ACIP Presentation

June 22, 2017

Yellow Fever Vaccine: Update on Implementation of IND Protocol and Vaccine Distribution

David Greenberg, MD

Associate Vice President and Regional Medical Head, North America
Sanofi Pasteur

SANOFI PASTEUR

YF-VAX® Supply Update

- To improve supply of yellow fever vaccine in the U.S., Sanofi Pasteur is transitioning manufacturing of YF-VAX to a new state-of-the-art facility by mid-2018
- Manufacturing issues resulted in a gap in YF-VAX vaccine supply from the time of the shutdown of the old facility to operation of the new facility
- Ordering restrictions have stretched the remaining supply of YF-VAX vaccine
- We expect to exhaust our supply of YF-VAX in early July 2017

Stakeholder Coordination

- Our focus has been to provide a continuous supply of yellow fever vaccine in the U.S. for travelers, government employees, military, and other response groups
- To this end, we have held stakeholder discussions for over a year with CDC, FDA, DoD, and others to manage the remaining supply of YF-VAX vaccine and to import an alternative yellow fever vaccine

Importation of Stamaril Vaccine

- Sanofi Pasteur worked closely with the FDA to import Stamaril vaccine under IND and distribute it in the U.S. in an Expanded Access Program (EAP)
- EAP protocol allows product to be used at authorized facilities in a restricted format
- Beginning May 23, 2017, Sanofi Pasteur began supplying Stamaril vaccine to EAP-certified clinics to maintain supply of yellow fever vaccine in the U.S.

Stamaril Vaccine Product Profile

- Yellow Fever vaccine manufactured by Sanofi Pasteur in France
- Yellow fever virus 17D-204 strain (live, attenuated)
  - **Same strain as in YF-VAX vaccine**
- Used globally in more than 70 countries
- Licensed for more than 30 years
- More than 430 million doses have been distributed globally
- Supplied as a vial of lyophilized powder and syringe prefilled with diluent

MMWR Publication of the Yellow Fever Vaccine Shortage and Remediation Plans

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Early Release / Vol. 66
April 28, 2017

Addressing a Yellow Fever Vaccine Shortage — United States, 2016–2017

Mark D. Gershman, MD[1]; Kristina M. Angelo, DO[1]; Julian Ritchey, MBA[2]; David P. Greenberg, MD[2]; Riyadh D. Muhammad, MD[2]; Gary Brunette, MD[1]; Martin S. Cetron, MD[1]; Mark J. Sotir, PhD[1]

Collaborative effort of CDC and Sanofi Pasteur to inform HCPs and the public about our plans to import Stamaril vaccine by mid-2017

Stamaril Vaccine EAP Implementation

- Sanofi Pasteur is in the process of enrolling ~250 clinical sites to administer Stamaril vaccine under the EAP

  Volume
  - Sites that ordered at least 250 doses of yellow fever vaccine in 2016
  - Multisite clinical organizations with an aggregate of at least 250 yellow fever vaccine doses ordered in 2016 were offered a single site each

  Geography
  - Smaller-volume sites were added for access in all 50 states, the District of Columbia, Guam, Puerto Rico, and the U.S. Virgin Islands

- Site personnel are required to undergo training and follow the EAP protocol to obtain informed consent, track vaccine use, and monitor safety

- HCPs of yellow fever vaccine have been notified to direct their patients to Stamaril vaccine sites at the following CDC website:
  - **wwwnc.cdc.gov/travel/page/search-for-stamaril-clinics**

Stamaril Site Onboarding Status as of June 20, 2016

Site Status	Number of Sites
Confirmed interest in participation	250
Signed protocol agreement	207
Waiting for site management or local IRB approval	43
Signed agreement and trained	199
Approved by IRB	175*
Ordered Stamaril vaccine	128 (13,000 doses)
Declined	17

* Additional sites undergoing review/approval by central IRB and local IRBs

Key Takeaways

- Sanofi Pasteur expects to be out of stock of YF-VAX vaccine in early July
- Stamaril vaccine is being distributed in the U.S. under IND using an Expanded Access Program approved by the FDA
- We plan on enrolling ~250 sites to administer Stamaril vaccine
- As of June 21, 250 sites have confirmed their interest, 199 have completed training, and 128 have Stamaril on site
- CDC website listing the Stamaril sites: **https://wwwnc.cdc.gov/travel/page/search-for-stamaril-clinics**
- Stamaril vaccine will be supplied to the designated sites until the new YF-VAX production facility is online mid-2018