



# Summary of Investigation Results

## Hydroxychloroquine sulfate

September 8, 2020

### **Non-proprietary name**

Hydroxychloroquine sulfate

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

Plaquenil 200 mg Tablets (Sanofi K.K.)

### **Indications**

Cutaneous lupus erythematosus, systemic lupus erythematosus

### **Summary of revisions**

“Prolonged QT, ventricular tachycardia (including torsades de pointes)” should be added to the Clinically Significant Adverse Reactions section.

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

Cases of prolonged QT, ventricular tachycardia (including torsades de pointes) have been reported in patients treated with hydroxychloroquine sulfate overseas. MHLW/PMDA in consultation with expert advisors concluded that revision of the package insert was necessary.

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

A total of 4 cases have been reported to date (A causal relationship between the drug and event could not be established for any of these cases.)

1 instance of patient mortality has been reported to date (A causal relationship between the drug and the death subsequent to event could not be established for this case.)



## Pharmaceuticals and Medical Devices Agency

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*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.*

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).

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