



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

# Revision of Precautions

## Nivolumab (genetical recombination)

February 12, 2019

### **Non-proprietary name**

Nivolumab (genetical recombination)

### **Safety measure**

Precautions should be revised in the package insert.

The following language concerning immune thrombocytopenic purpura in the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section should be revised as follows (revised language is underlined):

#### Serious blood disorder:

Serious blood disorder such as immune thrombocytopenic purpura, haemolytic anaemia, and agranulocytosis may occur. Patients should be carefully monitored. If any abnormalities are observed, administration of this drug should be discontinued and appropriate measures should be taken.

The following language should be added to the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section (revised language is underlined):

#### Haemophagocytic syndrome:

Haemophagocytic syndrome may occur. Patients should be carefully monitored. If any abnormalities are observed, administration of this drug should be discontinued and appropriate measures should be taken.