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

Ticagrelor

March 15, 2022

Non-proprietary name

Ticagrelor

Brand name (Marketing authorization holder)

Brilinta tablets 60 mg, 90 mg (AstraZeneca K.K.)

Indications

<Brilinta tablets 60 mg>

Old myocardial infarction at especially high risk of developing atherothrombosis with at least one of the following risk factors:

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.

<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) 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.)

Summary of revisions

“Bradyarrhythmia such as sinus arrest and an advanced type of atrioventricular” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of bradyarrhythmia have been reported in patients treated with ticagrelor in Japan and overseas. MHLW/PMDA, in consultation with expert advisors, concluded that revision of the package insert was necessary.

Number of cases and patient mortalities reported in Japan during the previous 3 fiscal years

A total of 3 cases involving bradyarrhythmia have been reported to date (including 1 case for which a causal relationship between the drug and event was reasonably possible).
No patient mortalities have been reported to date.

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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