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

This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Summary of Investigation Results

Venetoclax
Ceritinib

May 20, 2025

Non-proprietary name

a. Venetoclax

b. Ceritinib

Brand name (marketing authorization holder)

a. Venclexta Tablets 10 mg, 50 mg, 100 mg (AbbVie GK)

b. Zykadia tablets 150 mg (Novartis Pharma K.K.)

Japanese market launch

a. November 2019

b. November 2019

Indications

a.

• Relapsed or refractory chronic lymphocytic leukaemia (including small lymphocytic lymphoma)
• Relapsed or refractory mantle cell lymphoma
• Acute myeloid leukaemia

b. *Anaplastic lymphoma kinase (ALK)*-positive, unresectable, advanced or relapsed non-small cell lung cancer

Summary of revisions

a.

1. “Ceritinib” should be added to the “strong CYP3A inhibitor during the dose escalation phase” in 2. CONTRAINDICATIONS (This drug is contraindicated in 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.

b.

1. “Patients receiving the following drug: Venetoclax (relapsed or refractory chronic lymphocytic leukaemia (including small lymphocytic lymphoma) and relapsed or refractory mantle cell lymphoma during the dose escalation phase)” should be added to 2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.).
2. The 10.1 Contraindications for Co-administration (Do not co-administer with the following.) section should be newly added and “Venetoclax (relapsed or refractory chronic lymphocytic leukaemia (including small lymphocytic lymphoma) and relapsed or refractory mantle cell lymphoma during the dose escalation phase)” should be added.

Investigation results and background of the revision

Pharmacokinetic effects regarding the co-administration of venetoclax and ceritinib were evaluated. The strong inhibitory activity of ceritinib against CYP3A may lead to an increase in the exposure to venetoclax, and the occurrence of tumor lysis syndrome 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 impacts of contraindicating co-administration of venetoclax 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).