



# Summary of Investigation Results

## Apremilast

August 2, 2018

### **Non-proprietary name**

Apremilast

### **Branded name (Marketing authorization holder)**

Otezla Tablets 10 mg, 20 mg, 30 mg (Celgene K.K.)

### **Indications**

Psoriasis vulgaris in patients who were not sufficiently responsive to topical therapies

Psoriatic arthritis

### **Summary of revisions**

“Severe diarrhoea” should be added to the Clinically Significant Adverse Reactions section.

### **Investigation results and background of the revision**

Cases of severe diarrhoea have been reported in patients treated with apremilast overseas while no such cases have been reported in patients treated with the drug in Japan. Taking account of the relevant language concerning severe diarrhoea in the US and EU package inserts as well, MHLW/PMDA concluded that revision of the package insert was necessary based on the results of their investigation of the currently available evidence and in consultation with expert advisors.

### **Number of adverse reactions and patient mortalities reported in Japan during the previous 3 fiscal years**

No cases involving severe diarrhoea have been reported to date.