



Summary of Investigation Results

Bevacizumab (genetical recombination)

including the biosimilars

June 16, 2020

Non-proprietary name

Bevacizumab (genetical recombination) including the biosimilars (See Attachment)

Branded name (Marketing authorization holder)

Avastin for Intravenous Infusion 100 mg/4 mL, 400 mg/16 mL (Chugai Pharmaceutical Co., Ltd), and the biosimilars

Indications

See Attachment

Summary of revisions

“Artery dissection” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of artery dissection have been reported in patients treated with bevacizumab in Japan. MHLW/PMDA in consultation with expert advisors concluded that revision of the package insert was necessary



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.

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

A total of 7 cases involving artery dissection have been reported to date (including 1 case for which a causal relationship between the drug and event was reasonably possible).

A totals of 2 patient mortalities have been reported to date (A causal relationship between the drug and the deaths subsequent to event could not be established for either of these cases.)

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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Attachment

Non-proprietary name	Brand name	Marketing authorization holder	Japanese market launch	Indications
Bevacizumab (genetical recombination)	Avastin for Intravenous Infusion 100 mg/4 mL, 400 mg/16 mL	Chugai Pharmaceutical Co., Ltd.	June 2007	Incurable, unresectable, advanced/recurrent colorectal cancer, unresectable, advanced/recurrent non-small cell lung cancer except for squamous cell carcinoma, ovarian cancer, advanced or recurrent cervical cancer, inoperable or recurrent breast cancer; malignant glioma
Bevacizumab (genetical recombination) [Bevacizumab biosimilar 1]	Bevacizumab BS Intravenous Infusion 100 mg [Pfizer] Bevacizumab BS Intravenous Infusion 400 mg [Pfizer]	Pfizer Japan Inc.	December 2019	Incurable, unresectable, advanced/recurrent colorectal cancer
Bevacizumab (genetical recombination)	Bevacizumab BS Intravenous Drip Infusions 100 mg	Daiichi Sankyo Co., Ltd.	December 2019	Incurable, unresectable, advanced/recurrent



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Non-proprietary name	Brand name	Marketing authorization holder	Japanese market launch	Indications
[Bevacizumab biosimilar 2]	“Daiichi Sankyo” Bevacizumab BS Intravenous Drip Infusions 400 mg “Daiichi Sankyo”			colorectal cancer

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