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

COVID-19 (SARS-CoV-2) vaccine (recombinant chimpanzee adenovirus vector)

October 12, 2023

Non-proprietary name

COVID-19 (SARS-CoV-2) vaccine (recombinant chimpanzee adenovirus vector)

Brand name (marketing authorization holder)

Vaxzevria Intramuscular Injection (AstraZeneca K.K.)

Japanese market launch

May 2021

Indications

Prevention of disease caused by SARS-CoV-2 infection (COVID-19)

Summary of revisions

1. A statement should be added to the IMPORTANT PRECAUTIONS section that since immune thrombocytopenia has been reported following inoculation with this vaccine, a platelet count test should be performed as necessary.
2. A statement should be added to the Persons to Be Vaccinated with Caution (Persons in whom the decision to vaccinate must be made with caution) section in PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS that the platelet count should preferably be monitored in persons with a history of immune thrombocytopenia.
3. “Immune thrombocytopenia” should be added to the Clinically Significant Adverse Reactions section in ADVERSE REACTIONS.

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Investigation results and background of the revision

Cases involving immune thrombocytopenia were evaluated. Cases for which a causal relationship between COVID-19 (SARS-CoV-2) vaccine (recombinant chimpanzee adenovirus vector) and immune thrombocytopenia was reasonably possible have been reported. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.

Reference: Number of cases* and patient mortalities involving immune thrombocytopenia reported in Japan and overseas

No cases have been reported in Japan to date.

A total of 578 cases‡ have been reported overseas† to date.

A total of 11 patient mortalities§ have been reported to date.

*: Cases collected in the PMDA's database for adverse drug reactions, etc. reports

†: Cases which were presented as the basis for a revision of Company Core Data Sheet (CCDS) by the marketing authorization holder (MAH)

‡: The 3 cases for which the drug was considered by the MAHs to be strongly associated with the event were evaluated. For all of them, it was determined that a causal relationship between the drug and event was reasonably possible.

§: The 3 evaluated cases did not include cases of deaths.

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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