



Work Group Interpretation and Next Steps

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WG Interpretation of MERCK Data

- Encouraging evidence for effectiveness in prevention of EVD when administered in an outbreak setting using a ring-vaccination strategy
- Acceptable safety profile
- Arthritis was an adverse event in a subset of study participants (Europe, U.S.)
- No known immune correlate for protection
- EBOV-GP specific IgG antibodies can persist in vaccinees up to 24 months

Vaccine Safety Discussion Points

- **Virus dissemination and replication (skin, joints) can occur and persist for up to 2-3 weeks after vaccination**
 - Seeding of rVSV-ZEBOV into joints as demonstrated by detection of rVSV DNA in synovial fluid
 - Replicating rVSV-ZEBOV recovered from skin vesicles (culture)
- **Pathophysiology of chimeric rVSV-ZEBOV vaccine may include features attributable to both its VSV and ZEBOV glycoprotein components; may play a role in the development of arthralgia/arthritis**

Anticipated Next Steps

- GRADE and Evidence to Recommendations Framework
- Presentation of policy options
- Vote on policy options, pending vaccine licensure, February 2020
 - Potential for an emergency meeting in the event the vaccine is not licensed by February 2020

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