Brand	Ganirest
Launch Month	January 2009[*11]	Form	Injection	Strength	0.25mg/0.5mL/syringe
Therapeutic Classes[*2] (2nd level)	Pituitary and Hypothalamic Hormones	Mechanism of Action (MOA)	Gonadotropin releasing hormone (GnRH) receptor antagonism		
Therapeutic Classes[*2] (3rd level)	Hypothalamic Hormones				
Indication	Prevention of premature ovulation under controlled ovarian stimulation				
Manufacturer	Organon	Marketer	Organon	Originator/s	Roche
Price Maintenance Premium (PMP)	Applied	Unit Price (at the time of first listing)	¥9,085	Peak Sales (Predicted[*3])	¥0.8 Billion
Total Sales of the Therapeutic Category (Hypothalamic Hormones)[*4]					¥39 Billion
Contribution of the Brands in the Category (Hypothalamic Hormones)[*4]					53%
Hospital (≥100 beds) Sales Ratio in the Category (Hypothalamic Hormones)[*4]					67%

[*2]...Encise's Anatomical Therapeutic Chemical Classification
[*3]...according to the Ministry of Health, Labour and Welfare (MHLW)
[*4]...therapeutic category sales based on ATC 3 level in year 03/2023
[*10]...The drug was launched in October 2021 and listed in April 2022. It is only covered by insurance for use in the treatment of infertility.
[*11]...The drug was launched in January 2009 and listed in April 2022. It is only covered by insurance for use in the treatment of infertility.

Source: Encise Research Center, MHLW disclosures

Cetrotide

Drug Profile - Cetrotide					
Modality	Small Molecule	Molecule	Cetrorelix acetate	Brand	Cetrotide
Launch Month	September 2006[*12]	Form	Injection	Strength	0.25mg/vial
Therapeutic Classes[*2] (2nd level)	Pituitary and Hypothalamic Hormones	Mechanism of Action (MOA)	Gonadotropin releasing hormone (GnRH) receptor antagonism		
Therapeutic Classes[*2] (3rd level)	Hypothalamic Hormones				
Indication	Prevention of premature ovulation under controlled ovarian stimulation				
Manufacturer	Nippon Kayaku	Marketer	Merckbiopharma	Originator/s	Tulane University
Price Maintenance Premium (PMP)	Applied	Unit Price (at the time of first listing)	¥9,241	Peak Sales (Predicted[*3])	¥0.92 Billion
Total Sales of the Therapeutic Category (Hypothalamic Hormones)[*4]					¥39 Billion
Contribution of the Brands in the Category (Hypothalamic Hormones)[*4]					53%
Hospital (≥100 beds) Sales Ratio in the Category (Hypothalamic Hormones)[*4]					67%

Abecma

Drug Profile - Abecma					
Modality	Regenerative Medical Product	Molecule	Idecabtagene vicleucel	Brand	Abecma
Launch Month	April 2022	Form	Injection	Strength	Per patient
Therapeutic Classes[*2] (2nd level)	Antineoplastics	Mechanism of Action (MOA)	Chimeric antigen receptor (CAR) transfected T cell-dependent cytotoxicity		
Therapeutic Classes[*2] (3rd level)	All Other Antineoplastics				
Indication	Relapsed or refractory multiple myeloma (designated as an orphan regenerative medicine product)				
Manufacturer	Bristol-Myers Squibb	Marketer	Bristol-Myers Squibb	Originator/s	bluebird bio
Price Maintenance Premium (PMP)	Applied	Unit Price (at the time of first listing)	¥32,647,761	Peak Sales (Predicted[*3])	¥4.9 Billion
Total Sales of the Therapeutic Category (All Other Antineoplastics)[*4]					¥40 Billion
Contribution of the Brands in the Category (All Other Antineoplastics)[*4]					84%
Hospital (≥100 beds) Sales Ratio in the Category (All Other Antineoplastics)[*4]					100%

[*2]...Encise's Anatomical Therapeutic Chemical Classification
[*3]...according to the Ministry of Health, Labour and Welfare (MHLW)
[*4]...therapeutic category sales based on ATC 3 level in year 03/2023
[*12]...The drug was launched in September 2006 and listed in April 2022. It is only covered by insurance for use in the treatment of infertility.

Source: Encise Research Center, MHLW disclosures

Reyvow

Drug Profile - Reyvow					
Modality	Small Molecule	Molecule	Lasmiditan succinate	Brand	Reyvow
Launch Month	June 2022	Form	Tablet	Strength	50mg/tablet, 100mg/tablet
Therapeutic Classes[*2] (2nd level)	Analgesics	Mechanism of Action (MOA)	Suppression of trigeminal hyperactivity / Selective serotonin (5-HT) 1F receptor agonist		
Therapeutic Classes[*2] (3rd level)	Anti-migraine Preparations				
Indication	Migraine				
Manufecturer	Eli Lilly Japan	Marketer	Daiichi Sankyo	Originator/s	Eli Lilly and Company, Lundbeck A/S
Price Maintenance Premium (PMP)	Applied	Unit Price (at the time of first listing)	¥324.7, ¥570,9	Peak Sales (Predicted[*3])	¥2.8 Billion
Total Sales of the Therapeutic Category (Anti-migraine Preparations)[*4]					¥26 Billion
Contribution of the Brands in the Category (Anti-migraine Preparations)[*4]					25%
Hospital (≥100 beds) Sales Ratio in the Category (Anti-migraine Preparations)[*4]					65%

Lumakras

Drug Profile - Lumakras					
Modality	Small Molecule	Molecule	Sotorasib	Brand	Lumakras
Launch Month	April 2022	Form	Tablet	Strength	120mg/tablet
Therapeutic Classes[*2] (2nd level)	Antineoplastics	Mechanism of Action (MOA)	KRAS (G12C) inhibitor		
Therapeutic Classes[*2] (3rd level)	All Other Antineoplastics				
Indication	KRAS G12C-mutated unresectable advanced or recurrent non-small cell lung cancer that has progressed after cancer chemotherapy				
Manufecturer	Amgen	Marketer	Amgen	Originator/s	Amgen, Carmot Therapeutics
Price Maintenance Premium (PMP)	Applied	Unit Price (at the time of first listing)	¥4,204.3	Peak Sales (Predicted[*3])	¥2.3 Billion
Total Sales of the Therapeutic Category (All Other Antineoplastics)[*4]					¥40 Billion
Contribution of the Brands in the Category (All Other Antineoplastics)[*4]					84%
Hospital (≥100 beds) Sales Ratio in the Category (All Other Antineoplastics)[*4]					100%

[*2]...Encise's Anatomical Therapeutic Chemical Classification
[*3]...according to the Ministry of Health, Labour and Welfare (MHLW)
[*4]...therapeutic category sales based on ATC 3 level in year 03/2023

Source: Encise Research Center, MHLW disclosures

Ngenla

Drug Profile - Ngenla					
Modality	Biologics (not mAb)	Molecule	Somatrogon (genetical recombination)	Brand	Ngenla
Launch Month	April 2022	Form	Injection	Strength	24mg/1.2mL/kit, 60mg/1.2mL/kit
Therapeutic Classes[*2] (2nd level)	Other Hormones	Mechanism of Action (MOA)	Growth hormone (promotion of hepatic somatomedin production and secretion)		
Therapeutic Classes[*2] (3rd level)	Growth Hormones				
Indication	Growth hormone-deficient short stature without epiphyseal line closure				
Manufacturer	Pfizer	Marketer	Pfizer	Originator/s	Modigene
Price Maintenance Premium (PMP)	Not applied	Unit Price (at the time of first listing)	¥43,032, ¥107,580	Peak Sales (Predicted[*3])	¥6.4 Billion
Total Sales of the Therapeutic Category (Growth Hormones)[*4]					¥68 Billion
Contribution of the Brands in the Category (Growth Hormones)[*4]					51%
Hospital (≥100 beds) Sales Ratio in the Category (Growth Hormones)[*4]					97%

Rapifort

Drug Profile - Rapifort					
Modality	Small Molecule	Molecule	Glycopyrronium tosilate hydrate	Brand	Rapifort
Launch Month	May 2022	Form	Other Form	Strength	2.5%/2.5g/wipe
Therapeutic Classes[*2] (2nd level)	Other Dermatological Preparations	Mechanism of Action (MOA)	Acetylcholine receptor antagonism (Muscarinic receptor antagonism)		
Therapeutic Classes[*2] (3rd level)	Other Dermatological Preparations				
Indication	Primary axillary hyperhidrosis				
Manufacturer	Maruho	Marketer	Maruho	Originator/s	Stiefel Laboratories
Price Maintenance Premium (PMP)	Not applied	Unit Price (at the time of first listing)	¥262	Peak Sales (Predicted[*3])	¥3.4 Billion
Total Sales of the Therapeutic Category (Other Dermatological Preparations)[*4]					¥7 Billion
Contribution of the Brands in the Category (Other Dermatological Preparations)[*4]					11%
Hospital (≥100 beds) Sales Ratio in the Category (Other Dermatological Preparations)[*4]					87%

[*2]...Encise's Anatomical Therapeutic Chemical Classification
[*3]...according to the Ministry of Health, Labour and Welfare (MHLW)
[*4]...therapeutic category sales based on ATC 3 level in year 03/2023

Source: Encise Research Center, MHLW disclosures

Dysval

Drug Profile - Dysval					
Modality	Small Molecule	Molecule	Valbenazine tosilate	Brand	Dysval
Launch Month	June 2022	Form	Capsule	Strength	40mg/capsule
Therapeutic Classes[*2] (2nd level)	Other CNS Drugs	Mechanism of Action (MOA)	Vesicular monoamine transporter-2 (VMAT 2) inhibitor		
Therapeutic Classes[*2] (3rd level)	All Other CNS Drugs				
Indication	Tardive dyskinesia				
Manufacturer	Mitsubishi Tanabe Pharma	Marketer	Janssen Pharmaceutical	Originator/s	Neurocrine Biosciences
Price Maintenance Premium (PMP)	Applied	Unit Price (at the time of first listing)	¥2,331.2	Peak Sales (Predicted[*3])	¥6.2 Billion
Total Sales of the Therapeutic Category (All Other CNS Drugs)[*4]					¥153 Billion
Contribution of the Brands in the Category (All Other CNS Drugs)[*4]					60%
Hospital (≥100 beds) Sales Ratio in the Category (All Other CNS Drugs)[*4]					81%

Carogra

Drug Profile - Carogra					
Modality	Small Molecule	Molecule	Carotegrast methyl	Brand	Carogra
Launch Month	May 2022	Form	Tablet	Strength	120mg/tablet
Therapeutic Classes[*2] (2nd level)	Intestinal Disorder Products	Mechanism of Action (MOA)	α4 Integrin inhibitor		
Therapeutic Classes[*2] (3rd level)	Inflammatory Bowel Disorder Products				
Indication	Moderate ulcerative colitis (limited to cases in which treatment with 5-aminosalicylic acid preparations is inadequate)				
Manufacturer	EA Pharma	Marketer	Kissei Pharmaceutical	Originator/s	Ajinomoto
Price Maintenance Premium (PMP)	Not applied	Unit Price (at the time of first listing)	¥200	Peak Sales (Predicted[*3])	¥3.0 Billion
Total Sales of the Therapeutic Category (Inflammatory Bowel Disorder Products)[*4]					¥59 Billion
Contribution of the Brands in the Category (Inflammatory Bowel Disorder Products)[*4]					56%
Hospital (≥100 beds) Sales Ratio in the Category (Inflammatory Bowel Disorder Products)[*4]					77%

[*2]...Encise's Anatomical Therapeutic Chemical Classification
[*3]...according to the Ministry of Health, Labour and Welfare (MHLW)
[*4]...therapeutic category sales based on ATC 3 level in year 03/2023

Source: Encise Research Center, MHLW disclosures

Tavneos

Drug Profile - Tavneos					
Modality	Small Molecule	Molecule	Avacopan	Brand	Tavneos
Launch Month	June 2022	Form	Capsule	Strength	10mg/capsule
Therapeutic Classes[*2] (2nd level)	Other Cardiovascular Products	Mechanism of Action (MOA)	Selective C5a receptor inhibitor		
Therapeutic Classes[*2] (3rd level)	Other Cardiovascular Products				
Indication	Microscopic polyangiitis, Granulomatosis with polyangiitis (designated as an orphan drug)				
Manufecturer	Kissei Pharmaceutical	Marketer	Kissei Pharmaceutical	Originator/s	ChemoCentryx
Price Maintenance Premium (PMP)	Applied	Unit Price (at the time of first listing)	¥1,403.9	Peak Sales (Predicted[*3])	¥9.0 Billion
Total Sales of the Therapeutic Category (Other Cardiovascular Products)[*4]					¥10 Billion
Contribution of the Brands in the Category (Other Cardiovascular Products)[*4]					22%
Hospital (≥100 beds) Sales Ratio in the Category (Other Cardiovascular Products)[*4]					98%

Scemblix

Drug Profile - Scemblix					
Modality	Small Molecule	Molecule	Asciminib hydrochloride	Brand	Scemblix
Launch Month	May 2022	Form	Tablet	Strength	20㎎/tablet, 40㎎/tablet
Therapeutic Classes[*2] (2nd level)	Antineoplastics	Mechanism of Action (MOA)	Tyrosine kinase inhibitor (Bcr-Abl tyrosine kinase inhibitor)		
Therapeutic Classes[*2] (3rd level)	Protein Kinase Inhibitor Antineoplastics				
Indication	Chronic myeloid leukemia with resistance or intolerance to previous treatment (designated as an orphan drug)				
Manufecturer	Novartis Pharma	Marketer	Novartis Pharma	Originator/s	Novartis
Price Maintenance Premium (PMP)	Applied	Unit Price (at the time of first listing)	¥5,564.5, ¥10,618.3	Peak Sales (Predicted[*3])	¥3.9 Billion
Total Sales of the Therapeutic Category (Protein Kinase Inhibitor Antineoplastics)[*4]					¥482 Billion
Contribution of the Brands in the Category (Protein Kinase Inhibitor Antineoplastics)[*4]					74%
Hospital (≥100 beds) Sales Ratio in the Category (Protein Kinase Inhibitor Antineoplastics)[*4]					89%

[*2]...Encise's Anatomical Therapeutic Chemical Classification
[*3]...according to the Ministry of Health, Labour and Welfare (MHLW)
[*4]...therapeutic category sales based on ATC 3 level in year 03/2023

Source: Encise Research Center, MHLW disclosures

Samtasu

Drug Profile - Samtasu					
Modality	Small Molecule	Molecule	Tolvaptan sodium phosphate	Brand	Samtasu
Launch Month	May 2022	Form	Injection	Strength	8mg/vial, 16mg/vial
Therapeutic Classes[*2] (2nd level)	Diuretics	Mechanism of Action (MOA)	Vasopressin V2 receptor antagonist		
Therapeutic Classes[*2] (3rd level)	Diuretics				
Indication	Fluid retention in heart failure patients who have an inadequate response to other diuretics, such as loop diuretics				
Manufecturer	Otsuka Pharmaceutical	Marketer	Otsuka Pharmaceutical	Originator/s	Otsuka America Pharmaceutical, Otsuka Pharmaceutical
Price Maintenance Premium (PMP)	Not applied	Unit Price (at the time of first listing)	¥1,160, ¥2,169	Peak Sales (Predicted[*3])	¥1.3 Billion
Total Sales of the Therapeutic Category (Diuretics)[*4]					¥121 Billion
Contribution of the Brands in the Category (Diuretics)[*4]					43%
Hospital (≥100 beds) Sales Ratio in the Category (Diuretics)[*4]					28%

Arokaris

Drug Profile - Arokaris					
Modality	Small Molecule	Molecule	Fosnetupitant chloride hydrochloride	Brand	Arokaris
Launch Month	May 2022	Form	Injection	Strength	235mg/10mL/vial
Therapeutic Classes[*2] (2nd level)	Antiemetics and Antinauseants	Mechanism of Action (MOA)	Neurokinin 1 (NK1) receptor antagonist		
Therapeutic Classes[*2] (3rd level)	Antiemetics and Antinauseants				
Indication	Gastrointestinal symptoms (nausea and vomiting, including delayed phase) associated with cancer chemotherapy (cisplatin, etc.)				
Manufecturer	Taiho Pharmaceutical	Marketer	Taiho Pharmaceutical	Originator/s	Helsinn
Price Maintenance Premium (PMP)	Not applied	Unit Price (at the time of first listing)	¥11,276	Peak Sales (Predicted[*3])	¥4.1 Billion
Total Sales of the Therapeutic Category (Antiemetics and Antinauseants)[*4]					¥20 Billion
Contribution of the Brands in the Category (Antiemetics and Antinauseants)[*4]					95%
Hospital (≥100 beds) Sales Ratio in the Category (Antiemetics and Antinauseants)[*4]					9%

[*2]...Encise's Anatomical Therapeutic Chemical Classification
[*3]...according to the Ministry of Health, Labour and Welfare (MHLW)
[*4]...therapeutic category sales based on ATC 3 level in year 03/2023

Source: Encise Research Center, MHLW disclosures

Ondexxya

Drug Profile - Ondexxya					
Modality	Biologics (not mAb)	Molecule	Andexanet alfa (genetical recombination)	Brand	Ondexxya
Launch Month	May 2022	Form	Injection	Strength	200mg/vial
Therapeutic Classes[*2] (2nd level)	Blood Coagulation System, Other Products	Mechanism of Action (MOA)	Reversal effect on a direct factor Xa inhibitor		
Therapeutic Classes[*2] (3rd level)	Antagonists (Antidotes to Anticoagulants)				
Indication	For patients treated with a direct factor Xa inhibitor (apixaban, rivaroxaban, or edoxaban tosilate hydrate) when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding (designated as an orphan drug)				
Manufacturer	Alexion	Marketer	AstraZeneca	Originator/s	Portola Pharmaceuticals
Price Maintenance Premium (PMP)	Applied	Unit Price (at the time of first listing)	¥338,671	Peak Sales (Predicted[*3])	¥6.6 Billion
Total Sales of the Therapeutic Category (Antagonists (Antidotes to Anticoagulants))[*4]					¥5 Billion
Contribution of the Brands in the Category (Antagonists (Antidotes to Anticoagulants))[*4]					95%
Hospital (≥100 beds) Sales Ratio in the Category (Antagonists (Antidotes to Anticoagulants))[*4]					100%

Mepsevii

Drug Profile - Mepsevii					
Modality	Biologics (not mAb)	Molecule	Vestronidase alfa (genetical recombination)	Brand	Mepsevii
Launch Month	August 2022	Form	Injection	Strength	10mg/5mL/vial
Therapeutic Classes[*2] (2nd level)	Other Alimentary Tract and Metabolism Products	Mechanism of Action (MOA)	β-glucuronidase		
Therapeutic Classes[*2] (3rd level)	Other Alimentary Tract and Metabolism Products				
Indication	Mucopolysaccharidosis type VII (designated as an orphan drug)				
Manufacturer	Ultragenyx Japan	Marketer	Ultragenyx Japan	Originator/s	Saint Louis University
Price Maintenance Premium (PMP)	Applied	Unit Price (at the time of first listing)	¥259,932	Peak Sales (Predicted[*3])	¥0.62 Billion
Total Sales of the Therapeutic Category (Other Alimentary Tract and Metabolism Products)[*4]					¥109 Billion
Contribution of the Brands in the Category (Other Alimentary Tract and Metabolism Products)[*4]					66%
Hospital (≥100 beds) Sales Ratio in the Category (Other Alimentary Tract and Metabolism Products)[*4]					73%

[*2]...Encise's Anatomical Therapeutic Chemical Classification
[*3]...according to the Ministry of Health, Labour and Welfare (MHLW)
[*4]...therapeutic category sales based on ATC 3 level in year 03/2023

Source: Encise Research Center, MHLW disclosures

Xenpozyme

Drug Profile - Xenpozyme					
Modality	Biologics (not mAb)	Molecule	Olipudase alfa (genetical recombination)	Brand	Xenpozyme
Launch Month	June 2022	Form	Injection	Strength	20mg/vial
Therapeutic Classes[*2] (2nd level)	Other Alimentary Tract and Metabolism Products	Mechanism of Action (MOA)	Acid sphingomyelinase		
Therapeutic Classes[*2] (3rd level)	Other Alimentary Tract and Metabolism Products				
Indication	Acid sphingomyelinase deficiency (designated as an orphan drug)				
Manufecturer	Sanofi	Marketer	Sanofi	Originator/s	Genzyme
Price Maintenance Premium (PMP)	Applied	Unit Price (at the time of first listing)	¥570,420	Peak Sales (Predicted[*3])	¥0.33 Billion
Total Sales of the Therapeutic Category (Other Alimentary Tract and Metabolism Products)[*4]					¥109 Billion
Contribution of the Brands in the Category (Other Alimentary Tract and Metabolism Products)[*4]					66%
Hospital (≥100 beds) Sales Ratio in the Category (Other Alimentary Tract and Metabolism Products)[*4]					73%

Takhzyro

Drug Profile - Takhzyro					
Modality	Biologics (mAb)	Molecule	Lanadelumab (genetical recombination)	Brand	Takhzyro
Launch Month	May 2022	Form	Injection	Strength	300㎎/2mL/syringe
Therapeutic Classes[*2] (2nd level)	All Other Haematological Agents	Mechanism of Action (MOA)	Plasma kallikrein inhibitor		
Therapeutic Classes[*2] (3rd level)	Hereditary Angioedema Products				
Indication	Prevention of acute attacks of hereditary angioedema (designated as an orphan drug)				
Manufecturer	Takeda Pharmaceutical	Marketer	Takeda Pharmaceutical	Originator/s	Dyax
Price Maintenance Premium (PMP)	Applied	Unit Price (at the time of first listing)	¥1,288,729	Peak Sales (Predicted[*3])	¥6.1 Billion
Total Sales of the Therapeutic Category (Hereditary Angioedema Products)[*4]					¥5 Billion
Contribution of the Brands in the Category (Hereditary Angioedema Products)[*4]					61%
Hospital (≥100 beds) Sales Ratio in the Category (Hereditary Angioedema Products)[*4]					100%

[*2]...Encise's Anatomical Therapeutic Chemical Classification
[*3]...according to the Ministry of Health, Labour and Welfare (MHLW)
[*4]...therapeutic category sales based on ATC 3 level in year 03/2023

Source: Encise Research Center, MHLW disclosures

Mitchga

Drug Profile - Mitchga					
Modality	Biologics (mAb)	Molecule	Nemolizumab (genetical recombination)	Brand	Mitchga
Launch Month	August 2022	Form	Injection	Strength	60mg/syringe
Therapeutic Classes[*2] (2nd level)	Anti-pruritics, Including Topical Antihistamines, Anaesthetics, etc.	Mechanism of Action (MOA)	Inhibition of Interleukin-31 (IL-31) signaling		
Therapeutic Classes[*2] (3rd level)	Anti-pruritics, Including Topical Antihistamines, Anaesthetics, etc.				
Indication	Pruritus associated with atopic dermatitis (limited to cases in which existing treatment is inadequate)				
Manufecturer	Maruho	Marketer	Maruho	Originator/s	Chugai Pharmaceutical
Price Maintenance Premium (PMP)	Not applied	Unit Price (at the time of first listing)	¥117,181	Peak Sales (Predicted[*3])	¥2.3 Billion
Total Sales of the Therapeutic Category (Anti-pruritics, Including Topical Antihistamines, Anaesthetics, etc.)[*4]					¥10 Billion
Contribution of the Brands in the Category (Anti-pruritics, Including Topical Antihistamines, Anaesthetics, etc.)[*4]					37%
Hospital (≥100 beds) Sales Ratio in the Category (Anti-pruritics, Including Topical Antihistamines, Anaesthetics, etc.)[*4]					9%

Moizerto

Drug Profile - Moizerto					
Modality	Small Molecule	Molecule	Difamilast	Brand	Moizerto
Launch Month	June 2022	Form	Ointment	Strength	0.3%/g, 1%/g
Therapeutic Classes[*2] (2nd level)	Nonsteroidal Products for Inflammatory Skin Disorders	Mechanism of Action (MOA)	Phosphodiesterase 4 (PDE 4) inhibitor		
Therapeutic Classes[*2] (3rd level)	Other Nonsteroidal Products for Inflammatory Skin Disorders				
Indication	Atopic dermatitis				
Manufecturer	Otsuka Pharmaceutical	Marketer	Otsuka Pharmaceutical	Originator/s	Otsuka Pharmaceutical Development & Commercialization
Price Maintenance Premium (PMP)	Not applied	Unit Price (at the time of first listing)	¥142, ¥152.1	Peak Sales (Predicted[*3])	¥5.3 Billion
Total Sales of the Therapeutic Category (Other Nonsteroidal Products for Inflammatory Skin Disorders)[*4]					¥15 Billion
Contribution of the Brands in the Category (Other Nonsteroidal Products for Inflammatory Skin Disorders)[*4]					13%
Hospital (≥100 beds) Sales Ratio in the Category (Other Nonsteroidal Products for Inflammatory Skin Disorders)[*4]					86%

[*2]...Encise's Anatomical Therapeutic Chemical Classification
[*3]...according to the Ministry of Health, Labour and Welfare (MHLW)
[*4]...therapeutic category sales based on ATC 3 level in year 03/2023

Source: Encise Research Center, MHLW disclosures

Vocabria

Drug Profile - Vocabria					
Modality	Small Molecule	Molecule	Cabotegravir sodium Cabotegravir	Brand	Vocabria
Launch Month	June 2022	Form	Tablet Injection	Strength	30mg/tablet 400mg/2mL/vial, 600mg/3mL/vial
Therapeutic Classes[*2] (2nd level)	Antivirals for Systemic Use	Mechanism of Action (MOA)	Human Immunodeficiency Virus (HIV) integrase inhibitor		
Therapeutic Classes[*2] (3rd level)	HIV Antivirals				
Indication	HIV-1 infection (designated as an orphan drug)				
Manufecturer	Viiv Healthcare	Marketer	Glaxosmithkline	Originator/s	Shionogi-GlaxoSmithKline Pharmaceuticals
Price Maintenance Premium (PMP)	Applied	Unit Price (at the time of first listing)	¥3.541.6 ¥176,458, ¥253,850	Peak Sales (Predicted[*3])	¥0.25 Billion ¥6.8 Billion
Total Sales of the Therapeutic Category (HIV Antivirals)[*4]					¥71 Billion
Contribution of the Brands in the Category (HIV Antivirals)[*4]					86%
Hospital (≥100 beds) Sales Ratio in the Category (HIV Antivirals)[*4]					99%

Rekambys

Drug Profile - Rekambys					
Modality	Small Molecule	Molecule	Rilpivirine hydrochloride	Brand	Rekambys
Launch Month	June 2022	Form	Injection	Strength	600mg/2mL/vial, 900mg/3mL/vial
Therapeutic Classes[*2] (2nd level)	Antivirals for Systemic Use	Mechanism of Action (MOA)	Inhibition of non-nucleoside Human Immunodeficiency Virus (HIV) reverse transcriptase		
Therapeutic Classes[*2] (3rd level)	HIV Antivirals				
Indication	HIV-1 infection (designated as an orphan drug)				
Manufecturer	Janssen Pharmaceutical	Marketer	Glaxosmithkline	Originator/s	Tibotec Pharmaceuticals
Price Maintenance Premium (PMP)	Applied	Unit Price (at the time of first listing)	¥90,582, ¥130,310	Peak Sales (Predicted[*3])	¥3.5 Billion
Total Sales of the Therapeutic Category (HIV Antivirals)[*4]					¥71 Billion
Contribution of the Brands in the Category (HIV Antivirals)[*4]					86%
Hospital (≥100 beds) Sales Ratio in the Category (HIV Antivirals)[*4]					99%

[*2]...Encise's Anatomical Therapeutic Chemical Classification
[*3]...according to the Ministry of Health, Labour and Welfare (MHLW)
[*4]...therapeutic category sales based on ATC 3 level in year 03/2023

Source: Encise Research Center, MHLW disclosures

Jeselhy

Drug Profile - Jeselhy					
Modality	Small Molecule	Molecule	Pimitespib	Brand	Jeselhy
Launch Month	August 2022	Form	Tablet	Strength	40mg/tablet
Therapeutic Classes[*2] (2nd level)	Antineoplastics	Mechanism of Action (MOA)	Inhibition of heat shock protein 90 (HSP90)		
Therapeutic Classes[*2] (3rd level)	All Other Antineoplastics				
Indication	Gastrointestinal stromal tumor progressed after cancer chemotherapy				
Manufecturer	Taiho Pharmaceutical	Marketer	Taiho Pharmaceutical	Originator/s	Taiho Pharmaceutical
Price Maintenance Premium (PMP)	Applied	Unit Price (at the time of first listing)	¥6,265	Peak Sales (Predicted[*3])	¥0.1 Billion
Total Sales of the Therapeutic Category (All Other Antineoplastics)[*4]					¥40 Billion
Contribution of the Brands in the Category (All Other Antineoplastics)[*4]					84%
Hospital (≥100 beds) Sales Ratio in the Category (All Other Antineoplastics)[*4]					100%

Darvias

Drug Profile - Darvias					
Modality	Small Molecule	Molecule	Darinaparsin	Brand	Darvias
Launch Month	August 2022	Form	Injection	Strength	135mg/vial
Therapeutic Classes[*2] (2nd level)	Antineoplastics	Mechanism of Action (MOA)	Mitochondrial dysfunction, enhancement of intracellular reactive oxygen species production		
Therapeutic Classes[*2] (3rd level)	All Other Antineoplastics				
Indication	Relapsed or refractory peripheral T-cell lymphoma				
Manufecturer	Solasia Pharma	Marketer	Nippon Kayaku	Originator/s	Texas A&M University, University of Texas M. D. Anderson Cancer Center
Price Maintenance Premium (PMP)	Not applied	Unit Price (at the time of first listing)	¥31,692	Peak Sales (Predicted[*3])	¥1.1 Billion
Total Sales of the Therapeutic Category (All Other Antineoplastics)[*4]					¥40 Billion
Contribution of the Brands in the Category (All Other Antineoplastics)[*4]					84%
Hospital (≥100 beds) Sales Ratio in the Category (All Other Antineoplastics)[*4]					100%

[*2]...Encise's Anatomical Therapeutic Chemical Classification
[*3]...according to the Ministry of Health, Labour and Welfare (MHLW)
[*4]...therapeutic category sales based on ATC 3 level in year 03/2023

Source: Encise Research Center, MHLW disclosures

Enjaymo

Drug Profile - Enjaymo					
Modality	Biologics (mAb)	Molecule	Sutimlimab (genetical recombination)	Brand	Enjaymo
Launch Month	September 2022	Form	Injection	Strength	1.1g/22mL/vial
Therapeutic Classes[*2] (2nd level)	All Other Haematological Agents	Mechanism of Action (MOA)	Inhibition of C1s in the classical complement pathway		
Therapeutic Classes[*2] (3rd level)	Other Haematological Agents				
Indication	Cold agglutinin disease (designated as an orphan drug)				
Manufecturer	Sanofi	Marketer	Sanofi	Originator/s	iPierian
Price Maintenance Premium (PMP)	Applied	Unit Price (at the time of first listing)	¥244,074	Peak Sales (Predicted[*3])	¥2.2 Billion
Total Sales of the Therapeutic Category (Other Haematological Agents)[*4]					¥2 Billion
Contribution of the Brands in the Category (Other Haematological Agents)[*4]					97%
Hospital (≥100 beds) Sales Ratio in the Category (Other Haematological Agents)[*4]					100%

Fintepla

Drug Profile - Fintepla					
Modality	Small Molecule	Molecule	Fenfluramine hydrochloride	Brand	Fintepla
Launch Month	November 2022	Form	Liquid	Strength	0.22%/1mL
Therapeutic Classes[*2] (2nd level)	Anti-epileptics	Mechanism of Action (MOA)	Serotonin receptor agonist		
Therapeutic Classes[*2] (3rd level)	Anti-epileptics				
Indication	Combination therapy with antiepileptic drugs for epileptic seizures in patients with Dravet syndrome who do not respond adequately to other antiepileptic drugs (designated as an orphan drug)				
Manufecturer	UCB Japan	Marketer	Nippon Shinyaku	Originator/s	Brabant Pharma
Price Maintenance Premium (PMP)	Applied	Unit Price (at the time of first listing)	¥1,407.60	Peak Sales (Predicted[*3])	¥3.0 Billion
Total Sales of the Therapeutic Category (Anti-epileptics)[*4]					¥124 Billion
Contribution of the Brands in the Category (Anti-epileptics)[*4]					43%
Hospital (≥100 beds) Sales Ratio in the Category (Anti-epileptics)[*4]					35%

[*2]...Encise's Anatomical Therapeutic Chemical Classification
[*3]...according to the Ministry of Health, Labour and Welfare (MHLW)
[*4]...therapeutic category sales based on ATC 3 level in year 03/2023

Source: Encise Research Center, MHLW disclosures

Ezharmia

Drug Profile - Ezharmia					
Modality	Small Molecule	Molecule	Valemetostat tosilate	Brand	Ezharmia
Launch Month	December 2022	Form	Tablet	Strength	50mg/tablet, 100mg/tablet
Therapeutic Classes[*2] (2nd level)	Antineoplastics	Mechanism of Action (MOA)	Enhancer of zeste homolog (EZH) 1/2 inhibitor		
Therapeutic Classes[*2] (3rd level)	All Other Antineoplastics				
Indication	Relapsed/refractory adult T-cell leukemia/lymphoma (designated as an orphan drug)				
Manufacturer	Daiichi Sankyo	Marketer	Daiichi Sankyo	Originator/s	Daiichi Sankyo
Price Maintenance Premium (PMP)	Applied	Unit Price (at the time of first listing)	¥6,267.7, ¥12,017	Peak Sales (Predicted[*3])	¥0.55 Billion
Total Sales of the Therapeutic Category (All Other Antineoplastics)[*4]					¥40 Billion
Contribution of the Brands in the Category (All Other Antineoplastics)[*4]					84%
Hospital (≥100 beds) Sales Ratio in the Category (All Other Antineoplastics)[*4]					100%

Koselugo

Drug Profile - Koselugo					
Modality	Small Molecule	Molecule	Selumetinib sulfate	Brand	Koselugo
Launch Month	November 2022	Form	Capsule	Strength	10mg/capsule, 25mg/capsule
Therapeutic Classes[*2] (2nd level)	Antineoplastics	Mechanism of Action (MOA)	Mitogen-activated protein/extracellular signal-regulated kinase kinase (MEK) 1/2 inhibitor		
Therapeutic Classes[*2] (3rd level)	Protein Kinase Inhibitor Antineoplastics				
Indication	Plexiform neurofibromas in neurofibromatosis type 1 (designated as an orphan drug)				
Manufacturer	Alexion	Marketer	Alexion	Originator/s	Array BioPharma
Price Maintenance Premium (PMP)	Applied	Unit Price (at the time of first listing)	¥12,622.8, ¥30,257.8	Peak Sales (Predicted[*3])	¥5.7 Billion
Total Sales of the Therapeutic Category (Protein Kinase Inhibitor Antineoplastics)[*4]					¥482 Billion
Contribution of the Brands in the Category (Protein Kinase Inhibitor Antineoplastics)[*4]					74%
Hospital (≥100 beds) Sales Ratio in the Category (Protein Kinase Inhibitor Antineoplastics)[*4]					89%

[*2]...Encise's Anatomical Therapeutic Chemical Classification
[*3]...according to the Ministry of Health, Labour and Welfare (MHLW)
[*4]...therapeutic category sales based on ATC 3 level in year 03/2023

Source: Encise Research Center, MHLW disclosures

Cablivi

Drug Profile - Cablivi					
Modality	Biologics (mAb)	Molecule	Caplacizumab (genetical recombination)	Brand	Cablivi
Launch Month	December 2022	Form	Injection	Strength	10mg/vial (solution for dissolution supplied)
Therapeutic Classes[*2] (2nd level)	Antithrombotic Agents	Mechanism of Action (MOA)	Inhibition of platelet agglutination mediated by von Willebrand factor		
Therapeutic Classes[*2] (3rd level)	Other Antithrombotic Agents				
Indication	Acquired thrombotic thrombocytopenic purpura (designated as an orphan drug)				
Manufecturer	Sanofi	Marketer	Sanofi	Originator/s	Ablynx
Price Maintenance Premium (PMP)	Applied	Unit Price (at the time of first listing)	¥515,532	Peak Sales (Predicted[*3])	¥6.3 Billion
Total Sales of the Therapeutic Category (Other Antithrombotic Agents)[*4]					¥14 Billion
Contribution of the Brands in the Category (Other Antithrombotic Agents)[*4]					96%
Hospital (≥100 beds) Sales Ratio in the Category (Other Antithrombotic Agents)[*4]					100%

Spevigo

Drug Profile - Spevigo					
Modality	Biologics (mAb)	Molecule	Spesolimab (genetical recombination)	Brand	Spevigo
Launch Month	December 2022	Form	Injection	Strength	450mg/7.5mL/vial
Therapeutic Classes[*2] (2nd level)	Nonsteroidal Products for Inflammatory Skin Disorders	Mechanism of Action (MOA)	Interleukin-36 (IL-36) receptor antagonist		
Therapeutic Classes[*2] (3rd level)	Systemic Antipsoriasis Products				
Indication	Improvement of acute symptoms in pustular psoriasis				
Manufecturer	Nippon Boehringer Ingelheim	Marketer	Nippon Boehringer Ingelheim	Originator/s	Boehringer Ingelheim
Price Maintenance Premium (PMP)	Applied	Unit Price (at the time of first listing)	¥963,821	Peak Sales (Predicted[*3])	¥3.2 Billion
Total Sales of the Therapeutic Category (Systemic Antipsoriasis Products)[*4]					¥14 Billion
Contribution of the Brands in the Category (Systemic Antipsoriasis Products)[*4]					86%
Hospital (≥100 beds) Sales Ratio in the Category (Systemic Antipsoriasis Products)[*4]					100%

[*2]...Encise's Anatomical Therapeutic Chemical Classification
[*3]...according to the Ministry of Health, Labour and Welfare (MHLW)
[*4]...therapeutic category sales based on ATC 3 level in year 03/2023

Source: Encise Research Center, MHLW disclosures

Nanozora

Drug Profile - Nanozora					
Modality	Biologics (mAb)	Molecule	Ozoralizumab (genetical recombination)	Brand	Nanozora
Launch Month	December 2022	Form	Injection	Strength	30mg/0.375mL/syringe
Therapeutic Classes[*2] (2nd level)	Anti-inflammatory and Anti-rheumatic Products	Mechanism of Action (MOA)	Tumor necrosis factor-α (TNF-α) inhibitor		
Therapeutic Classes[*2] (3rd level)	Specific Anti-rheumatic Agents				
Indication	Rheumatoid arthritis inadequately responding to existing treatments				
Manufecturer	Taisho Pharmaceutical	Marketer	Taisho Pharmaceutical	Originator/s	Ablynx
Price Maintenance Premium (PMP)	Not applied	Unit Price (at the time of first listing)	¥112,476	Peak Sales (Predicted[*3])	¥9.1 Billion
Total Sales of the Therapeutic Category (Specific Anti-rheumatic Agents)[*4]					¥131 Billion
Contribution of the Brands in the Category (Specific Anti-rheumatic Agents)[*4]					51%
Hospital (≥100 beds) Sales Ratio in the Category (Specific Anti-rheumatic Agents)[*4]					83%

Menquadfi

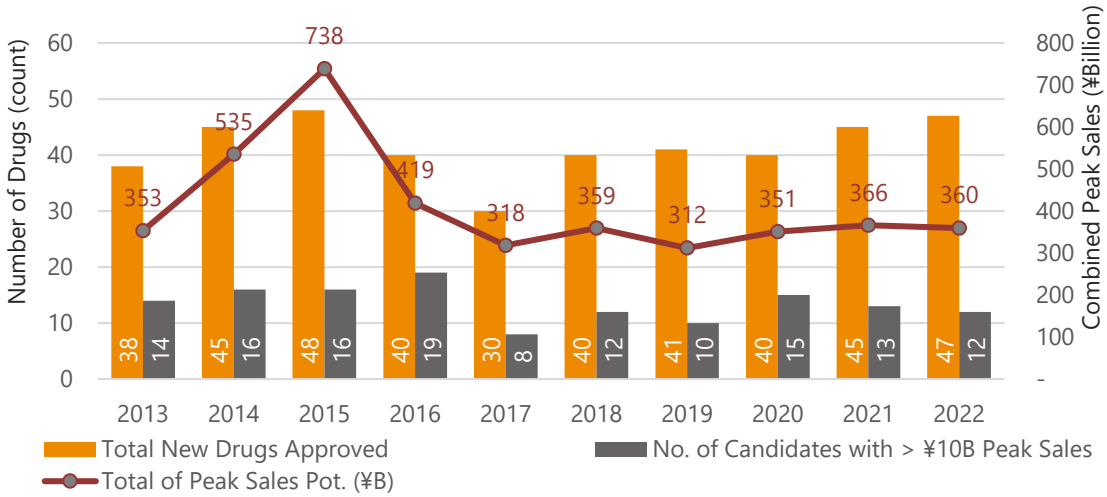
Drug Profile - Menquadfi					
Modality	Vaccine	Molecule	Tetravalent meningococcal vaccine (tetanus toxoid conjugate)	Brand	Menquadfi
Launch Month	February 2023	Form	Injection	Strength	0.5mL/vial
Therapeutic Classes[*2] (2nd level)	Vaccines	Mechanism of Action (MOA)	Production of anti-meningococcal antibodies		
Therapeutic Classes[*2] (3rd level)	Bacterial Vaccines				
Indication	Prevention of invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, W, and Y				
Manufecturer	Sanofi	Marketer	Sanofi	Originator/s	sanofi-aventis
Price Maintenance Premium (PMP)	Not applied	Unit Price (at the time of first listing)	¥20,194	Peak Sales (Predicted[*3])	¥6.0 Million
Total Sales of the Therapeutic Category (Bacterial Vaccines)[*4]					¥8 Billion
Contribution of the Brands in the Category (Bacterial Vaccines)[*4]					14%
Hospital (≥100 beds) Sales Ratio in the Category (Bacterial Vaccines)[*4]					100%

[*2]...Encise's Anatomical Therapeutic Chemical Classification
[*3]...according to the Ministry of Health, Labour and Welfare (MHLW)
[*4]...therapeutic category sales based on ATC 3 level in year 03/2023

Source: Encise Research Center, MHLW disclosures

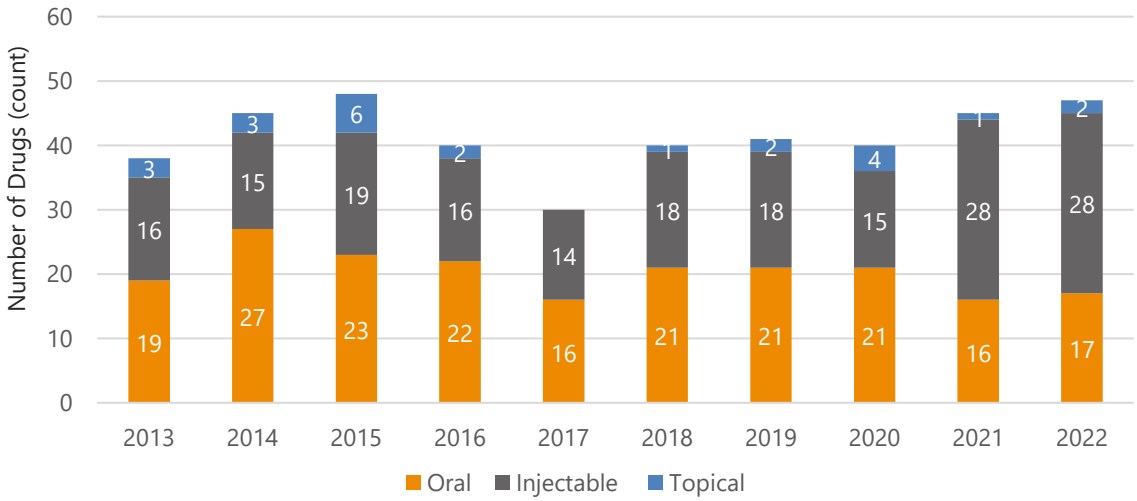
Appendix: New Drugs Approvals in Past 10 Years - Key Statistics (Figures only)

Figure 7. New Drugs vs Peak Sales



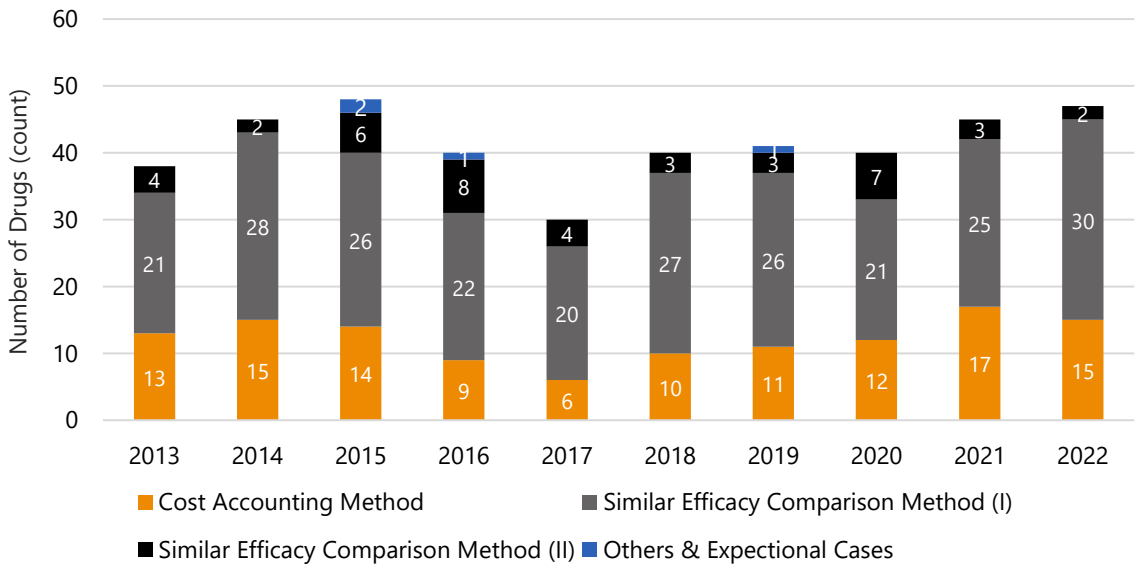
Source: MHLW, Encise Research Center

Figure 8. New Drugs Listing by Formulation Type



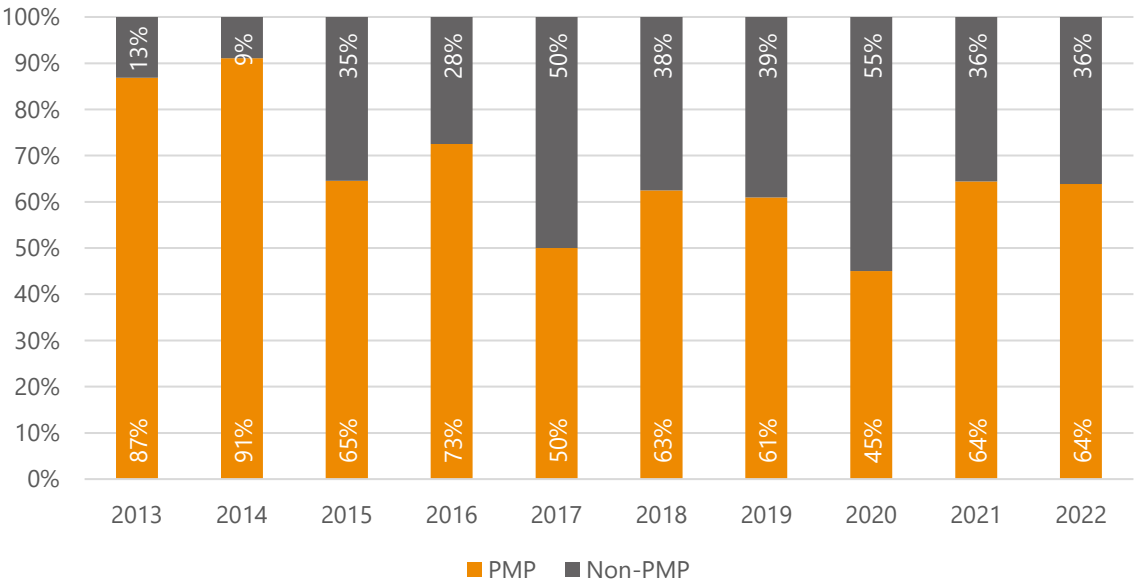
Source: MHLW, Encise Research Center

Figure 9. New Drugs Listing by Pricing Method



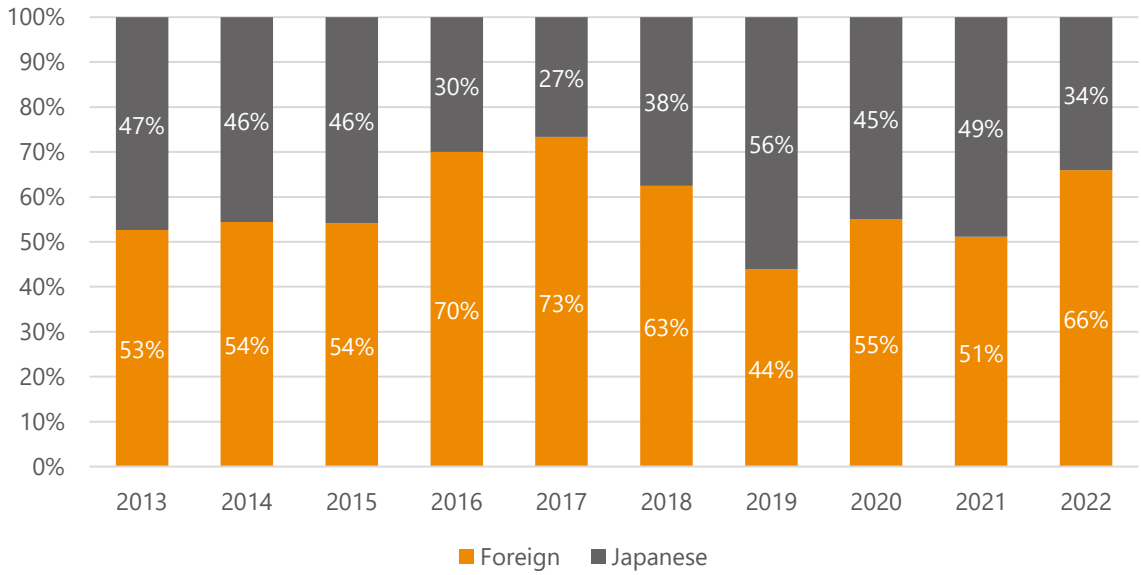
Source: MHLW, Encise Research Center

Figure 10. New Drugs Listing by PMP vs Non-PMP



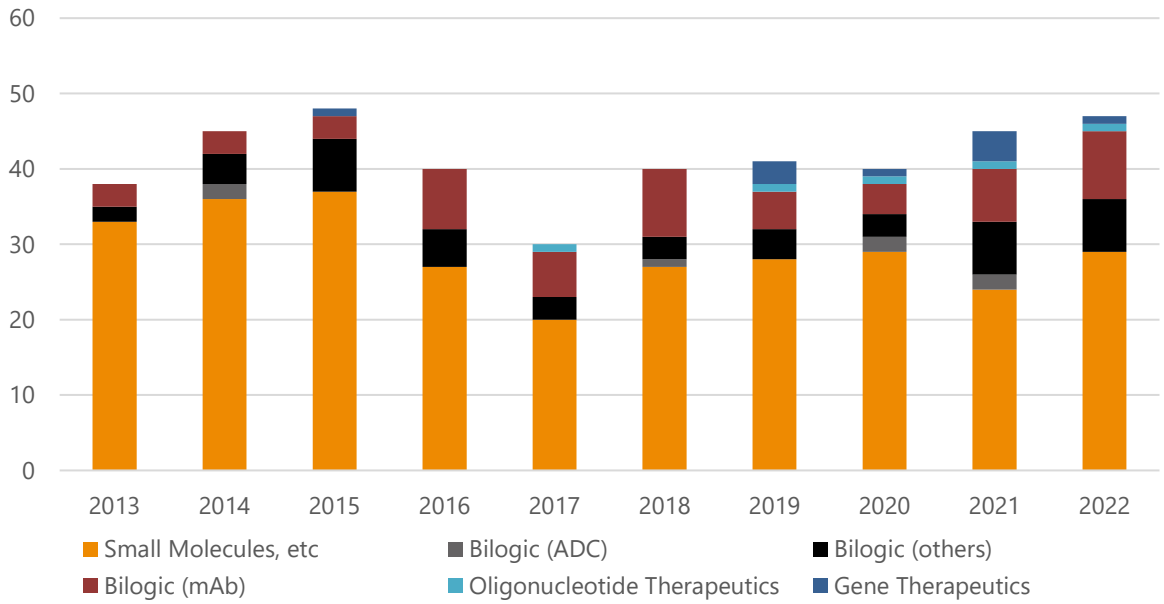
Source: MHLW, Encise Research Center

Figure 11. New Drugs Listing by Sponsor's Origin of Country



Source: MHLW, Encise Research Center

Figure 12. New Drugs Listing by Type of Modality



Source: MHLW, Encise Research Center

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