

Summary of Investigation Results

Trastuzumab (genetical recombination) and other follow-on biologics

February 12, 2019

Non-proprietary name

Trastuzumab (genetical recombination) and other follow-on biologics

Branded name (Marketing authorization holder)

Herceptin Intravenous Infusion 60, 150 (Chugai Pharmaceutical Co., Ltd.), and other follow-on biologics (see the Attachment)

Indications

HER2-overexpressing breast cancer

HER2-overexpressing, advanced/recurrent gastric cancer not amenable to curable resection

Summary of revisions

“Tumour lysis syndrome” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of tumour lysis syndrome have been reported in patients treated with trastuzumab in Japan. MHLW/PMDA concluded that revision of the package insert was necessary based on the results of their investigation of the currently available evidence and in consultation with expert advisors.

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

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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.

A total of 3 cases involving tumour lysis syndrome have been reported to date (including 2 cases for which a causal relationship with the product could not be ruled out.)

One instance of patient mortality has been reported to date (a causal relationship with the product could not be established in this case.)

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Attachment

Non-proprietary name	Branded name	Marketing authorization holder
Trastuzumab (genetical recombination)	Herceptin Intravenous Infusion 60 Herceptin Intravenous Infusion 150	Chugai Pharmaceutical Co., Ltd.
Trastuzumab (genetical recombination) follow-on biologic 1	Trastuzumab BS for I.V. Infusion 60mg "CTH" Trastuzumab BS for I.V. Infusion 150mg "CTH"	Celltrion Inc.
	Trastuzumab BS for I.V. Infusion 60mg "NK" Trastuzumab BS for I.V. Infusion 150mg "NK"	Nippon Kayaku Co., Ltd.
Trastuzumab (genetical recombination) follow-on biologic 2	Trastuzumab BS for Intravenous Drip Infusions 60mg "Daiichi Sankyo" Trastuzumab BS for Intravenous Drip Infusions 150mg "Daiichi Sankyo"	Daiichi Sankyo Co., Ltd.
Trastuzumab (genetical recombination) follow-on biologic 3	Trastuzumab BS for Intravenous Infusion 60mg "Pfizer" Trastuzumab BS for Intravenous Infusion 150mg "Pfizer"	Pfizer Japan Inc.

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