Vaccines and Related Biological Products Advisory Committee Meeting
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Development of Chikungunya Vaccines: Approaches to Demonstrating Effectiveness

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Background

Chikungunya (CHIK)

- CHIK is an emerging viral disease of increasing concern that can cause significant long-term sequelae (chronic arthritis) in infected individuals.

- The disease mostly occurs in Africa, Asia and the Indian subcontinent. However, a major outbreak in 2014-2015 affected several countries of the Americas.

- Increased scope and frequency of CHIK outbreaks with high attack rates may allow for field efficacy trials of CHIK vaccines; however, the outbreaks are irregular and unpredictable, and therefore feasibility of such trials is uncertain.

- The VRBPAC will be asked to discuss various approaches to demonstrating effectiveness of CHIK vaccines and to identify the gaps in information needed to support these approaches.

Overview of Today's Agenda

- **Introduction**
  - Bharat Khurana, DVM, PhD, MBA (FDA/CBER/OVRR)
- **Epidemiology of Chikungunya**
  - Ann Powers, PhD (CDC)
- **Animal Models for Chikungunya**
  - Pierre Roques, PhD (François Jacob Institute of Biology)
- **Evidence of Ongoing CHIKV Transmission in Southern Thailand**
  - MAJ Damon W. Ellison, PhD (DOD)
- **Comments from Manufacturers**
  - ModernaTX Inc
  - Themis Bioscience GmbH
  - Emergent formerly PaxVax Inc
  - Valneva Austria GmbH

Overview of Today's Agenda (continued)

- **Open Public Hearing**
- **Passive Transfer Studies to Determine Correlates of Protective Immunity Against Chikungunya Fever**
  - Scott Weaver, Ph.D. (University of Texas Medical Branch)
- **Approaches to Assessing Effectiveness of Chikungunya Vaccines**
  - Sudhakar Agnihothram, Ph.D. (DVRPA/CBER/FDA)
- **Committee Discussion and Recommendations**

Topics for VRBPAC Discussion

1. **Discuss the following aspects of clinical studies to assess effectiveness of CHIK vaccines:**

   – Feasibility of randomized, controlled clinical disease endpoint efficacy trials

   – Role of sero-epidemiologic data in identifying an immune marker reasonably likely to predict vaccine effectiveness

Topics for VRBPAC Discussion

2. **Discuss the utility of the non-human primate (NHP) challenge model to assess effectiveness of CHIK vaccines, including:**

   - Effectiveness endpoints, such as viremia, arthritis-related endpoints, or other essential endpoints

   - Role of passively transferred sera or purified IgG from vaccinated humans in identifying an immune marker reasonably likely to predict vaccine effectiveness

   - Whether additional information is needed to support the utility of the NHP challenge model?

Thank you!