



# Summary of Investigation Results

## Baloxavir marboxil

March 31, 2020

### **Non-proprietary name**

Baloxavir marboxil

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

Xofluza Tablets 10 mg, 20 mg, Xofluza granule 2% portions (Shionogi & Co., Ltd.)

### **Indications**

Influenza A or B viral infections

### **Summary of revisions**

“Ischaemic colitis” should be added to the Clinically Significant Adverse Reactions section.

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

Cases of ischaemic colitis have been reported in patients treated with baloxavir marboxil in Japan. MHLW/PMDA in consultation with expert advisors concluded that revision of the package insert was necessary.



*This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.*

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

A total of 13 cases involving ischaemic colitis have been reported to date (including 8 cases for which a causal relationship between the drug and event could not be ruled out).

No patient mortalities have been reported to date.

(Japanese market launch: March 2018 for Xofluza Tablets 10 mg, 20 mg; Xofluza granule 2% portions unreleased)

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).