SUMMARY OF KEY SCIENTIFIC AND TECHNICAL CONSIDERATIONS TO ADVANCE *P. vivax* mRNA VACCINE DEVELOPMENT

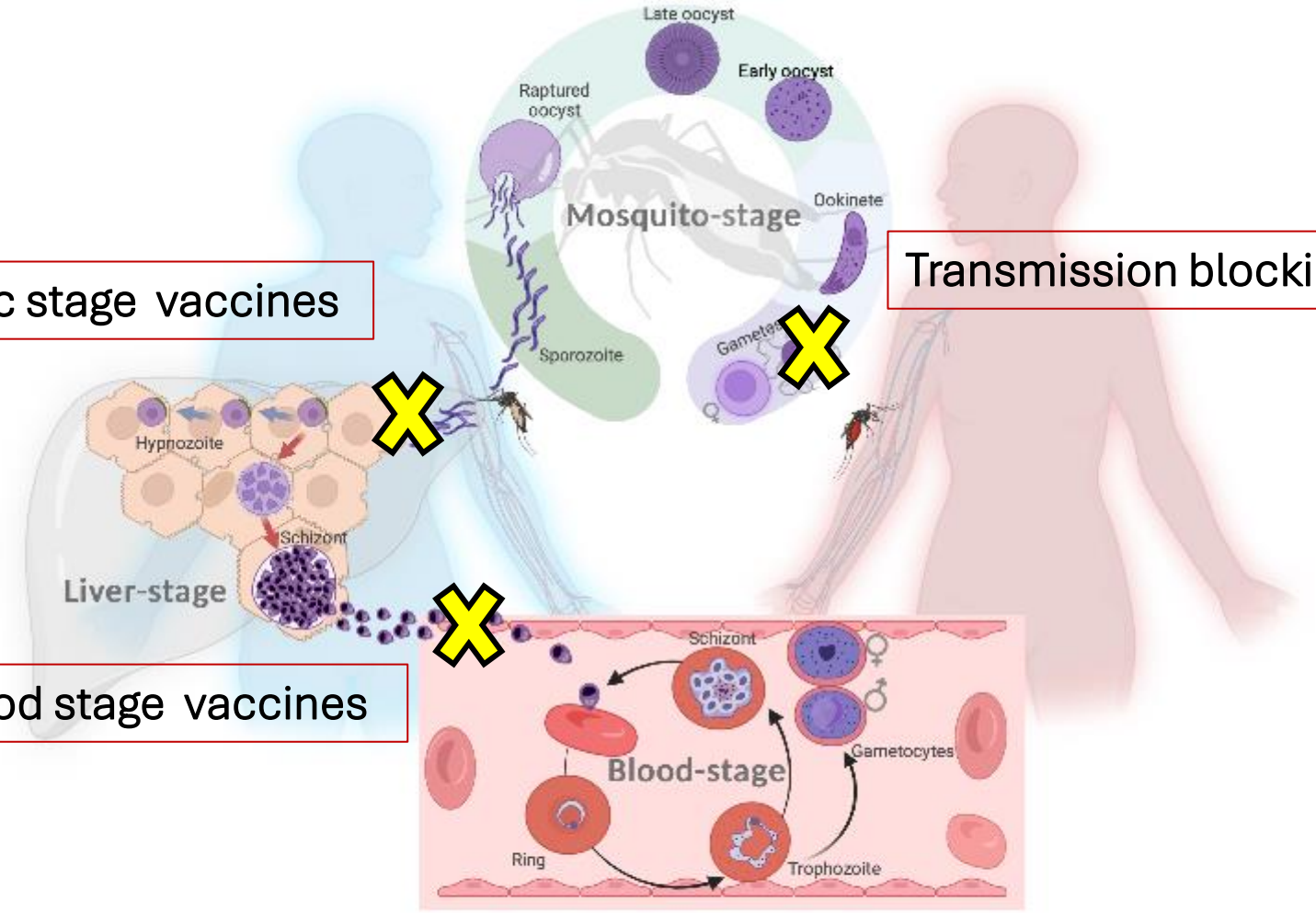
JETSUMON SATTABONGKOT PRACHUMSRI, PHD.

MAHIDOL VIVAX RESEARCH UNIT (MVRU)

CENTER OF EXCELLENCE FOR MALARIA, FACULTY OF TROPICAL MEDICINE

MAHIDOL UNIVERSITY, BANGKOK, THAILAND

Malaria transmission life cycle



Pre-erytrocytic stage vaccines

Transmission blocking vaccine

Blood stage vaccines

FUNDING FOR CURRENT *Plasmodium vivax* mRNA ANTIGEN VACCINE DISCOVERY @ MVRU

- GHIT for transmission blocking vaccines
- Fundamental Fund from Ministry of Higher Education Science & Research Innovation for pre-erythrocytic stage vaccines
- Wellcome Trust for Establishment of CHMI for *P. vivax* (collaboration between MVRU, Mahidol U. & Mahidol Oxford Research Unit (Oxford U.)

KEY SCIENTIFIC CONSIDERATIONS

- Liver stage hypnozoite: causing relapse, inducing multiple episodes of symptom, challenging to transmission interruption /elimination
- Multiple vectors in endemic countries, relatively more vectors susceptible to *P. vivax* comparing to *P. falciparum*
- Limited drugs of to cure relapse and they cannot be used in G6PD deficiency patients
- More population at risk globally, including Africa due establishment of *Anopheles stephensi*.
- Not deadly parasite by itself but can be severe when co-infection with other diseases
- A few of *P. vivax* vaccine candidates (protein/DNA) were poised to enter Phase 1/2 trials but there was not efficacious enough for further development.

KEY TECHNICAL CONSIDERATIONS

- No continuous *in vitro* culture thus R&D of *P. vivax* drugs and vaccines is limited
- Humanized mouse model is established for liver & blood stages research there are other concern including high cost and production sources (~ US$5,000 per mouse)
- Additional capacity on production of local vector & establishment of more field laboratories to perform research on *P. vivax* are will accerelate R&D of *P. vivax* vaccines

AVAILABLE RESOURCES IN ASIA

- Establishment of Controlled Human Malaria Infection (CHMI) for *P. vivax* in Thailand
- High prevalence of *P. vivax* in Asia
- There are biopharmaceutical companies producing GMP products (Proteins, DNA and mRNA vaccines)

CONSORTIUM CAPACITY FOR *Plasmodium vivax* mRNA VACCINES R&D

- Antigen discovery for single and multiple stages *P. vivax* mRNA vaccines
- Assays to evaluate the vaccines efficacy (*in vitro*, *ex vivo*, *in vivo*)
- Mouse and non-human primate model to determine go/no go for further development
- GMP production of mRNA vaccines for Phase1/2 trials
- CHMI for *P. vivax*
- Funding to support at each developmental stages

ESTIMATED COST AND TIMELINE FOR *P. vivax* mRNA VACCINES R&D

YR1:US$ 450,000

- antigen discovery (6 antigens in mice)
- preclinical test (2 Antigens in monkeys)

YR 2:

- US$ 450,000-900,000 for Phase 1 (CHMI)
- US$ 3,200,000 for GMP production of mRNA vaccines (enough for phase 1&2)

QUESTIONS??