Pharmaceuticals and Medical Devices Safety Information

No. 425 December 2025

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This *Pharmaceuticals and Medical Devices Safety Information (PMDSI)* publication is issued reflective of safety information collected by the Ministry of Health, Labour and Welfare (MHLW). It is intended to facilitate safer use of pharmaceuticals and medical devices by healthcare providers. The PMDSI is available on the Pharmaceuticals and Medical Devices Agency (PMDA) web page (https://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0002.html) and on the MHLW website (https://www.mhlw.go.jp/, only in Japanese).

Available information is listed here

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Pharmaceuticals and Medical Devices Safety Information

No. 425 December 2025

Ministry of Health, Labour and Welfare
Pharmaceutical Safety Bureau, Japan

[Outline of Information]

E: Distribution of Dear Healthcare Professional Letters of Emergency Communications, *R:* Distribution of Dear Healthcare Professional Letters of Rapid Communications, *P*: Revision of PRECAUTIONS, *C*: Case Reports

Reporting of safety information such as adverse reactions to the Minister of Health, Labour and Welfare is a duty of healthcare professionals.

If healthcare professionals such as physicians, dentists, and pharmacists detect adverse reactions, infections, or malfunctions associated with drugs, medical devices, or regenerative medical products, please report them to the Minister of Health, Labour and Welfare directly or through the marketing authorization holder. As healthcare professionals, drugstore and pharmacy personnel are also required to report adverse reactions, etc.

Please utilize the Report Reception Site for reporting.
(This service is available only in Japanese.)

https://www.pmda.go.jp/safety/reports/hcp/0002.html

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Abbreviations

MAH	Marketing Authorization Holder
MHLW	Ministry of Health, Labour and Welfare
NICU	Neonatal Intensive Care Unit
PMDA	Pharmaceuticals and Medical Devices Agency
PSB	Pharmaceutical Safety Bureau
PSD	Pharmaceutical Safety Division

1

Revision of “PRECAUTIONS” for Andexanet Alfa (Genetical Recombination)

1. Introduction

Andexanet Alfa (Genetical Recombination) (hereinafter referred to as "this drug") is a drug indicated for the reversal of the anticoagulant effect when life-threatening or uncontrolled haemorrhage occurs in patients receiving direct factor Xa inhibitors (apixaban, rivaroxaban, or edoxaban tosilate hydrate) (hereinafter referred to as "FXa inhibitors") and has been marketed since May 2022.

On November 26, 2025, the Ministry of Health, Labour and Welfare instructed a revision of the precautions concerning interactions between this drug and low-molecular-weight heparin, so that healthcare professionals can make decisions on the use of low-molecular-weight heparin, after administration of this drug based on more detailed information. This document introduces the contents of the examination about the revision.

2. Background

In the electronic package insert of this drug in Japan, it is described that where anticoagulant activity is reversed by using this drug in the case of occurrence of haemorrhage during treatment with FXa inhibitors, resumption of appropriate anticoagulant therapy should be considered as soon as possible after haemostasis was achieved to reduce the risks of thromboembolism in the “IMPORTANT PRECAUTIONS” section. However, the duration of the reversal of the anticoagulant activity of FXa inhibitors with this drug is unknown, and until now no information on the timing of resumption of anticoagulant therapy had been provided.

As already cautioned in the "IMPORTANT PRECAUTIONS" section and "Precautions for Co-administration (this drug should be administered with caution when co-administered with the following.)" in the “INTERACTIONS” section of the electronic package insert, heparin resistance may occur after administration of this drug when this drug is used in the perioperative period, and therefore the necessity of administration of this drug should be carefully determined where this drug is used in settings of surgery/procedures that require anticoagulation with heparin. However, no information had been provided regarding the timing at which this drug can be administered in the perioperative period, during which there is concern about heparin resistance.

Recently, a simulation using pharmacokinetic/pharmacodynamic (PK/PD) models conducted by the marketing authorization holder has revealed that the original anticoagulant activity of FXa inhibitors or low-molecular-weight heparin is expected at 4 hours after the end of administration of this drug. Based on the results of this simulation, the necessity of revising the electronic package insert in Japan was examined. The effect of this drug on the anticoagulant activity of unfractionated heparin has not been evaluated.

3. Details of the examination

The anticoagulant activity obtained when low-molecular-weight heparin (enoxaparin 40 mg) was administered after anticoagulant activity was reversed by this drug was simulated using PK/PD models. The result suggested that the anticoagulant activity of enoxaparin is not affected by this drug 4 hours after the end of intravenous infusion of this drug, regardless of the dose of the anticoagulant used before administration of this drug.

Although attention has already been called to the necessity of re-anticoagulation and

occurrence of heparin resistance after administration of this drug, adding new information on interactions between this drug and low-molecular-weight heparin based on the results of simulation using the PK/PD models was considered beneficial for healthcare professionals when they examine the timing for the start of re-anticoagulation and influence of heparin resistance during surgery. For this reason, it was decided to add a description to the effect that original anticoagulant effect of FXa inhibitors or low-molecular-weight heparin can be expected at 4 hours after the end of administration of this drug in the “IMPORTANT PRECAUTIONS” section and a description to the effect that it is presumed that the anticoagulant activity of low-molecular-weight heparin is not affected by this drug 4 hours after the end of administration of this drug in the “Precautions for Co-administration (this drug should be administered with caution when co-administered with the following.)" in the “INTERACTIONS” section in the electronic package insert to provide precautions.

4. Conclusion

Healthcare professionals are encouraged to understand the purpose of this revision and carefully check the electronic package insert to make a judgment carefully and to continuously cooperate for proper use.

[References]

• Revision of PRECAUTIONS (PSB/PSD Notification No. 1126-1, dated November 26, 2025)

2

Important Safety Information

Regarding the revision of the PRECAUTIONS of package inserts of drugs in accordance with the Notification dated November 26 ,2025, this section will present the details of important revisions as well as the case summary serving as the basis for these revisions.

1 Imiglucerase (genetical recombination)

Brand name (name of company)	Cerezyme for i.v. injection 400 units (Sanofi K.K.)
Therapeutic category	Enzyme preparations
Indications	Improvement of various symptoms of Gaucher disease (anemia, thrombocytopenia,hepatosplenomegaly, and bone symptoms)

PRECAUTIONS (Revised language is underlined.)

8. IMPORTANT PRECAUTIONS	Administration of this drug may cause hypersensitivity and infusion reaction. If clinically significant symptoms occur, administration should be discontinued. After appropriate measures are taken, resumption should be considered while the clinical course is monitored (measures such as prior administration of antihistamine and reducing the infusion rate enabled continuation of administration of this drug).
11. ADVERSE REACTIONS	Anaphylaxis, Infusion reaction
11.1 Clinically Significant Adverse Reactions (newly added)	Hypersensitivity reactions including pruritus, flushing, urticaria, angioedema, chest discomfort, dyspnoea, wheezing, blood pressure decreased, cyanosis, cough, hypotension, and hypertension may occur.
Reference information	Among the cases collected in the PMDA's safety database for drugs, those meeting the following conditions were retrieved: Cases (for which a causal relationship between the drug and the event is reasonably possible) involving Infusion reaction reported in Japan: 1 (No patient mortalities) Number of patients using the drug as estimated by the MAH during the previous 1-year period: Approximately 46 Japanese market launch: ［1］ Cerezyme for i.v. injection 400 units ：March 2011

Case summary

No.	Patient		Daily dose/ Administration duration	Adverse reaction	
	Sex/ age	Reason for use (complication)		Clinical course and treatment	
1	Male Younger than 1 year	Gaucher's disease type II (anaemia, cholestasis, respiratory disorder, decreased platelet count, collodion baby, hepatosplenomegaly, mucopolysaccharidosis II, decreased oxygen saturation, neonatal disorder)	60 U/kg/2 weeks	**Infusion related reaction (wheezing, pyrexia)**	
				Approximately 2 months before administration	Labored breathing and poor oxygenation were noted. In addition, ichthyosis-like skin features were identified on the whole body. Since decreased platelet count was noted at the age of 0 day, the patient was transferred to and admitted to the NICU.
				Day of initiation of administration (the first dose)	Administration of imiglucerase was initiated for Gaucher's disease type II. A 0.2-micron in-line filter was not used.
				Day 28 of administration (the third dose)	Before administration of imiglucerase, temperature: 37.3℃, blood pressure: 66 to 114 mmHg, pulse: 138 bpm, γ-GTP level was around 1,810 IU/L, and the patient's condition: Good. Imiglucerase 60 U/kg was administered over 3 hours. Infusion related reactions including pyrexia and wheezing occurred immediately after the initiation of infusion. Approximately 1 hour after the initiation of administration, polypnoea, retractive breathing, wheezing, and pyrexia occurred. During the event: Body temperature: 38.3℃, blood pressure: 69 to 128 mmHg, pulse: 168 bpm. Since an adverse reaction was suspected, administration for the day was discontinued. Observation after the discontinuation of administration: Body temperature: 38.6℃, blood pressure: 69 to 121 mmHg, pulse: 150 bpm. Treatment for pyrexia and wheezing: Hydrocortisone 6 mg/kg and inhalation of adrenaline. Wheezing disappeared in approximately 1 hour and pyrexia persisted. Steroid 3 mg/kg was additionally administered, but no obvious effect was obtained.
				Day 29 of administration	Pyrexia disappeared 24 hours after the third dose.
				Day 31 of administration	IgE antibody: Negative, IgG antibody: Negative.
	Suspected concomitant drug: Phenobarbital Concomitant drugs: Ferric pyrophosphate, soluble and ursodeoxycholic acid				

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Revisions of PRECAUTIONS (No. 365)

This section presents details of revisions to the PRECAUTIONS and brand names of drugs that have been revised in accordance with the Notifications dated November 26, 2025.

1 Other cardiovascular agents
Bosentan hydrate

Brand name	Tracleer 62.5 mg film-coated tablets, Tracleer 32 mg dispersible tablets for pediatric (Janssen Pharmaceutical K.K.), and the others
1. WARNINGS	This drug may cause hepatic function disorder or autoimmune hepatitis. Patients must undergo liver function tests before administration and at least once a month during administration. It is desirable for patients to undergo the test once every 2 weeks for 3 months after the start of administration. If any abnormality is observed in liver function test values, appropriate measures such as dose reduction or discontinuation of administration should be taken according to the severity and clinical symptoms.
7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION	In the case where AST increased or ALT increased is accompanied by clinical symptoms of liver disorder or autoimmune hepatitis, including queasy, vomiting, pyrexia, abdominal pain, jaundice, lethargy or fatigue, and flu-like symptoms (arthralgia, myalgia, pyrexia), or bilirubin level is 2 times the upper limit of the reference range or higher, administration should be discontinued.
11. ADVERSE REACTIONS	Autoimmune hepatitis
11.1 Clinically Significant Adverse Reactions (newly added)	Autoimmune hepatitis may occur with a latency of a few months to years after the start of administration of this drug.

2 Anticoagulants
Apixaban

Brand name	Eliquis tablets 2.5 mg, 5 mg (Bristol-Myers Squibb K.K.)
11. ADVERSE REACTIONS	Haemorrhage
11.1 Clinically Significant Adverse Reactions	Haemorrhage including haemorrhage intracranial, haemorrhage of digestive tract, haemorrhage intraocular, and splenic haemorrhage leading to splenic rupture may occur.

3 Anticoagulants
Edoxaban tosilate hydrate

Brand name	Lixiana tablets 15 mg, 30 mg, 60 mg, Lixiana OD Tablets 15 mg, 30 mg, 60 mg (Daiichi Sankyo Co., Ltd.)

11. ADVERSE REACTIONS	Haemorrhage
11.1 Clinically Significant Adverse Reactions	Significant haemorrhage affecting various tissues and organs may occur, including haemorrhage of digestive tract, haemorrhage intracranial, haemorrhage intraocular, wound haemorrhage, retroperitoneal haemorrhage, and splenic haemorrhage leading to splenic rupture. Some fatal cases have also been reported. If clinically significant haemorrhage occurs or worsens, administration should be discontinued.

4 Anticoagulants

Dabigatran etexilate methanesulfonate

Brand name	Prazaxa Capsules 75 mg, 110 mg (Nippon Boehringer Ingelheim Co., Ltd.)
11. ADVERSE REACTIONS	Hemorrhage (Haemorrhage of digestive tract, haemorrhage intracranial, and the others.)
11.1 Clinically Significant Adverse Reactions	Haemorrhage including haemorrhage of digestive tract, haemorrhage intracranial, and splenic haemorrhage leading to splenic rupture may occur.

5 Anticoagulants

Rivaroxaban

Brand name	Xarelto tablets 2.5 mg, 10 mg, 15 mg, Xarelto OD tablets 10 mg, 15 mg, Xarelto fine granules 10 mg, 15 mg, Xarelto dry syrup for pediatric 51.7 mg, Xarelto dry syrup for 103.4 mg, and the others (Bayer Yakuhin, Ltd., and the others)
11. ADVERSE REACTIONS	Haemorrhage
11.1 Clinically Significant Adverse Reactions	Serious haemorrhage including haemorrhage intracranial, cerebral haemorrhage, haemorrhagic stroke, eye haemorrhage, retinal haemorrhage, rectal haemorrhage, gastrointestinal haemorrhage,melaena, upper gastrointestinal haemorrhage, lower gastrointestinal haemorrhage, gastric ulcer haemorrhage, intraarticular haemorrhage, muscle haemorrhage with compartment syndrome, and splenic haemorrhage leading to splenic rupture may occur. Some fatal cases have been reported. If any abnormalities such as serious haemorrhage are observed, administration should be discontinued. Complications associated with haemorrhage including shock, renal failure, dyspnoea, oedema, headache, dizziness, pallor, and feelings of weakness may occur. Chest pain or angina pectoris-like cardiac ischaemia symptoms have occurred as a result of anaemia in some cases

6 Anticoagulants

Warfarin potassium

Brand name	Warfarin tablets 0.5 mg, 1 mg, 5 mg, Warfarin granules 0.2%, and the others (Eisai Co., Ltd., and the others.)
11. ADVERSE REACTIONS	Haemorrhage Intraorgan haemorrhage such as cerebral haemorrhage and splenic haemorrhage leading to splenic rupture, mucosal haemorrhage, haemorrhage subcutaneous, etc. may occur. If the anticoagulant effect

11.1 Clinically Significant Adverse Reactions

of this drug needs to be rapidly decreased, administration should be discontinued and administration of vitamin K preparation should be considered. If serious haemorrhage including cerebral haemorrhage occurs, appropriate measures such as intravenous injection of prothrombin complex or transfusion of fresh frozen plasma should be taken as necessary. When these measures are taken, sufficient attention should be paid to recurrence of thrombus.

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7 Other agents relating to blood and body fluids

Andexanet alfa (genetical recombination)

Brand name

Ondexxya for Intravenous Injection 200 mg (AstraZeneca K.K.)

8. IMPORTANT PRECAUTIONS

After hemostasis is achieved, to reduce the risk of thromboembolism, patients' conditions should be carefully monitored and resumption of anticoagulant therapy should be considered as soon as medically appropriate after the benefit of resuming anticoagulant therapy and the risk of recurrence of haemorrhage are evaluated. A normal degree of anticoagulation from direct factor Xa inhibitors or low-molecular weight heparin can be expected after 4 hours following the end of administration of this drug based on the simulation results.

10. INTERACTIONS
10.2 Precautions for Co-administration (This drug should be administered with caution when co-administered with the following.)

Drugs	Signs, symptoms, and treatment	Mechanism/risk factors
Unfractionated heparin Heparin sodium Heparin calcium	The anticoagulant effect of heparin may be attenuated, and heparin resistance may be observed.	In vitro data suggests that this drug acts on heparin-antithrombin III complex, and attenuates the anticoagulant effect of heparin. The effects of andexanet alfa on the pharmacological action of unfractionated heparin (anticoagulant activity) have not been studied in healthy volunteers or bleeding patients.
Low-molecular weight heparin Enoxaparin sodium Dalteparin sodium Parnaparin sodium	The anticoagulant effect of heparin may be attenuated, and heparin resistance may be observed.	In vitro data suggests that this drug acts on heparin-antithrombin III complex, and attenuates the anticoagulant effect of heparin. Based on the simulation results, the anticoagulant activity of low-molecular weight heparin is estimated to be affected up to 4 hours following the end of administration of this drug.

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8 Enzyme preparations

Imiglucerase (genetical recombination)

Brand name

Cerezyme for i.v. injection 400 units (Sanofi K.K.)

8. IMPORTANT PRECAUTIONS	Administration of this drug may cause hypersensitivity and infusion reaction. If clinically significant symptoms occur, administration should be discontinued. After appropriate measures are taken, resumption should be considered while the clinical course is monitored (measures such as prior administration of antihistamine and reducing the infusion rate enabled continuation of administration of this drug).
11. ADVERSE REACTIONS	Anaphylaxis, Infusion reaction
11.1 Clinically Significant Adverse Reactions	Hypersensitivity reactions including pruritus, flushing, urticaria, angioedema, chest discomfort, dyspnoea, wheezing, blood pressure decreased, cyanosis, cough, hypotension, and hypertension may occur.

9 Other antitumor agents

Atezolizumab (genetical recombination)

Brand name	Tecentriq for Intravenous Infusion 840 mg, 1200 mg (Chugai Pharmaceutical Co., Ltd.)
11. ADVERSE REACTIONS **11.1 Clinically Significant Adverse Reactions (newly added)**	Haemolytic anaemia

10 Synthetic antibacterials

Tosufloxacin tosilate hydrate (oral dosage form)

Brand name	Ozex Tab. 75, 150, Ozex fine granules 15% for pediatric, Ozex Tab. 60 mg for pediatric (Fuji Film Toyama Chemical Co., Ltd.), Tosuxacin Tablets 75 mg, 150 mg (Viatris Pharmaceuticals Japan G.K.), and the others
11. ADVERSE REACTIONS	Acute kidney injury, nephritis interstitial, nephrogenic diabetes insipidus, calculus urinary
11.1 Clinically Significant Adverse Reactions	Serious renal disorders including acute kidney injury, nephritis interstitial, and nephrogenic diabetes insipidus may occur. In addition, crystalluria containing this drug as a component may occur and cause acute kidney injury and calculus urinary. This condition has been reported especially more frequently in children.

11 Onasemnogene abeparvovec

Brand name	Zolgensma Intravenous Infusion (Novartis Pharma K.K.)
8. IMPORTANT PRECAUTIONS	Mild increased cardiac troponin I may occur after administration of this product. Cardiac troponin I levels should be measured before administration and within approximately 1 month after administration of this product. If any abnormality in cardiac troponin I levels is observed, the measurement should be continued until recovery of the levels.

4

List of Products Subject to Early Post-marketing Phase Vigilance

Early Post-marketing Phase Vigilance (EPPV) was established in 2001. This unique system for newly-approved drug products refers to any safety assurance activities that are conducted within a period of 6 months just after marketing of a new drug. The MAH responsible for a new drug in the EPPV period is required to collect adverse drug reactions (ADRs) data from all medical institutions where the drug is used and to take safety measures as appropriate. The aim of EPPV is to promote the rational and appropriate use of drugs in medical treatments and to facilitate prompt action for the prevention of serious ADRs. EPPV is specified as a condition of product approval.

(As of November 30, 2025)
◎: Products for which EPPV was initiated after November 1, 2025

	Nonproprietary name Brand name	Name of the MAH	Date of EPPV initiation
◎	Midazolam Dormicum syrup 2 mg/mL	Maruishi Pharmaceutical Co., Ltd.	November 27, 2025
◎	Avacincaptad pegol sodium Izervay for intravitreal injection 20 mg/mL	Astellas Pharma Inc.	November 27, 2025
◎	Vornorexant hydrate Vorzzz tablets 2.5 mg, 5 mg, 10 mg	Taisho Pharmaceutical Co., Ltd.	November 27, 2025
◎	Chenodeoxycholic Acid[*1] Fujichenon granular tablets 125	Fujimoto Pharmaceutical Corporation	November 21, 2025
◎	Bempedoic Acid Nexletol tablets 180 mg	Otsuka Pharmaceutical Co., Ltd.	November 21, 2025
◎	Repotrectinib[*2] Augtyro capsules 40 mg, 160 mg	Bristol-Myers Squibb K.K.	November 20, 2025
◎	Inebilizumab (genetical recombination)[*3] Uplizna for intravenous infusion 100 mg	Mitsubishi Tanabe Pharma Corporation	November 20, 2025
◎	Gallium (68Ga) gozetotide Locametz kit	Novartis Pharma K.K.	November 12, 2025
◎	Lutetium (177Lu) vipivotide tetraxetan Pluvicto injection	Novartis Pharma K.K.	November 12, 2025
◎	Taletrectinib adipate Ibtrozi capsules 200 mg	Nippon Kayaku Co., Ltd.	November 12, 2025
◎	Zongertinib Hernexeos tablets 60 mg	Nippon Boehringer Ingelheim Co., Ltd.	November 12 2025
◎	Nusinersen Sodium Spinraza intrathecal injection 28 mg, 50 mg	Biogen Japan Ltd.	November 12, 2025
◎	Selumetinib sulfate Koselugo granules 5 mg, 7.5 mg	Alexion Pharma Godo Kaisha	November 12, 2025
◎	Nipocalimab (genetical recombination) Imaavy intravenous infusion 1200 mg	Janssen Pharmaceutical K.K.	November 12, 2025

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	Nonproprietary name Brand name	Name of the MAH	Date of EPPV initiation
◎	Palopegteriparatide Yorvipath subcutaneous injection 168 μg pen, 294 μg pen, 420 μg pen	Teijin Pharma Limited	November 6, 2025
◎	Gallium (^{68}Ga) chloride GalliaPharm 68Ge/68Ga generator	Eckert & Ziegler Radiopharma GmbH (Oversee products designated MAH) Novartis Pharma K.K.	November 5, 2025
◎	Remimazolam besilate[*4] Anerem 20 mg for I.V. injection	Mundipharma K.K.	November 4, 2025
	Pneumococcal 21-valent Conjugate Vaccine (joint component of nontoxic diphtheria toxin derivatives) Capvaxive for intramuscular injection syringes	MSD K.K.	October 29, 2025
	Sepetaprost Setaneo ophthalmic solution 0.002%	Santen Pharmaceutical Co., Ltd.	October 23, 2025
	Coronavirus (SARS-CoV-2) RNA Vaccine DAICHIRONA INTRAMUSCULAR INJECTION	Daiichi Sankyo Co., Ltd.	September 19, 2025
	Etrasimod L-Arginine Velsipity Tablets 2 mg	Pfizer Japan Inc.	September 12, 2025
	Miglustat[*5] Opfolda Capsules 65 mg	Amicus Therapeutics, Inc.	August 27, 2025
	Cipaglucosidase alfa (genetical recombination) Pombiliti for I.V. Infusion 105 mg	Amicus Therapeutics, Inc.	August 27, 2025
	Recombinant adsorbed 9-valent human papillomavirus virus-like particle vaccine (yeast origin)[*6] Silgard 9 Aqueous Suspension for Intramuscular Injection Syringes	MSD K.K.	August 25, 2025
	Selumetinib Sulfate Koselugo Capsules 10 mg, 25 mg	Alexion Pharma Godo Kaisha	August 25, 2025
	Avatrombopag Maleate[*7] Doptelet tablets 20 mg	Swedish Orphan Biovitrum Japan Co., Ltd.	August 25, 2025
	Belzutifan Welireg Tablets 40 mg	MSD K.K.	August 18, 2025
	Sotatercept (genetical recombination) Airwin for Subcutaneous Injection 45 mg, 60 mg	MSD K.K.	August 18, 2025
	Talquetamab (genetical recombination)	Janssen	August 14, 2025

	Nonproprietary name Brand name	Name of the MAH	Date of EPPV initiation
	Talvey Subcutaneous Injection 3 mg, 40 mg	Pharmaceutical K.K.	
	Erdafitinib Balversa Tablets 3 mg, 4 mg, 5 mg	Janssen Pharmaceutical K.K.	July 16, 2025
	Tislelizumab (genetical recombination) Tevimbra I.V. Infusion 100 mg	BeOne Medicines Japan	July 1, 2025
	Drospirenone[*8] Slinda 28 Tablets	Aska Pharmaceutical Co., Ltd.	June 30, 2025
	Purified Vi polysaccharide typhoid vaccine Typhim Vi Syringe for Injection	Sanofi K.K.	June 30, 2025
	Vutrisiran sodium[*9] Amvuttra Subcutaneous Injection 25 mg Syringe	Alnylam Japan K.K.	June 24, 2025
	pH4-Treated acidic normal human immunoglobulin (subcutaneous injection), vorhyaluronidase alfa (genetical recombination)[*10] HyQvia 10% S.C. Injection Set 5 g/50 mL, 10 g/100 mL, 20 g/200 mL	Takeda Pharmaceutical Company Limited	June 24, 2025
	IncobotulinumtoxinA Xeomin 50 units, 100 units, 200 units for injection	Teijin Pharma Limited	June 24, 2025
	Remimazolam besilate[*11] Anerem 50 mg for I.V. Injection	Mundipharma K.K.	June 24, 2025
	Maralixibat chloride Livmarli Oral Solution 10 mg/mL	Takeda Pharmaceutical Company Limited	June 12, 2025
	pH4-Treated acidic normal human immunoglobulin (subcutaneous injection), vorhyaluronidase alfa (genetical recombination) HyQvia 10% S.C. Injection Set 5 g/50 mL, 10 g/100 mL, 20 g/200 mL	Takeda Pharmaceutical Company Limited	June 12, 2025
	Ivosidenib Tibsovo Tablets 250 mg	Nihon Servier Co., Ltd.	June 2, 2025

*1 Cerebrotendinous xanthomatosis

*2 NTRK fusion gene-positive advanced or recurrent solid tumor

*3 Suppression of relapse in IgG4-related diseases

*4 Sedation during gastrointestinal endoscopy

*5 Combination therapy with cipaglucosidase alfa (genetical recombination) for late onset pompe's disease

*6 Prevention of the following diseases caused by infection with human papillomavirus types 6, 11, 16, 18, 31, 33, 45, 52, and 58
• Anal cancer (squamous cell carcinoma) and its precursor lesions (anal intraepithelial neoplasia (AIN) grades 1, 2, and 3)

*7 Persistent and chronic immune thrombocytopenia

*8 Contraception

*9 Transthyretin cardiac amyloidosis (wild type and mutant type)

*10 Slowing the progression of motor function decline in chronic inflammatory demyelinating polyradiculoneuritis and multifocal motor neuropathy (when improvement in muscle weakness is observed)

*11 Sedation during gastrointestinal endoscopy