

Summary of Investigation Results Selpercatinib

Non-proprietary name Brand name	Non-proprietary name	Brand name (marketing authorization holder)
	Selpercatinib	Retevmo Tablets 40 mg, 80 mg, Retevmo Capsules 40 mg, 80 mg (Eli Lilly Japan K.K.)
Japanese market launch	December 2021 (Capsules) December 2025 (Tablets)	
Indications	○RET fusion-positive advanced or recurrent solid tumours ○RET mutation-positive unresectable medullary thyroid carcinoma	
Summary of revisions	“Oculomucocutaneous syndrome (Stevens-Johnson syndrome)” 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 oculomucocutaneous syndrome (Stevens-Johnson syndrome) were evaluated. As cases in which a causal relationship between selpercatinib and oculomucocutaneous syndrome (Stevens-Johnson syndrome) was reasonably possible have been reported, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary	
Reference: Number of cases* involving oculomucocutaneous syndrome reported in Japan and overseas	Japan	Overseas
	A total of 3 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.	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.

*: Cases collected in PMDA's safety database for drugs.

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).