Expanded Access

MSF rVSV Contingency Plan

Geneva, 26th April 2017
Compassionate use or rVSV during EVD flare-ups in Guinée forestière, February–April 2016

1 day
Index case confirmed on 17/03/2016

2 days
Report to WHO & to Ring Trial coordination

1 day
Study protocol approval NRA & Ethics Committee

1 day
Organization of 4 teams including 4 people Logistics, cold chain preparations

1 day
TRANSPORT to Forest area by air and road

WFP support

2 days

11 days

13 EVD cases in total, of which 10 confirmed (included 3 in Liberia)

4 rings
1510 persons eligible were vaccinated (6 years of age and older)

No cases reported among vaccinees 10 or more days after vaccination

Note: Similar activities were done Sierra Leone (end of 2015,) and in Liberia in (November 2015 and April 2016).

Source= WHO, April 2017, partially supported by Gavi
Pre- Licensure access to rVSV ZEBO

• rVSV is an investigational product
• No Emergency Use Assessment and Listing (EUAL) or licensure has been obtained yet
• The investigational product can only be exported & used in the framework of a study protocol (Expanded Use)

Study Protocol & Contingency Plan

Phase 3b trial: “Open-label, non-randomized, single arm study of one dose of rVSV vaccine to prevent EVD when implemented in a ring vaccination strategy”
MSF rVSV Contingency Plan

Countries where MSF is present and willing to intervene

| Sierra Leona | Guinea | DRC | Liberia |
| Mali         | Gabon  | Guinea Bissau | Senegal |
| Niger        | Nigeria | Sud Sudan | Ivory Coast |
| Uganda       |        |              |         |

Limiting the MSF interventions to:

a) countries with **no contingency plan** for expanded use or **limited resources** to assume the coordination and costs of such intervention

b) during the estimated **period of 9 to 12 months** until the registration for emergency use of this vaccine.
Rebecca Grais – Sponsor representative
GCP – Research Implementation Mobile Team
• Coordination
• Clinical research ref
• Support lab and vaccine aspects
• Support
• Support & review

SPONSOR:
Micaela Serafini, MSF-Geneva

HEADQUARTERS 5 SECTIONS:
Medical/Operational Directors
Focal point
Desk
Technical referents

FIELD:
Head of Mission
Medical Coordination
...

Country Representatives
National ERB/Regulations
Preparation – Protocols and SOPs

• Primary objective:
  – **Incidence** of laboratory-confirmed EVD cases 84-days after vaccination

• Secondary objectives:
  – **Serious Adverse Events** over 84 days of follow-up
  – **Adverse Events** over 28 days
  – Pregnancy outcome
  – Effectiveness
Preparation – National Level

• Contingency Plan presentation to relevant national authorities

• Definition of the inclusion of age group/pregnancy in the study

• ERB submission & follow up and approval

• Negotiations with regulatory agencies, producer and projects
Preparation: Materials

- **Study documents**
  - Protocol
  - Case Report Forms
  - Standard Operating Procedures

- **Training & Information**
  - Briefings at HQ and Mission levels
  - Information Material available
  - GCP/Protocol implementation mobile team

- **List of medical and logistical needs**
  - Study Kits – eg 20 cases
  - Cold chain modules
Preparation: State of affairs

- ERB approvals for few countries
- MoUs under discussion for some others
- Some countries expressed no need for MSF support
- Some countries expressed their interest but MSF in not present in the country
- Further negotiations (internally and externally) on going

This contingency plan is open to new vaccines as they advance in their phase of research
Questions?

Thank you!
Thank you