MALARIA VACCINE PILOTS
AND LONG-TERM SUPPLY

BOARD MEETING
Aurélie Nguyen
4-5 December 2019, Delhi, India
Funding required to complete malaria pilots and enable policy and investment decision-making

**2017-2020**

- Gavi committed US$ 24.6m in 2016
- Matched by Global Fund (US$ 15m) and Unitaid (US$ 9.6m)

**2021-2023**

- Unitaid committed US$ 3.6m in 2016
- GF approved up to US$ 8m in May
- **Gavi request: US$ 11.6m (match GF and Unitaid)**
Impending manufacturing decision has long-term implications

Short-term supply context

• GSK: 10m donation doses for MVIP
• Manufacturing site re-commissioned, production of donation doses complete end 2020
• Stop or continue production?

Long-term supply context

• GSK: facility to cease antigen supply in 2028
• Product transfer to lower cost manufacturer
• Separate funding / financing mechanism required: product transfer, scale-up adjuvant
Two RTS,S production scenarios have different indicative timelines…

Funding decision (following WHO recommendation)

Stop production scenario
- Donation doses
  - Stop production
  - Yes
  - Restart production
- Donation doses
  - Stop production
  - No

Continue production scenario
- Donation doses
  - At-risk production
  - Yes
  - Production for broader roll out
  - Supply from LCM
- Donation doses
  - At-risk production
  - No
  - No further production
  - Stop/restart risks successful product transfer

Switch to supply from lower cost manufacturer (LCM)

Supply from LCM

Production for broader roll out

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…with have long-term implications for supply

Illustrative

Risk to product transfer

Delayed introduction

Slower scale-up

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The two production scenarios have different programmatic and financial trade-offs

**Stop production scenario**

+ No financing at risk
+ Defer further investment until additional data / policy rec’d
- ~3 year delay in introduction, slower scale-up
- Risk to programme continuity
- Risk successful product transfer
- Negative signal for R&D

**Continue production scenario**

+ Faster introduction (up to ~40k additional lives saved through 2028)
+ Programme continuity
+ Potential future price reduction
- Financial liability (US$ 25-75m)
- Opportunity cost
- Funding at risk: future programme not assured
Gavi engagement: two options presented to PPC, third has been explored at PPC request

1. No financial guarantee
2. Gavi shares risk with GSK
3. Identify 3rd party to share risk
Recommends to the Gavi Alliance Board that it:

a) **Approve** an amount up to US$ 11.6 million to continue the malaria vaccine implementation programme from 2021-2023;
Recommendation (2/3): Long-term malaria vaccine supply

The Gavi Alliance Programme and Policy Committee recommends to the Gavi Alliance Board that it:

EITHER:

Option 1

b) **Defer** providing an investment for continued production of RTS,S bulk antigen pending a WHO policy decision and Gavi investment case for broader roll-out;

OR:

Option 2

c) **Approve** providing an investment for continued production of RTS,S bulk antigen pending a WHO policy decision and Gavi investment case for broader roll-out; and
d) **Note** that the Market Sensitive Decisions Committee will make a final determination of the structure of the investment.
Recommendation (3/3): Long-term malaria vaccine supply

OR:

Option 3

e) Request the Secretariat to work with stakeholders to identify third-parties to cost share whereby Gavi’s financial risk should be minimised or reduced to zero to provide for an investment for continued production of RTS,S bulk antigen pending a WHO policy decision and Gavi investment case for broader roll-out; and

f) Approve an investment for continued production of RTS,S bulk antigen between Gavi and third-parties whereby Gavi’s financial risk exposure should be minimised as much as possible, with reassessment of support on an annual basis, subject to the final terms being reviewed and endorsed by the Market Sensitive Decisions Committee.
THANK YOU