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

Romosozumab (genetical recombination)

September 6, 2019

Non-proprietary name

Romosozumab (genetical recombination)

Branded name (Marketing authorization holder)

Evenity subcutaneous injection 105 mg syringe (Amgen Astellas BioPharma K.K.)

Indications

Osteoporosis at a higher risk of fracture

Summary of revisions

1. A statement should be added to the Warning section concerning proper patient selection required before this drug is administered based on adequate understanding of the benefit of reducing the risk of fracture and the onset risk of cardiovascular events.
2. Information for proper patient selection for the administration of this drug should be added to the Precautions concerning Indications section.
3. A statement should be added to the Important Precautions section that administration of this drug should not be initiated to patients with a history of cardiovascular events within the past year.

Investigation results and background of the revision

In the post-marketing experience in Japan, cases of cardiovascular events (ischaemic heart disease or cerebrovascular disorder) have been reported, some of which resulted in death. No cases have been identified in which a causal relationship between the drug and the cardiovascular events or the death subsequent to event could not be ruled out. However, considering the seriousness of the reported events and status of related overseas measures, MHLW/PMDA concluded that revision of the package insert was necessary

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based on the results of their investigation of the currently available evidence and in consultation with expert advisors.

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

A total of 36 cases involving ischaemic heart disease, cerebrovascular disorder, or death of unknown cause have been reported to date (A causal relationship between the drug and events could not be established for any of these cases).

A total of 7 patient mortalities have been reported to date (A causal relationship between the drug and events preceding the death could not be established in any of these cases.)

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