Malaria Vaccine Development through Innovation and Partnerships

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Outline

• Mission of PATH’s Malaria Vaccine Initiative as a PDP
• The first malaria vaccine, RTS,S/AS01 (RTS,S), is a product of innovation and partnerships
• Developing 2nd generation malaria interventions through innovation and partnership
• Key elements in a productive partnership
PATH Mission:
advance health equity through innovation and partnerships
Center for Vaccine Innovation and Access (CVIA)

spans every stage of vaccine research, development, and introduction to make lifesaving vaccines widely available to communities around the globe.

Malaria Vaccine Initiative

Enteric & Diarrheal
Respiratory infection and Maternal Immunization
Polio
WHO recommends groundbreaking malaria vaccine for children at risk

Historic RTS,S/AS01 recommendation can reinvigorate the fight against malaria

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RTS,S/AS01 is a Product of Innovation + Partnership
RTS,S pilot introduction (MVIP) involves many partners
2nd Gen Malaria Vaccine Development

Clinically validated Ph 3 (Pilot introduction, RTS,S)

Early stage (Ph 1/Ph 2)

Transmission-blocking

Pfs48/45, Pfs230

Adapted from: Maier et al., Trends in Parasitology Vol 35, Issue 6, p. 481-2
<table>
<thead>
<tr>
<th>Year</th>
<th>Project</th>
<th>Partners</th>
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<tbody>
<tr>
<td>2013</td>
<td>Express pre-erythrocytic stage antigen, screen for anti-infection malaria vaccine candidate</td>
<td><img src="image1" alt="PATH" /> <img src="image2" alt="Ehime University" /></td>
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<tr>
<td>2014</td>
<td>Express mosquito stage antigen, screen for transmission blocking vaccine candidate</td>
<td><img src="image1" alt="PATH" /> <img src="image2" alt="Ehime University" /></td>
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<td>2016</td>
<td>Design and display Pfs230 as TBV candidate</td>
<td><img src="image1" alt="PATH" /> <img src="image2" alt="Ehime University" /></td>
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<td>2019</td>
<td>Co-delivery of Pfs230 and CSP with a novel CoPoP liposomes-based adjuvant</td>
<td><img src="image1" alt="PATH" /> <img src="image2" alt="Ehime University" /> <img src="image3" alt="University at Buffalo" /></td>
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<td>2019</td>
<td>Preclinical development of Pfs230 as TBV candidate formulated with SA-1, a novel TLR7 adjuvant</td>
<td><img src="image1" alt="PATH" /> <img src="image2" alt="Ehime University" /> <img src="image3" alt="University at Buffalo" /> <img src="image4" alt="Sumitomo Dainippon Pharma" /></td>
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<td>2020</td>
<td>Evaluate full-length CSP formulated with SA-1, in comparison with RTS,S/AS01 as a benchmark</td>
<td><img src="image1" alt="PATH" /> <img src="image2" alt="Ehime University" /> <img src="image3" alt="University at Buffalo" /> <img src="image4" alt="Sumitomo Dainippon Pharma" /> <img src="image5" alt="GSK" /> <img src="image6" alt="Eisai" /></td>
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<td>2022</td>
<td>Preclinical development of an anti-CSP mAb derived from RTS,S human trial</td>
<td><img src="image1" alt="PATH" /> <img src="image2" alt="Ehime University" /> <img src="image3" alt="University at Buffalo" /> <img src="image4" alt="Sumitomo Dainippon Pharma" /> <img src="image5" alt="GSK" /> <img src="image6" alt="Eisai" /></td>
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Innovation + Partnership Advanced Pfs230D1/SA-1 as a TBV Candidate

Pre-IND meeting with FDA

IND-Enabling
Repeated-dose
Toxicology in Rats

SA-1

Sumitomo Dainippon Pharma

Pre-IND meeting with FDA

IND-Enabling
Repeated-dose
Toxicology in Rats

Tangential Flow Filtration
Chromatography
Large Scale Fermentation
Pre-culture Scale up
Seed Stock

ELISA

SMFA

p<0.003

p<0.01

p<0.05
Innovation + Partnership enabled evaluation of fIPfCSP in new adjuvants

SA-1 + Full-Length CSP

Head-to-Head comparison with RTS,S as benchmark

+ Full-Length CSP
Key elements in a productive partnership

• Excellence in science, innovation
  • Ehime University, a premier academic malaria research partner
  • Sumitomo Dainippon Pharma, a big pharma with novel adjuvant technology
  • PATH MVI, a leading PDP in malaria vaccine development

• Complementary skill sets for a common goal
  • Target product profile to guide project design
  • Clear go/no go criteria to guide investment
Special Challenges for Global Health Initiatives

• Partnership critical for product development
  • Assemble complementary skill sets: specialized knowledge required
    • Pathogen
    • Cutting edge technology
    • Production, quality, safety testing
    • Regulatory
    • Clinical trials

• Target Product Profile guides process toward impact
  • Developing world and developed world have different requirements
  • IP must meet global access requirement
  • Clear go/no go criteria to assure efficient use of precious resources

• Connect partnerships to accelerate toward success
  • Research to Development to Implementation
Thank you