



独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

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Summary of Investigation Results

Ceritinib

Azelnidipine

Olmesartan medoxomil/azelnidipine

Anamorelin hydrochloride

Ivabradine hydrochloride

Ibrutinib

Eplerenone

Ergotamine tartrate/anhydrous

caffeine/isopropylantipyrine

Quinidine sulfate hydrate

Colchicine

Simvastatin

Suvorexant

Tadalafil (pulmonary arterial hypertension)

Ticagrelor

Triazolam

Vardenafil hydrochloride hydrate

Finerenone

Blonanserin

Macitentan/tadalafil

Methylergometrine maleate

Lurasidone hydrochloride

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Lomitapide mesilate

March 17, 2026

Non-proprietary name

See attachment

Brand name (marketing authorization holder)

See attachment

Japanese market launch

See attachment

Indications

See attachment

Summary of revisions

a.:

1. “Patients receiving the following drugs: anamorelin hydrochloride, ivabradine hydrochloride, quinidine sulfate hydrate, ticagrelor, azelnidipine, olmesartan medoxomil/azelnidipine, eplerenone, ergotamine tartrate/anhydrous caffeine/isopropylantipyrene, simvastatin, tadalafil (Adcirca) , macitentan/tadalafil, finerenone, lomitapide mesilate, suvorexant, triazolam, blonanserin, lurasidone hydrochloride, vardenafil hydrochloride hydrate, methylergometrine maleate, ibrutinib” should be added to 2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.). In addition, “Patients with hepatic or renal impairment receiving colchicine” should be also added.
2. Precautions for patients receiving colchicine should be added to the 9.2 Patients with Renal Impairment and the 9.3 Patients with Hepatic Impairment sections in 9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS.
3. “Anamorelin hydrochloride, ivabradine hydrochloride, quinidine sulfate hydrate, ticagrelor, azelnidipine, olmesartan medoxomil/azelnidipine, eplerenone, ergotamine

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tartrate/anhydrous caffeine/isopropylantipyrine, simvastatin, tadalafil (Adcirca) , macitentan/tadalafil, finerenone, lomitapide mesilate, suvorexant, triazolam, blonanserin, lurasidone hydrochloride, vardenafil hydrochloride hydrate, methylergometrine maleate, ibrutinib” should be added to the 10.1 Contraindications for Co-administration (Do not co-administer with the following.) section in 10. INTERACTIONS.

b. to i., k. to v.:

1. “Ceritinib” should be added to 2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.).
2. “Ceritinib” should be added to the 10.1 Contraindications for Co-administration (Do not co-administer with the following.) section in 10. INTERACTIONS.

j.:

“Ceritinib” should be added to the 10.1 Contraindications for Co-administration (Do not co-administer with the following.) section in 10. INTERACTIONS.

Investigation results and background of the revision

The pharmacokinetic effects of the co-administration of ceritinib with CYP3A substrate drugs were evaluated. The strong inhibitory activity of ceritinib against CYP3A may lead to increased exposure to CYP3A substrate drugs, and the occurrence of adverse reactions may increase. As a result of consultation with expert advisors, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary. Of note, opinions regarding the impact of contraindicating co-administration of CYP3A substrate drugs and ceritinib on clinical settings were sought from relevant academic societies, and no specific major problems were confirmed.

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the “Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency” (PMDA Administrative Rule No. 20-8, dated December 25, 2008).



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Attachment

Number	Non-proprietary name	Brand name (Marketing authorization holder)	Date of Initial Marketing in Japan	Indications
a.	Ceritinib	Zykadia tablets 150 mg (Novartis Pharma K.K.)	November 2019	<i>Anaplastic lymphoma kinase (ALK)</i> -positive, unresectable, advanced or relapsed non-small cell lung cancer
b.	Azelnidipine	Calblock Tablets 8 mg, 16 mg (Daiichi Sankyo Co., Ltd.), and others	May 2003	Hypertension
c.	Olmesartan medoxomil/azelnidipine	Rezaltas Combination Tablets LD, HD (Daiichi Sankyo Co., Ltd.)	April 2010	Hypertension
d.	Anamorelin hydrochloride	Adlumiz Tablets 50 mg (Ono Pharmaceutical Co., Ltd.)	April 2021	Cancer cachexia in the following malignancies: Non-small cell lung cancer, gastric cancer, pancreatic cancer, and colorectal cancer
e.	Ivabradine hydrochloride	Coralan Tablets 2.5 mg, 5 mg, and 7.5 mg (Ono Pharmaceutical Co., Ltd.)	November 2019	Chronic heart failure with sinus rhythm and a resting heart rate of 75 bpm or greater at baseline



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				(for use only in patients receiving standard treatment of chronic heart failure, including β -blockers).
f.	Ibrutinib	Imbruvica Capsules 140 mg (Janssen Pharmaceutical K.K.)	May 2016	<ul style="list-style-type: none">○ Chronic lymphocytic leukemia (including small lymphocytic lymphoma)○ Primary macroglobulinemia and lymphoplasmacytic lymphoma○ Mantle cell lymphoma○ Chronic graft-versus-host disease after hematopoietic stem cell transplant (for patients who have an inadequate response to steroids)
g.	Eplerenone	Selara Tablets 25 mg, 50 mg, 100 mg (Viatris Pharmaceuticals Japan G.K.), and others	November 2007	<Selara Tablets 25 mg, 50 mg, 100 mg> Hypertension <Selara Tablets 25 mg, 50 mg> Patients with the following disease who are receiving basic treatment with angiotensin converting enzyme inhibitors



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				or angiotensin II receptor antagonists, β -blockers, diuretics, etc.: Chronic heart failure
h.	Ergotamine tartrate/anhydrous caffeine/isopropylantipyrine	Cleamine Combination Tablets A1.0, S0.5 (Nichi-Iko Pharmaceutical Co., Ltd.)	Combination Tablets A1.0: February 1979 Combination Tablets S0.5: July 1990	Vascular headache, migraine and tension headache
i.	Quinidine sulfate hydrate	Quinidine Sulfate Powder "VTRS", Quinidine Sulfate Tablets 100 mg "VTRS" (Viartis Pharmaceuticals Japan Inc.)	Powder: September 1956 Tablets 100 mg "VTRS": January 1973	Extrasystoles (supraventricular, ventricular), paroxysmal tachycardia (supraventricular, ventricular), new-onset atrial fibrillation, prophylaxis of atrial fibrillation paroxysmal, old atrial fibrillation, atrial flutter, maintenance of sinus rhythm during and after concomitant use with electric shock therapy, prophylaxis of ventricular arrhythmia when acute myocardial infarction occurs



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j.	Colchicine	Colchicine Tablets 0.5 mg "Takata" (TAKATA Pharmaceutical Co., Ltd.)	November 1964	○ Relief and prophylaxis of gout attacks ○ Familial mediterranean fever
k.	Simvastatin	Lipovas Tablets 5, 10, 20 (Organon K.K.), and others	Tablets 5: December 1991 Tablets 10, 20: June 2002	Hyperlipidemia, familial hypercholesterolemia
l.	Suvorexant	Belsomra Tablets 10 mg, 15 mg, 20 mg (MSD K.K.)	Tablets 10 mg: December 2016 Tablets 15 mg, 20 mg: November 2014	Insomnia
m.	Tadalafil (pulmonary arterial hypertension)	Adcirca Tablets 20 mg (Nippon Shinyaku Co., Ltd.), and others	December 2009	Pulmonary arterial hypertension
n.	Ticagrelor	Brilinta tablets 60 mg, 90 mg (AstraZeneca K.K.)	February 2017	< Brilinta tablets 90 mg > Acute coronary syndrome (unstable angina, non-ST-segment elevation myocardial infarction, and ST-segment elevation myocardial infarction) for which percutaneous coronary intervention (PCI)



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				<p>is indicated. (This is limited to patients for whom dual antiplatelet therapy including aspirin is appropriate and for whom it is difficult to administer other antiplatelet drugs in combination with aspirin.)</p> <p>< Brilinta tablets 60 mg ></p> <p>Old myocardial infarction at especially high risk of developing atherothrombosis with at least one of the following risk factors:</p> <p>Age of 65 years or older, diabetes mellitus requiring drug therapy, history of two or more episodes of myocardial infarction, angiography-confirmed multivessel coronary artery disease, or non-end-stage chronic renal dysfunction</p>
o.	Triazolam	Halcion Tablets 0.125 mg, 0.25 mg (Pfizer Japan Inc.), and others	Tablets 0.125 mg: July 1990	<ul style="list-style-type: none"><input type="radio"/> Insomnia<input type="radio"/> Preanesthesia



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			Tablets 0.25 mg: April 1983	
p.	Vardenafil hydrochloride hydrate	Vardenafil Tablets 5 mg "FCI", 10 mg "FCI", 20 mg "FCI" (Fuji Chemical Industries Co., Ltd.), and others	June 2004 (market launch of Levitra Tablets)	Erectile dysfunction (patients unable to obtain or maintain erections sufficient for satisfactory sexual activity)
q.	Finerenone	Kerendia tablets 10 mg, 20 mg (Bayer Yakuhin, Ltd.)	June 2022	○ Chronic kidney disease associated with type 2 diabetes mellitus (excluding patients who have end-stage renal failure or are undergoing dialysis) ○ Chronic heart failure (for use only in patients receiving standard treatment of chronic heart failure).
r.	Blonanserin	Lonasen Tablets 2 mg, 4 mg, 8 mg, Lonasen Powder 2%, Lonasen Tapes 20 mg, 30 mg, 40 mg (Sumitomo Pharma Co., Ltd.), and others	Tablets 2 mg, 4 mg, Powder 2%: April 2008 Tablets 8 mg: April 2010 Tapes 20 mg, 30 mg, 40 mg: September 2019	Schizophrenia



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s.	Macitentan/tadalafil	Yuvanci Combination Tablets (Janssen Pharmaceutical K.K.)	November 2024	Pulmonary arterial hypertension
t.	Methylergometrine maleate	Partan M Tablets 0.125 mg, Partan M Injection 0.2 mg (Mochida Pharmaceutical Co., Ltd.), Methylergometrine Tablets 0.125 mg "Aska", Methylergometrine Injection 0.2 mg "Aska" (Aska Pharmaceutical Co., Ltd.), and others	Partan M Tablets 0.125 mg: December 1994 Partan M Injection 0.2 mg: November 1994 Methylergometrine Tablets 0.125 mg "Aska", Methylergometrine Injection 0.2 mg "Aska": May 1971	<Tablets> This product is used to promote uterine contraction and to prevent and treat uterine bleeding in the following cases: After delivery of the placenta, uterine subinvolution, miscarriage or induced abortion. <Injection> This product is used to promote uterine contraction and to prevent and treat uterine bleeding in the following cases: Before and after delivery of the placenta, atonic hemorrhage, uterine subinvolution, cesarean section, miscarriage, or induced abortion.
u.	Lurasidone hydrochloride	Latuda Tablets 20 mg, 40 mg, 60 mg, 80 mg (Sumitomo Pharma Co., Ltd.)	June 2020	○ Schizophrenia

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				○ Improvement of depressive symptoms in patients with bipolar disorder.
v.	Lomitapide mesilate	Juxtapid Capsules 5 mg, 10 mg, 20 mg (Recordati Rare Diseases Japan K.K.)	December 2016	Homozygous familial hypercholesterolemia

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