SANOFI

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Sponsor: Sanofi Pasteur **Drug substance(s):** Live attenuated stabilized yellow fever vaccine	**Study Identifiers:** NCT03541694 **Study code:** STA10

Title of the study: Passive Enhanced Safety Surveillance of the Live Attenuated Yellow Fever Virus Vaccine Stamaril® in Korea

Study center(s): Single center in the Republic of Korea

Study period:

Date first subject enrolled: 11/Apr/2018

Date last subject completed: 30/May/2018

Phase of development: Not applicable (observational study)

Objectives: The primary objective of this surveillance study was to collect all adverse event following immunizations (AEFIs) after vaccination with Stamaril, in order to estimate the incidence rate of suspected adverse reactions (AR). Moreover, the secondary objective was to collect all AEFIs after vaccination with Stamaril, in order to estimate the incidence rate of suspected serious adverse reaction (SAR).

Methodology:

This was a single-center, prospective, passive Enhanced Safety Surveillance (ESS), approved by Ministry of Food and Drug Safety (MFDS). Principle of passive ESS is to rapidly estimate vaccine usage (or number of vaccinated subjects) and to stimulate passive AR reporting, in order to derive reporting rate (i.e. number of reporting AR/number of vaccinated subjects). Passive ESS relies on routine pharmacovigilance (PV) and estimation of number of vaccinated individuals during the Surveillance period.

Spontaneous PV AR reporting was stimulated through:

- Informing vaccinated subjects through trained Health Care Professionals (HCPs) on the importance of reporting AR following vaccination;
- Distributing Safety Report Cards (SRCs) to allow the vaccinated subjects to report ARs;
- Sending text message or e-mail notice encouraging voluntary reporting of ARs, 7 days after vaccination,

Number of subjects: Planned: 600

Vaccinated: 622

Evaluated:

Safety: 622

Diagnosis and criteria for inclusion:

Subjects who have been vaccinated against yellow fever with Stamaril vaccine in National Medical Center, Korea during the enhanced surveillance period.

Study treatments **Investigational medicinal product(s):** Stamaril yellow fever vaccine Formulation: Live attenuated stabilized yellow fever vaccine Route(s) of administration: Subcutaneous or intramuscular injection Dose regimen: Single dose of 0.5 ml of the reconstituted vaccine
Administration schedule: 1 injection **Duration of observation:** from April 11, 2018 to June 29, 2018
Criteria for evaluation: **Safety**: The primary and secondary endpoints of this surveillance study were the spontaneous reporting rates of suspected ARs and SARs, respectively, after vaccination with Stamaril.
Statistical methods: All analyses were descriptive
Summary: **Population characteristics:** Vaccination with Stamaril was completed for a total of 622 subjects by an investigator, from April 11, 2018 to June 29, 2018. **Safety results:** Summary of suspected ARs collected during the Passive ESS period A total of 47 AEFIs were reported, of which 1 was SAR and 46 were non-serious ARs SARs 1 suspected SAR was reported, which was 'Kidney dysfunction' and was an expected AR. Unexpected ARs A total of 14 suspected unexpected ARs were reported and 33 were suspected expected adverse reactions. The most frequently reported unexpected AR was 'Dizziness' (2 cases) Non-serious ARs A total of 46 suspected non-serious ARs were reported. The most frequently reported ARs were 'Myalgia' (8 cases), 'Headache' (7 cases), and 'Fever (4 cases).
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