

Summary of Investigation Results

Apremilast

Non-proprietary name Brand name	Non-proprietary name	Brand name (marketing authorization holder)
	Apremilast	Otezla Tablets 10mg, 20mg, 30mg (Amgen K.K.)
Japanese market launch	March 2017	
Indications	○Plaque psoriasis inadequately controlled with topical therapy ○Psoriatic arthritis ○Palmoplantar pustulosis inadequately controlled with topical therapy ○Oral ulcers associated with Behçet's disease inadequately controlled with topical therapy	
Summary of revisions	1. A cautionary statement regarding “Hepatic impairment” 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 11. ADVERSE REACTIONS.	
Investigation results and background of the revision	Cases involving hepatic impairment were evaluated. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of PRECAUTIONS, MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.	
Reference: Number of cases* involving Hepatic impairment reported in Japan	A total of 11 cases have been reported to date (including 5 cases in which a causal relationship between the drug and the event was reasonably possible). No deaths have been reported to date.	

*: Among cases that fell under the MedDRA ver. 28.1 SMQ "Drug related hepatic disorders - comprehensive search (broad)", cases with AST and/or ALT elevations 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).