Innovative approaches to accelerate vaccine development for low-resource countries

11th Annual General Meeting & Conference of DCVMN

September 16, 2010
PATH’s vision

A world where innovation ensures that health is within reach for everyone.
PATH’s mission

Improving the health of people around the world by:

- Advancing technologies
- Strengthening systems
- Encouraging healthy behaviors
PATH’s global presence

PATH is working in countries shaded orange. Area of square indicates staff per office.
PATH’s vaccine development projects

- Pneumococcal disease
- Diarrheal disease
  - Rotavirus
  - Enterotoxigenic *E. coli* and *Shigella*
- Influenza
- Malaria
- Meningococcal disease
Malaria: market opportunity?

- Each year 350–500 million cases of malaria occur worldwide
- Over one million people die, most of them young children in sub-Saharan Africa
- In 2002, malaria was the fourth cause of death in children in developing countries.

Source: United States Centers for Disease Control
PATH & GSK: RTS,S malaria vaccine

- **Background**
  - GlaxoSmithKline Biologicals (GSK) created RTS,S vaccine candidate in 1987 in close collaboration with Walter Reed Army Institute of Research
  - In 2001 GSK and the PATH Malaria Vaccine Initiative (MVI) formed PDP with support from the Bill & Melinda Gates Foundation

- **Goal**
  - Develop vaccine for infants and young children, with a geographic focus on sub-Saharan Africa
RTS,S malaria vaccine status – Phase 2

Phase 2 clinical trials completed March 2007

- Beneficial effect on clinical and severe disease over 42 months

- Favorable safety profile (9000 doses to 3000 infants and children)

- Can be co-administered within the infant EPI immunization schedule
RTS,S malaria vaccine status – Phase 3 trial

Burkina Faso
IRSS - Centre Muraz

Ghana
KHRC, Kintampo
KCCR, Kumasi

Gabon
HAS, Lambarene

Kenya
KEMRI/WRAIR – Kombewa
KEMRI/CDC – Siaya
KEMRI/Kilifi

Tanzania
JMP, Korogwe, Tanzania
IHDRC, Bagamoyo, Tanzania

Malawi
UNC, Lilongwe

Mozambique
CISM, Manhiça
Role of product-development partnerships

- Potential returns
- Development risk

Private sector

Developing world risk/return

Risk-return threshold
Role of product-development partnerships

- Mitigate risk
- Share costs

Potential returns

Risk-return threshold

Private sector

Developing world risk/return

Development risk

PDP
Mutually beneficial, collaborative partnerships

WHAT PATH BRINGS
- Expertise in developing country health systems
- Presence in poor countries
- Ability to strengthen clinical trial capacity
- Financial support
- Technical expertise
- Strategic relationships
- Intellectual property

WHAT PARTNERS BRING
- Expertise in product development
- Scientific and technical capacity
- Intellectual property
- Manufacturing facilities & equipment
- Large-scale distribution systems
- Market-based approach

Mutual benefit
Drivers of partnership diversity

State of Science or Technology

Intellectual Property

Time to Market

Clarity of Market

Distribution System Readiness

Partnership Complexity

More certain

Less certain
Global access: critical terms

- Ensuring product supply
  - Impact requires scale
- Making products affordable
  - Market segmentation enables tiered pricing structures
- Managing intellectual property
  - Relative value of supply and price concessions vs royalties
  - Reserve rights if supply/pricing commitments not met
Case: RTS,S malaria vaccine

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More certain  Less certain
Case: RTS,S malaria vaccine

- Partnership terms
  - GSK to supply and provide preferred pricing for infants and children in malaria-endemic regions of Africa
  - MVI to research and project demand in Africa
  - MVI and GSK work together with government and other partners to ensure that clinical trials adhere to the highest clinical, ethical, and safety standards.
PATH Meningitis Vaccine Project (MVP)

- **Background**
  - Created in June 2001 by a grant from the Bill & Melinda Gates Foundation as a 10-year partnership between WHO and PATH

- **Goal**
  - Eliminate epidemic meningitis as a public health problem in Sub-Saharan Africa through the development, testing, licensure and widespread use of conjugate meningococcal vaccines
MVP Men A vaccine development model

A PS produced by SynCo BioPartners, Amsterdam for initial development then transferred to Serum Institute of India.

Serum Institute of India process development and manufacturing.

Conjugation method developed at CBER/FDA, Bethesda, USA, transferred and scaled-up at Serum Institute of India.

Target price US$ <0.50/dose.
Men A conjugate vaccine- “MenAfriVac”
MVP status

*MenAfriVac*<sup>TM</sup>, the Men A Conjugate Vaccine (PsA-TT) developed by MVP & Serum Institute of India has shown:

- Equivalent safety profile to the licensed polysaccharide and Hib vaccines in 1-29 year-olds in Africa and India
- The characteristics of a conjugate vaccine:
  - Superior immunogenicity (rSBA & hSBA) in 12-23 month olds vs. the licensed polysaccharide vaccine
  - Effective inducement of immunological memory in 12-23 month olds
  - Inducement of bactericidal antibodies persisting at sustained levels in 12-23 month olds vs. polysaccharide vaccine
  - Superior immunogenicity (rSBA) confirmed in 2-29 year olds in Africa & in 2-10 year olds in India vs. polysaccharide vaccine
MVP introduction strategies

- Single dose in catch up vaccination campaigns for 1 to 29 year olds to rapidly induce herd immunity
  - Start with Burkina Faso, Mali and Niger
  - Other belt countries are prioritized on the basis of epidemiologic need and absorptive capacity
- Protect birth cohorts
  - Single dose at 9-12 months or two doses (14 weeks and 9 months) within the EPI schedule
    - or
  - Follow-up campaigns targeted at 1-4 year olds every 5 years
MVP 2010 timelines for introduction

- Market authorization by the Indian National Regulatory Agency in Q1 2010
- WHO Prequalification achieved June 23, 2010
- Introduction in Burkina Faso, Mali, and Niger in Q4 2010
Case: Men A conjugate vaccine

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Case: Men A conjugate vaccine

- Partnership terms
  - Serum Institute of India to supply guaranteed volume vaccine/year at USD<.50/dose
  - WHO to assist in registration activities in Sub-Saharan Africa
  - WHO to assist in vaccine introduction activities in Sub-Saharan Africa
Case: Japanese Encephalitis Vaccine

- **Background**
  - Efforts to control vector, the Culex mosquito, have been ineffective
  - Inactivated vaccine exists, but cost out of reach for public sector programs; millions of children at risk
  - Chengdu Institute of Biological Products had manufactured improved vaccine to protect over 200 million children in China over a 20-year period

- **Goal**
  - Ensure equitable access to a safe, efficacious vaccine
Case: Japanese Encephalitis Vaccine

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Less certain
Case: Japanese Encephalitis Vaccine

- Partnership terms
  - CDIBP caps public-sector price until 2026 for low-income countries; gains access to international markets
  - PATH builds evidence base for use by collecting data required for country-by-country licensure and eventually for WHO prequalification
  - Collaboration supports construction of new facility to ensure sufficient, sustainable, and affordable supply. PATH provides technical assistance to confirm that equipment, installation and production meet global standards
Product development partnerships and global access

- Expand the risk/return threshold for the private sector
- Identify unique partnership characteristics
- Negotiate global access consistent with partnership
Conclusions

- Vaccines represent one of the most successful and cost-effective public health interventions available today.

- Millions of children remain underimmunized or unimmunized because of the shortage of affordable and available vaccines.

- PATH is working to close the immunization gap by partnering to develop new vaccines and ensuring access to those vaccines for developing-country populations.
For further information

- Maximizing the benefits of public-private partnerships
- Availability
- Accessibility
- Affordability

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