Discussion Points

- Scope of the problem: the burden and challenge of malaria
- Malaria vaccine goals
- State of malaria vaccine development
- Vaccine challenges
- MVI focus and perspective
Malaria’s Reach and Retreat
Ultimate Goal (again): Malaria Eradication
What is the Goal of the Malaria Vaccine Community?

• To develop an 80% efficacious malaria vaccine by 2025 that would provide protection for longer than four years.
The Deadliest Parasite: *Plasmodium Falciparum*

- > 90% of disease burden in sub-Saharan Africa
- Africa's leading cause of mortality (20%) in children age 0 to 5 years
- Main cause of clinical and severe malaria and death

Image: *Plasmodium falciparum* from Medical Structural Genomics of Pathogenic Protozoa
State of Malaria Vaccine Development

*Source: The Malaria Product Pipeline, The George Institute for International Health, September 2007, modified to reflect recent changes in MVI’s portfolio*
What are the Challenges?

• R&D Challenges
• Business Development Challenges
• Financing Challenges
R&D Challenges

• No vaccine has ever been developed for human use against parasites

• There are no known correlates of immunity for malaria vaccines to establish proof of concept
Business Development Challenges

• Historically, work on malaria vaccines has been conducted by the military, government and academia, due to
  – Limited financial return anticipated
  – Major technical and scientific hurdles
  – Complicated regulatory pathways
Financing Challenges

- Current funding for malaria research is starkly inadequate
  - Vaccine costs at least $500 million from “lab to jab”
- Government and NGO “push” funding is essential (i.e. MVI with Gates Foundation support)
- “Pull” mechanisms also needed
  - Advance market commitments from governments and promises of future purchases by the public sector
PATH Malaria Vaccine Initiative

• Created in 1999 with a grant from the Bill & Melinda Gates Foundation
• A program of PATH
• Mission: To accelerate the development of malaria vaccines and ensure their availability and accessibility in the developing world
• Vision: A world free from malaria
Malaria Vaccine Targets and the *Plasmodium* Lifecycle

<table>
<thead>
<tr>
<th>If the vaccine targets</th>
<th>Its goal is to</th>
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<tr>
<td>Pre-erythrocytic Stage</td>
<td>Prevent infection</td>
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<tr>
<td>Blood-stage</td>
<td>Reduce clinical disease</td>
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<tr>
<td>Sexual transmission blocking</td>
<td>Prevent the spread of parasites by mosquitoes</td>
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MVI R&D Strategy

Antigens

SBRI
WEHI

≥80% efficacious vaccine

Adjuvants / Formulations
IDRI
Intercell etc.

Evaluation Technologies
ELISA, GIA,
T Cell, ADCI
Human Challenge

Platforms (& Delivery)
Viral and bacterial vectors etc.
MVI’s Portfolio, June 2008

Future Portfolio Goals:
- 8 Preclinical Candidates (4)
- 4 Early Clinical Programs (3)
- 1 Late Clinical Program (1)
Objective of the RTS,S Program

Successfully test the most advanced malaria vaccine that may protect infants and children, living in malaria endemic regions, from *Plasmodium falciparum* malaria disease
RTS,S Clinical Research Center Network

Number of months of suitable climate:
- No transmission in average year
- 1 - 3 months: Epidemic or strongly seasonal
- 4 - 6 months: Endemic and seasonal
- 7 - 12 months: Endemic and perennial

RTS,S - MVI-GSK Program in Africa
Sanaria—A Different Approach

- Targets the whole parasite
- Uses a live, attenuated parasite
Preparing for Malaria Vaccines

- **Availability:**
  - Assessing demand
  - Regulatory processes

- **Accessibility:**
  - Preparing countries for the vaccine introduction
  - Decision-making framework

A world free from malaria
Final Thoughts…

• Goal is to eradicate malaria: this will not happen without vaccines
• Malaria vaccine R&D needs more funding
• Partnerships are the key to success