MALARIA VACCINE PILOTS

BOARD MEETING
Judith Kallenberg
22-23 June 2016, Geneva
Developments since 2013 (1/5)

2013

- Malaria vaccine ‘shortlisted’ in Vaccine Investment Strategy
- Board decision deferred until after trials are complete

Vaccine Investment Strategy

*Under 5 future deaths averted, 2015-2030 ('000)*
Developments since 2013 (2/5)

2015

- Publication of trial results
  - 39% efficacy after 4 doses (with high bednet coverage)
  - Unable to measure mortality impact
  - No serious adverse events
  - Questions on meningitis and cerebral malaria
- European Medicines Agency issued ‘positive scientific opinion’
Developments since 2013 (3/5)

2015

- WHO recommendation for large scale pilot
- Gavi Board advises to engage in WHO-led process to prepare for the pilots, together with other potential funders
Developments since 2013 (4/5)

2016

- Gavi, UNITAID, Global Fund joint engagement with WHO
WHO Malaria Vaccine Pilot proposal

Initial implementation of a newly licensed vaccine

Purpose

• Demonstrate operational feasibility of 4 dose-schedule
• Assess impact on mortality in real-life settings
• Additional data on potential adverse events

Led by WHO with support from PATH

• Programme Advisory Committee with SAGE and MPAC members
• Programme Safety Committee
• Funders Forum

Funding gap

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<tr>
<th></th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Total</th>
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<tr>
<td>US$</td>
<td>55 m</td>
<td>21 m</td>
<td>76 m</td>
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Board meeting 22-23 June 2016
Malaria vaccine investments to date

Pre-clinical | Clinical development | Post-licensure

1984 | GSK team set up to find malaria vaccine
1998 | Start of the first studies in adults in Africa
2001 | GSK and PATH partnership established
2004 | Proof of concept demonstrated in African children
2009 | Phase 3 trials begin
2011 | First results of Phase 3 trials published
2015 | April: Phase 3 efficacy and safety trial published
      | July: EMA positive opinion
      | October: SAGE/MPAC recommendation for pilots
2016 | Funding decisions

GSK: $365 million
BMGF: $237 million

Pilot funding gap: $76 million

Pilot contributions*:
GSK: vaccine doses
BMGF: $8 million
WHO: $17 million

GSK: >$200–250 million

Cumulative investments are illustrative and may not reflect precise cash flows
*Some co-funding contributions are not reflected in the graph, such as in-kind contributions by pilot countries (e.g. frontline health workers, supply chains, supervision and information systems)
Developments since 2013 (5/5)

2016

- PPC: recommendation to co-fund the pilots
- AFC: funding in accordance with Programme Funding Policy
- External Review Committee: budget is reasonable value for money, cost reductions of at least 10% possible

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Terms of Reference (ToR) for Review Committee
Review of the WHO RTS,S/AS01 Malaria Vaccine Pilot Implementation Proposal

1. Background
The Gavi Secretariat seeks to undertake a review to obtain external advice on the financial details of a WHO proposal for the implementation of the “RTS,S/AS01” Malaria Vaccine Pilot, as per the WHO recommendation published in January 2016. The proposal has been
Pilot milestones

<table>
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<th>Phase 1</th>
<th>Phase 2</th>
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<tr>
<td>2017</td>
<td>2018</td>
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<tr>
<td>🟢 Children complete 3 doses</td>
<td>🟩 Children complete 4 doses</td>
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Preliminary data

Final data

2020
Advisory committee review and recommendation on continuation of pilots

2022
WHO policy recommendation for use of RTS,S in Africa

360,000 children vaccinated
Risks

Raising expectations
• pilot support perceived as guarantee for future Gavi funding window

Setting a precedent
• pilot support for other vaccines

Opportunity cost
• not included in Investment Opportunity
Considerations for a funding commitment

Relevant past experience

• ADIPs, HPV demonstration, rabies and cholera vaccine studies

Considerations

• collective cost-sharing for LIC vaccine development
• advance the science on a potential malaria vaccine
Recommendations (1/2)

The Gavi Programme and Policy Committee recommended to the Gavi Board that, using available resources from the current strategic period, and contingent upon WHO securing funding from other sources to fully finance the Malaria Vaccine Pilots, it:

(a) **Approve** in principle an amount of up to US$ 27.5 million (equivalent to half of the funding request) for Phase 1 of the WHO-led Malaria Vaccine pilots to be implemented during 2017-2020; and
Recommendations (2/2)

(b) **Note** that this investment is contingent upon:

i. Other funders contributing an equivalent amount to cover the pilot costs

ii. Independent review of the proposed budget amount ensuring that this is being done as cost effectively as possible

iii. Further assessment of the selection of pilot settings

iv. Close engagement with the Global Fund and UNITAID including through the proposed Funders Forum

v. WHO seeking input from Alliance partners in the planning and implementation of the pilots

vi. Communication that this investment is for implementation evaluation of a newly licensed vaccine as distinct from R&D

vii. Clear communication that this recommendation does not constitute a precedent for future funding related to the implementation of the malaria vaccine regardless of the outcome of the pilots, nor for future funding of similar pilots for other vaccines

viii. Regular reports to the PPC, and a detailed report to the PPC and Board on progress no later than 2019
THANK YOU