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*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

## Tisagenlecleucel

February 25, 2021

### **Non-proprietary name**

Tisagenlecleucel

### **Safety measure**

Precautions should be revised in the package insert.

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Revised language is underlined.

Current	Revision
MALFUNCTION/ADVERSE REACTIONS Clinically Significant Adverse Reactions (N/A)	MALFUNCTION/ADVERSE REACTIONS Clinically Significant Adverse Reactions <u>Infusion reaction, anaphylaxis</u> <u>Infusion reaction or anaphylaxis may occur. Patients should be carefully monitored and appropriate measures should be taken if any abnormalities are observed.</u>

N/A: Not Applicable, because the section is not included in the current package insert.

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