Work Group interpretation of data for virus-like particle chikungunya vaccine

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Vaccine effectiveness (immunogenicity) data availability

- No vaccine effectiveness data
- Short-term* immunogenicity data available from ~2,750 vaccinated subjects in two Phase 3 studies
  - Majority adults aged 18–64 years (~2350 subjects)
  - Smaller numbers of adolescents aged 12–17 years and older adults aged ≥65 years (~200 subjects in each group)

*Seroresponse rates at 21 days after vaccination

Key immunogenicity results

- Robust response to vaccination with seroresponse rates* at **21 days** after vaccination of 98% in adolescents/younger adults vs. 87% in older adults
- Relatively good seroresponse rates maintained at **6 months** after vaccination with rates in younger and older age groups of 86% vs. 76%
- No longer-term (>6 months) data available from Phase 3 studies so need for booster dose unknown

*Percent of subjects with anti-chikungunya virus 80% serum neutralizing antibody titer ≥100

Safety data availability

- Safety data available from ~3,000 vaccinated subjects in two Phase 3 studies
  - Majority adults aged 18–64 years (~2,580 subjects)
  - Smaller numbers of adolescents aged 12–17 years and older adults aged ≥65 years (~210 subjects in each group)

Key safety results in adolescents and adults aged 12–64 years

- Solicited adverse events within 8 days of vaccination
  - Local: 24%; severe in 0.2%; mostly injection site pain
  - Systemic: 32%; severe in 1.5%; fatigue, headache, and myalgia in 18%–20%
- New onset or worsening arthralgia requiring medical attention in 0.2%
- One serious adverse event (i.e., retinal detachment) assessed as related by investigator but unrelated by safety monitoring committee chair
- All rates lower in older adults aged ≥65 years

Work Group summary for chikungunya virus-like particle vaccine

- Will provide option, in addition to the licensed live attenuated vaccine, for vaccination of adults aged ≥18 years
- Will provide option for adolescents aged 12–17 years
- Immunogenic vaccine but no vaccine effectiveness data which will be gathered post-licensure, and need for booster dose currently unknown
- No apparent safety concerns but safety data only from ~3,000 people so insufficient to detect rare events, and post-marketing surveillance important
- Work Group to conduct comprehensive data review and present GRADE assessment as part of Evidence to Recommendations framework at future meeting

Chikungunya Vaccines Work Group plans

Anticipated votes on vaccine recommendations, 2025

Population	Live attenuated vaccine	Virus-like particle vaccine
Travelers	≥18 years completed YES*	YES†
Laboratory workers	Completed	YES
Residents of U.S. territories with transmission risk	YES	YES
Residents of U.S. states with transmission risk	YES	YES

*12–17 years

†≥12 years

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.