UPDATE ON MALARIA VACCINE AND NEXT STEPS

BOARD MEETING
Judith Kallenberg
2-3 December 2015, Geneva
1984 - GSK scientific team set up to develop a malaria vaccine

1995 - Phase I trials begin in the USA

2001 - PDP established by GSK and PATH (with BMGF funding)

2009 - Phase III trials begin in Africa

2011 - First results of Phase III trials published

July 2015 - EMA provides positive opinion

April 2015 - Final results of Phase III trials published

2013 - Malaria vaccine shortlisted in Gavi Vaccine Investment Strategy

2015 - Launch of Gavi-Global Fund joint working groups & agreement on principles for initial collaboration

Oct 2015: SAGE/MPAC recommendation for pilot implementations

Gavi review process

RTS,S malaria vaccine timeline
Critical questions to be answered

Can new immunisation visits be leveraged to deliver other primary health care interventions?

What is the vaccine’s impact on child mortality?

Is it feasible to administer 4 doses of RTS,S in routine vaccination programmes outside the EPI schedule?

What will be the effect on other malaria interventions?

What is the safety profile when given to a larger group of people?

What is the cost of delivering the vaccine?
Critical questions to be answered

How much will the pilots cost?

Who will finance them?

What are the prospects for future supply of the vaccine?

Are donated vaccines available for the pilots?

When can pilots begin?

What are the risks if pilots are underfunded?
Milestones and timing of Gavi review process

- **Oct 2015:** SAGE/MPAC recommendation for pilot implementations
- **Pilot design & planning**
- **Pilot implementations**
  - **Phase IV safety, impact & effectiveness study (RMP)**
  - **Dec 2015**
    - **Board Guidance**
    - on work areas to pursue in order to gather more information to develop options
  - **June 2016**
    - **Board Decision**
    - on a possible Gavi role in pilot implementations based on options presented, including potential financial support for pilots
  - **3-5 years**
    - **Board Decision**
    - on a possible Gavi role in support of broader roll-out (opening a funding window) or discontinuation of engagement

- **SAGE/MPAC review of pilot experience & WHO recommendation**
Work area 1

Strategic engagement with stakeholders to help design and plan for pilot implementations under the leadership of WHO

Aim:
• To ensure that pilots are set up to address key areas of uncertainty to inform future decision making by Gavi, if and when WHO recommends broader use of the vaccine

Implies:
• To participate in planning and coordination meetings convened by WHO
Work area 2

Explore requirements for short and long term supply availability at sustainable cost

Aim:
• To generate a better understanding of the production economics of RTS,S and of vaccine availability for pilot implementations and a potential future rollout, if recommended by WHO

Implies:
• To engage in conversations with manufacturer and other stakeholders (including PATH, BMGF)
• Includes assessment of potential financing tools to achieve better outcomes if and when WHO recommends the vaccine for broader use
Work area 3

Assess funding needs and potential sources of funding for pilot implementations

Aim:
• To understand cost of pilots, availability of funding from different stakeholders and risks associated with a potential funding deficit

Implies:
• To work with WHO and other partners to estimate cost of pilots
• To achieve greater visibility on potential availability of funding from different sources
THANK YOU