Sanofi: Important Information on Plaquenil® and COVID-19

Hong Kong, 16 April 2020 – There has been increased media coverage around the off-label use of hydroxychloroquine in the management of COVID-19 based on preliminary results from independent studies from different countries. The situation is raising many questions from our different stakeholders.

Patient safety is the priority

To date there is insufficient clinical evidence to draw any conclusions over the clinical efficacy or safety of hydroxychloroquine (or chloroquine) in the management of COVID-19. The preliminary results from different independent studies require further analysis and more robust and larger clinical studies to assess the patient benefit/risk profile of Plaquenil® in COVID-19.

Today, in Hong Kong, Plaquenil® (hydroxychloroquine) is registered in Hong Kong.

Any use of this medicine in the management of COVID-19 is an off-label use (i.e. in absence of a marketing authorization for the indication of COVID-19 even when national guidance/recommendations have been issued).

Ensure supply continuity

One of our top priorities is to ensure supply continuity for use of Plaquenil® in the current indications.

Sanofi is working with local health authorities and scientific experts in different countries impacted by the outbreak in order to investigate the patient benefit/risk profile of Plaquenil® (hydroxychloroquine) in the treatment of COVID-19 and, if requested by the local governments and / or health authorities, to provide the product to the extent that it can.

For medical information or questions: Please contact the Sanofi Hong Kong Medical Information at Medinfo.HK@sanofi.com

For pharmacovigilance reporting: Please contact Sanofi Hong Kong Pharmacovigilance at pv.hk@sanofi.com.

IMPORTANT SAFETY REMINDER ABOUT PLAQUENIL®

The main side effects of hydroxychloroquine are described in the product information. At the recommended daily dose for approved indications, ranging from 200 to 400 mg (without exceeding 6.5mg/kg/day based on ideal body weight) daily in adults and paediatric population, the most serious side effects of hydroxychloroquine are eye disorders following long term use, including retinopathy, with changes in pigmentation and visual field defects and severe hypoglycemia including loss of consciousness (in patients treated with and without antidiabetic medications). Cardiotoxic effects are rare but serious complications of hydroxychloroquine, which include acute cardiac conduction disorders (QT prolongation, ventricular arrhythmia) have also been

observed. Neurological, hepatic, severe skin disorders, allergic reactions have also been described.

Hydroxychloroquine should be used with caution in patients receiving drugs known to prolong the QT interval such as halofantrine and other arrhythmogenic drugs, e.g. amiodarone and moxifloxacin, due to an increased risk of ventricular arrhythmia.

The risk and severity of side-effects may increase with a higher posology (dosage) of hydroxychloroquine.

Healthcare professionals should consult the current Summary of Product Characteristics for the most up to date safety information. Patients taking hydroxychloroquine-containing medicines, like any other medicines, should follow the instructions provided in the Patient Information Leaflet.

Patients must not take Plaquenil® without medical prescription or advice. They should always consult with their healthcare professionals.

Sanofi is asking local Health Authorities to communicate a clear position regarding current lack of robust clinical data for the use of Plaquenil®, in the management of COVID-19, emphasizing that such use will be off-label, and to communicate the known serious adverse reactions associated with Plaquenil®, namely the contraindications in patients with known hypersensitivity to 4-aminoquinoline compounds; with pre-existing maculopathy of the eye; children with an ideal body weight <31 kg and the risk of retinal toxicity, hypoglycemia and cardiac toxicity as well as the known risk of interactions.

Sanofi also requests that all off-label use is communicated to the Sanofi affiliate pharmacovigilance team at pv.hk@sanofi.com, including adverse event, off label, overdose and other PV data.