

COLLABORATORS PUBLISH ARTICLE IN NATURE COMMUNICATIONS: *PLASMODIUM FALCIPARUM* 7G8 CHALLENGE PROVIDES CONSERVATIVE PREDICTION OF EFFICACY OF PFNF54-BASED PFSPZ VACCINE IN AFRICA

ROCKVILLE, MD, USA – July 12, 2022 – Sanaria Inc., University of Maryland School of Medicine, Naval Medical Research Center, National Institutes of Health (USA), University of Bamako Malaria Research and Training Center (Mali), and University of Tübingen (Germany) published results in *Nature Communications* showing *Plasmodium falciparum* 7G8 human challenge trials provide a conservative prediction of efficacy of PfNF54-based PfSPZ Vaccine in Africa.

The efficacy of malaria vaccines and drugs can be tested by challenging volunteers with live, infectious parasites, a procedure known as Controlled Human Malaria Infection (CHMI). CHMI using the same *P. falciparum* (Pf) malaria strain as the vaccine, potentially overestimates vaccine efficacy (VE) against the naturally occurring antigenically heterogeneous, variant parasite populations. Consequently, expensive field trials requiring large sample sizes and long-duration have been necessary to obtain accurate measures of VE. To counter this, the investigative team increased the stringency of CHMI by selecting a Brazilian isolate, Pf7G8, which is genetically distant from the West African strain (PfNF54) in Sanaria® PfSPZ Vaccine.

Using two identical regimens to immunize US and Malian adults, VE over 24 weeks in the field was as good as or better than VE against Pf7G8 CHMI at 24 weeks in the US. To explain this finding, the University of Maryland team quantified differences in the genome, proteome, and predicted CD8 T cell epitopes of PfNF54 relative to Pf7G8 and 704 Pf isolates from Africa. Pf7G8 is genetically more distant from PfNF54 than any of the African isolates. The investigators propose that VE against Pf7G8 CHMI can provide pivotal data for malaria vaccine licensure for travelers to Africa, and potentially for endemic populations, because the genetic distance of Pf7G8 from PfNF54 makes it a stringent surrogate for naturally occurring Pf parasites in Africa.

Prof. Claire Fraser, the Dean's Endowed Professor of Medicine at the University of Maryland School of Medicine (UMSOM) and Director of the Institute for Genome Sciences, University of Maryland, School of Medicine, commented, "This study clearly highlights the importance of integrating genomics and computational biology into the development plan for vaccines against the highly complex and genetically variant parasites that cause malaria."

"This study offers important insights into the potential power of CHMI for accelerating malaria vaccine development," said Dr. Peter McElroy, Malaria Branch Chief, U.S. Centers for Disease Control and Prevention. "It can inform the assessment of future vaccines slated for use in Africa and worldwide, to provide better predictability and possibly shorten development timelines."

Forward Looking Statement

Except for historical information, this news release contains certain forward-looking statements that involve known and unknown risk and uncertainties, which may cause actual results to differ materially from any future results, performance or achievements expressed or implied by

the statements made. Such statements include the availability of an effective vaccine, the expectations for conquering malaria, beliefs concerning the suitability of a successful vaccine, and the establishment of a path toward prevention of infection. These forward-looking statements are further qualified by important factors that could cause actual results to differ materially from those in the forward-looking statements.

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