



# Summary of Investigation Results

## Quetiapine fumarate

March 19, 2019

### Non-proprietary name

Quetiapine fumarate

### Branded name (Marketing authorization holder)

- a. Seroquel 25 mg Tablets, 100 mg Tablets, 200 mg Tablets, Seroquel Fine Granules 50% (Astellas Pharma Inc.), and the others
- b. Bipresso Extended Release Tablets 50 mg, 150 mg (Astellas Pharma Inc.)

### Indications

- a. Schizophrenia
- b. Improvement of depressive symptoms in patients with bipolar disorder

### Summary of revisions

“Toxic epidermal necrolysis (TEN), oculomucocutaneous syndrome (Stevens-Johnson syndrome), erythema multiforme” should be added to the Clinically Significant Adverse Reactions section.

### Investigation results and background of the revision

Cases of toxic epidermal necrolysis, oculomucocutaneous syndrome, and erythema multiforme have been reported in patients treated with quetiapine fumarate in Japan and overseas. 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.



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

1 case involving toxic epidermal necrolysis has been reported to date (a causal relationship with the product could not be ruled out in this case.) No patient mortalities have been reported to date.

1 case involving oculomucocutaneous syndrome has been reported to date (a causal relationship with the product could not be established in this case.) No patient mortalities have been reported to date.

1 case involving erythema multiforme has been reported to date (a causal relationship with the product could not be established in this case.) No patient mortalities have been reported to date.