August 25, 2026
Pharmaceuticals and Medical Devices Agency, Japan

Summary of Investigation Results

Anti-PD-L1 antibody drugs and anti-CTLA-4 antibody drugs *1

Non-proprietary name Brand name	Non-proprietary name	Brand name (marketing authorization holder)
	a. Avelumab (genetical recombination) b. Atezolizumab (genetical recombination) c. Durvalumab (genetical recombination) d. Tremelimumab (genetical recombination)	a. Bavencio intravenous infusion 200 mg (Merck Biopharma Co., Ltd) b. Tecentriq for Intravenous Infusion 840 mg, 1200 mg (Chugai Pharmaceutical Co., Ltd.) c. Imfinzi Injection 120 mg, 500 mg (AstraZeneca K.K.) d. Imjudo Injection 25 mg, 300 mg (AstraZeneca K.K.)
Japanese market launch	See Attachment.	
Indications	See Attachment.	
Summary of revisions	1. A cautionary statement regarding uveitis should be added to the 8. IMPORTANT PRECAUTIONS section. 2. "Uveitis" should be added to the 11.1 Clinically Significant Adverse Reactions section in 11. ADVERSE REACTIONS.	
Investigation results and background of the revision	Cases involving uveitis were evaluated. Cases in which a causal relationship between anti-PD-L1 antibody drugs and anti-CTLA-4 antibody drugs and uveitis 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*2 involving uveitis*3 reported in Japan	a. A total of 0 cases have been reported to date No deaths have been reported to date. b. A total of 5 cases have been reported to date (including 3 cases in which a causal relationship between the drug and the event was reasonably possible). No deaths have been reported to date. c. A total of 2 cases have been reported to date (including 1 case in which a causal relationship between the drug and the event was reasonably possible). No deaths have been reported to date.	

	d. A total of 1 case has been reported to date (including 1 case in which a causal relationship between the drug and the event was reasonably possible). No deaths have been reported to date.

*1: Anti-PD-L1 antibody drugs and anti-CTLA-4 antibody drugs, excluding ipilimumab (genetical recombination)
*2: Cases collected in PMDA's safety database for drugs.
*3: Among cases that fell under MedDRA ver. 28.1 PTs "Chorioretinitis," "Choroiditis," "Iridocyclitis," "Iritis," "Uveitis," "Anterior chamber inflammation," "Chorioretinopathy," "Keratouveitis," "Noninfective chorioretinitis," "Autoimmune uveitis," "Serpiginous choroiditis," "Immune-mediated uveitis," "Vogt-Koyanagi-Harada disease," and "Birdshot chorioretinopathy," cases assessed as Grade 3 or higher according to CTCAE ver. 6.0 were retrieved.

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).

Attachment

Brand name(Marketing authorization holder)	Japanese market launch	Indications
a. Bavencio intravenous infusion 200 mg (Merck Biopharma Co., Ltd)	November 2017	○ Radically unresectable Merkel cell carcinoma ○ Radically unresectable or metastatic renal cell carcinoma ○ Maintenance treatment of radically unresectable urothelial carcinoma following chemotherapy
b. Tecentriq for Intravenous Infusion 1200 mg Tecentriq for Intravenous Infusion 840 mg (Chugai Pharmaceutical Co., Ltd.)	April 2018 November 2019	< Common to both preparations > ○ Unresectable, advanced or recurrent non-small cell lung cancer ○ Postoperative adjuvant treatment for PD-L1 positive non-small cell lung cancer ○ Extensive stage small cell lung cancer ○ Unresectable alveolar soft part sarcoma ○ Recurrent or refractory extranodal NK/T-cell lymphoma/nasal type < Tecentriq for Intravenous Infusion 1200 mg > ○ Unresectable hepatocellular carcinoma ○ Unresectable thymic carcinoma < Tecentriq for Intravenous Infusion 840 mg > ○ PD-L1 positive, hormone receptor negative and HER2 negative inoperable or recurrent breast cancer
c. Imfinzi Injection 120 mg, 500 mg (AstraZeneca K.K.)	August 2018	○ Maintenance treatment of locally-advanced, unresectable non-small cell lung cancer following definitive chemoradiotherapy ○ Unresectable, advanced or recurrent non-small cell lung cancer ○ Preoperative and postoperative adjuvant treatment for non-small cell lung cancer ○ Extensive stage small cell lung cancer ○ Maintenance treatment of limited-stage small cell lung cancer following definitive chemoradiation therapy ○ Unresectable hepatocellular carcinoma ○ Unresectable biliary tract cancer ○ Advanced or recurrent endometrial cancer ○ Preoperative and postoperative adjuvant treatment for bladder cancer ○ High-risk non-muscle-invasive bladder cancer ○ Preoperative and postoperative adjuvant treatment for gastric cancer
d. Imjudo Injection 25 mg, 300 mg (AstraZeneca K.K.)	March 2023	< Imjudo Injection 25 mg > ○ Unresectable, advanced or recurrent non-small cell lung cancer ○ Unresectable hepatocellular carcinoma < Imjudo Injection 300 mg > ○ Unresectable hepatocellular carcinoma