GHIT-PDPs WEBINAR SERIES

March 24, 2022

Malaria Vaccine Development

through

Innovation and Partnerships

PATH

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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

Pollio

PATH

World Health Organization

Health Topics | Countries | Newsroom | Emergencies

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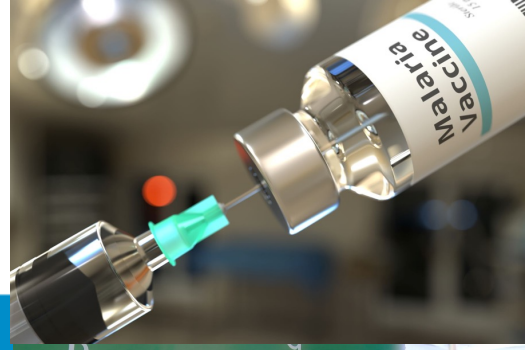
WHO recommends groundbreaking malaria vaccine for children at risk

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

6 October 2021 | News release | Geneva | Reading time: 3 min (859 words)



RTS,S/AS01 is a Product of Innovation + Partnership

1984 GSK and WRAIR begin collaboration

1987 RTS,S construct is first created

1992 First clinical tests in human volunteers begin in US adults

1998 First trials in African adults begin in The Gambia

2001 GSK and PATH begin collaboration

2004 Key proof-of-concept study in children in Mozambique

2007 Phase 2 results in African children and infants published

2008 Choice of AS01 adjuvant confirmed

2009 Phase 3 efficacy and safety trial begins

2014 Phase 3 efficacy and safety trial ends

2015 Final results of Phase 3 trial published

2015 European Medicines Agency awards Positive Scientific Opinion

2016 WHO recommends large-scale pilot introduction

2019 Start of vaccinations in pilot introduction

Oct 2021 WHO recommends widespread use of RTS,S

Dec 2021 Gavi Board approves financing for a malaria vaccination program

Q2 2022 (TBC) WHO Pre-Qualification

2023 End of pilot introduction; possible start of routine implementation

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WRAIR Walter Reed Army Institute of Research

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RTS,S pilot introduction (MVIP) involves many partners

World Health Organization

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LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

gsk

unicef

Ministry of Health

Ghana, Kenya Malawi

REPUBLIC OF KENYA

MINISTRY OF HEALTH

MINISTRY OF HEALTH
REPUBLIC OF GHANA

Evaluation partners

Commissioned by WHO

Ghana

UNIVERSITY OF GHANA
SCHOOL OF PUBLIC HEALTH

NAVRONGO HEALTH RESEARCH CENTRE

GHANA HEALTH SERVICE

UNIVERSITY OF HEALTH AND ALLIED SCIENCES
Health for Development

NOGUCHI MEMORIAL INSTITUTE FOR MEDICAL RESEARCH
UNIVERSITY OF GHANA , LEGON

Kenya

CDC

KEMRI | Wellcome Trust

CDC Foundation
Together our impact is greater

Malawi

UNIVERSITY OF MALAWI
COLLEGE OF MEDICINE

Malawi-Liverpool-Wellcome Clinical Research Programme

UNC PROJECT
Lilongwe , Malawi

Funders

Gavi
The Vaccine Alliance

The Global Fund

Unitaid

External monitor

Pharmalys
Clinical Research

ClinWin Research Services
Quality. Efficiency. Ethics

Reference laboratories

MRC Unit The Gambia

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

NATIONAL INSTITUTE FOR COMMUNICABLE DISEASES
Division of the National Health Laboratory Service

Partners qualitative study Commissioned by PATH

UNIVERSITY OF HEALTH AND ALLIED SCIENCES
Health for Development

Malawi-Liverpool-Wellcome Clinical Research Programme

CDC

LSTM

PATH

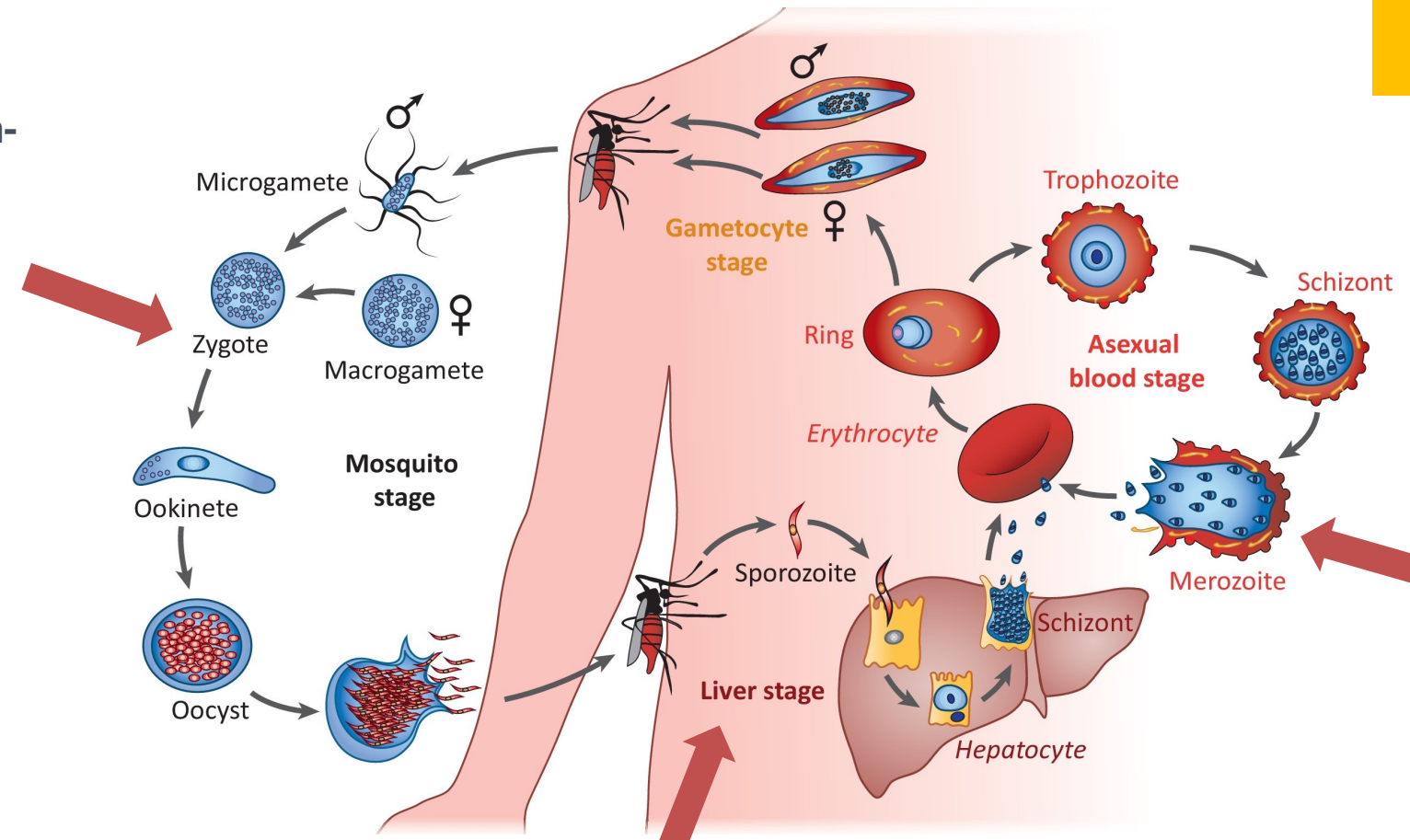
2nd Gen Malaria Vaccine Development

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

Early stage (Ph 1/Ph 2)

Transmission-blocking

Pfs48/45, Pfs230



Blood-stage

Rh5 Complex

Var2CSA

Sporozoite infection

CSP

Killing infected hepatocytes

Whole SPZ

Adapted from: Maier et al., Trends in Parasitology Vol 35, Issue 6, p. 481-2

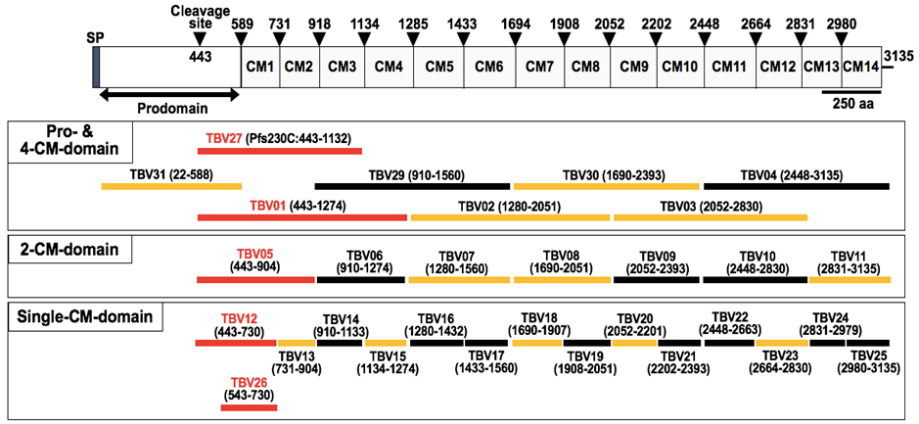
2nd gen malaria vaccine development via Innovations + partnership

GHIT Fund

Global Health Innovative Technology Fund

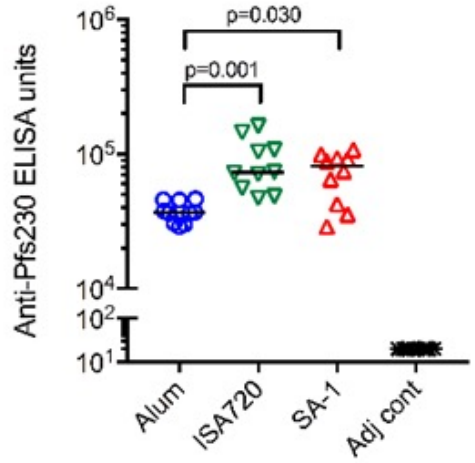
Year	Project	Partners
2013	Express pre-erythrocytic stage antigen, screen for anti-infection malaria vaccine candidate	PATH, 愛媛大学 EHIME UNIVERSITY
2014	Express mosquito stage antigen, screen for transmission blocking vaccine candidate	PATH, 愛媛大学 EHIME UNIVERSITY
2016	Design and display Pfs230 as TBV candidate	PATH, 愛媛大学 EHIME UNIVERSITY
2019	Co-delivery of Pfs230 and CSP with a novel CoPoP liposomes-based adjuvant	PATH, 愛媛大学 EHIME UNIVERSITY, University at Buffalo The State University of New York
2019	Preclinical development of Pfs230 as TBV candidate formulated with SA-1, a novel TLR7 adjuvant	PATH, 愛媛大学 EHIME UNIVERSITY, Sumitomo Dainippon Pharma
2020	Evaluate full-length CSP formulated with SA-1, in comparison with RTS,S/AS01 as a benchmark	PATH, 愛媛大学 EHIME UNIVERSITY, Sumitomo Dainippon Pharma
2022	Preclinical development of an anti-CSP mAb derived from RTS,S human trial	PATH, 愛媛大学 EHIME UNIVERSITY, gsk, Eisai

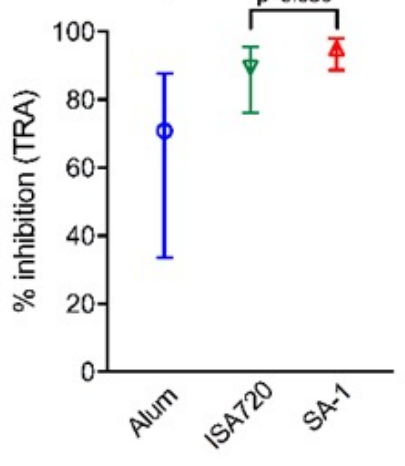
Innovation + Partnership Advanced Pfs230D1/SA-1 as a TBV Candidate

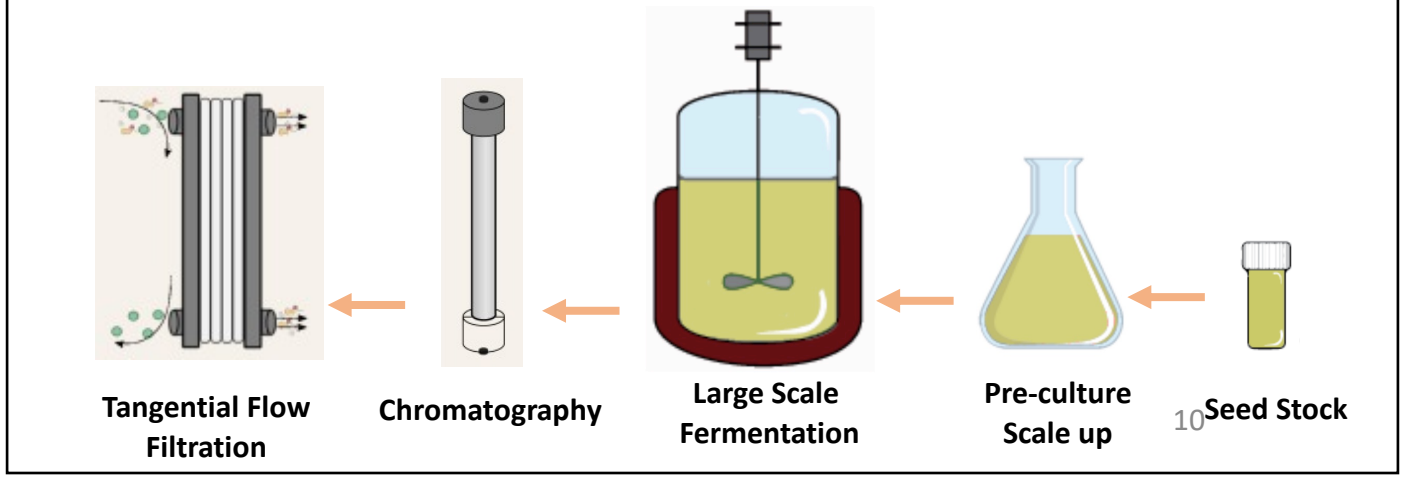


SA-1

Sumitomo Dainippon Pharma







Pre-IND meeting with FDA

IND-Enabling Repeated-dose Toxicology in Rats

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Global Health Innovative Technology Fund

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Innovation + Partnership enabled evaluation of flPfCSP in new adjuvants

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Global Health Innovative Technology Fund

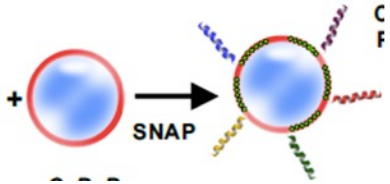
SA-1 Sumitomo Dainippon Pharma + PATH Full-Length CSP

Sumitomo Dainippon Pharma

愛媛大学 EHIME UNIVERSITY

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

University at Buffalo
The State University of New York



\+ PATH Full-Length CSP

愛媛大学 EHIME UNIVERSITY

PATH

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



University at Buffalo
The State University of New York

gsk

Eisai

PATH

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