July 14, 2026
Pharmaceuticals and Medical Devices Agency, Japan

Summary of Investigation Results
Guselkumab (genetical recombination)

Non-proprietary name Brand name	Non-proprietary name	Brand name (marketing authorization holder)
	Guselkumab (genetical recombination)	Tremfya Subcutaneous Injection 100 mg Syringe, 200 mg Syringe, Tremfya Subcutaneous Injection 200 mg Pen, Tremfya Intravenous Infusion 200 mg (Janssen Pharmaceutical K.K.)
Japanese market launch	Tremfya Subcutaneous Injection 100 mg Syringe: May 2018 Tremfya Subcutaneous Injection 200 mg Syringe, Tremfya Subcutaneous Injection 200 mg Pen, Tremfya Intravenous Infusion 200 mg: May 2025	
Indications	< Tremfya Subcutaneous Injection 100 mg Syringe > ○ The following diseases (for use only in patients who have not sufficiently responded to conventional treatments): Plaque psoriasis, psoriatic arthritis, pustular psoriasis, erythrodermic psoriasis, and palmoplantar pustulosis ○ Remission induction therapy and maintenance therapy for moderate to severe ulcerative colitis (for use only in patients who have not sufficiently responded to conventional treatments) ○ Treatment of moderate to severe active Crohn's disease (for use only in patients who have not sufficiently responded to conventional treatments). < Tremfya Subcutaneous Injection 200 mg Syringe, Tremfya Subcutaneous Injection 200 mg Pen > ○ Remission induction therapy and maintenance therapy for moderate to severe ulcerative colitis (for use only in patients who have not sufficiently responded to conventional treatments) ○ Treatment of moderate to severe active Crohn's disease (for use only in patients who have not sufficiently responded to conventional treatments). < Tremfya Intravenous Infusion 200 mg > ○ Remission induction therapy for moderate to severe ulcerative colitis (for use only in patients who have not sufficiently responded to conventional treatments) ○ Treatment of moderate to severe active Crohn's disease (for use only in patients who have not sufficiently responded to conventional treatments).	
Summary of revisions	1. Precautions for hepatic impairment including autoimmune hepatitis should be added to the 8. IMPORTANT PRECAUTIONS section. 2. “Hepatic impairment” should be added to the 11.1 Clinically Significant	

	Adverse Reactions section in the 11. ADVERSE REACTIONS.
Investigation results and background of the revision	Cases involving hepatic impairment were evaluated. Cases in which a causal relationship between guselkumab (genetical recombination) and hepatic impairment including autoimmune hepatitis 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* involving hepatic impairment reported in Japan	A total of 19 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.

*: Among cases collected in the PMDA's safety database for drugs, cases that fell under MedDRA ver. 28.1 SMQ (narrow) “Drug related hepatic disorders - comprehensive search” 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).