

March 31, 2021

Proteo-Science Center, Ehime University
Sumitomo Dainippon Pharma Co., Ltd.

The GHIT Fund Awards Grant for the Development of a New Malaria Pre-erythrocytic Vaccine

The Proteo-Science Center at Ehime University (Director: Takafumi Tsuboi, MD, PhD; hereinafter, “Ehime University”) and Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President and CEO: Hiroshi Nomura) announced today that the preclinical development project for a new malaria pre-erythrocytic vaccine, which the two organizations are jointly conducting with PATH of the United States (hereinafter, the “Project”), has been awarded a grant from the Global Health Innovative Technology Fund (hereinafter, the “GHIT Fund”). Ehime University and Sumitomo Dainippon Pharma are implementing joint research and development of malaria vaccine programs for an asexual blood-stage vaccine and a transmission-blocking vaccine. Each program has also been awarded a grant from the GHIT Fund.

This novel *Plasmodium falciparum* (malaria) vaccine approach that incorporates an optimized immunogen, fICSP formulated with novel TLR7 adjuvant (DSP-0546E), could lead to a vaccine that could block malaria parasite infection from mosquito to human, thus advancing the goal of malaria elimination.

Malaria is a parasitic, mosquito-borne disease that represents one of the international community’s most pressing public health problems. Although the number of deaths from the disease began to decline around 2005, it still afflicts more than 200 million people around the world, and caused over 400,000 deaths in 2019 (*World Malaria Report 2020*). Efforts to develop malaria vaccines preventing infection have been ongoing for more than 40 years, however, first-generation vaccine RTS,S/AS01, designed to prevent the infection from mosquito to human, has proved only moderately effective, preventing about 40 percent of cases of clinical malaria and about 30 percent of cases of severe malaria. Thus, there is a pressing need for next-generation vaccines with higher levels of effectiveness.

Beginning April 2021, PATH will serve as Project Lead for this one and a half-year project and will provide project management support, recombinant protein fICSP, and RTS,S/AS01 as a benchmark and coordinate the design and execution of *in vivo* studies and immune assays. Ehime University will focus on evaluating immunogenicity and *in vitro/in vivo* function of the vaccine candidates. Sumitomo Dainippon Pharma will be responsible for

providing the DSP-0546E adjuvant, and conducting the nonclinical study. The three organizations intend to advance this vaccine to preclinical studies after completion of the Project.

Ehime University has high hopes that the success of the Project will accelerate the development of next generation revolutionary pre-erythrocytic malaria vaccines, thereby helping to combat malaria, which remains a high-priority global health issue.

Sumitomo Dainippon Pharma is eager to create a new ground-breaking vaccine through collaborative innovation with Ehime University and PATH using our adjuvant technology, in a bid to contribute to global health.

Reference

Previous joint research and development programs by the two organizations

For more information on the joint research and development of malaria vaccine programs by Ehime University and Sumitomo Dainippon Pharma, please visit

- Malaria disease prevention vaccine (April 9, 2019)
<https://www.ds-pharma.com/ir/news/2019/20190409-1.html>
- Malaria transmission-blocking vaccine (April 3, 2020)
<https://www.ds-pharma.com/ir/news/2020/200403.html>

fICSP

Plasmodium falciparum circumsporozoite protein (PfCSP) is a well-known malaria vaccine antigen. A portion of the PfCSP is used as a vaccine antigen in the first generation pre-erythrocytic vaccine, RTS,S/AS01. fICSP is a recombinant protein of full-length PfCSP and is expected to provide improved vaccine efficacy compared with PfCSP. fICSP is used in the on-going GHIT Fund Project jointly conducted by Ehime University and PATH (G2019-111). For more information on the G2019-111 project, please visit <https://www.ghitfund.org/investment/portfoliodetail/detail/145/en>.

TLR7 adjuvant (DSP-0546E)

The adjuvant enhances, re-directs, and/or sustains the immune responses to a co-administered antigen. DSP-0546E is a formulated adjuvant activating TLR7, a toll-like receptor that triggers innate immune responses on sensing viral RNA.

The Global Health Innovative Technology Fund (GHIT Fund)

The GHIT Fund is a Japan-based international public-private partnership fund (PPP) between the government of Japan, multiple pharmaceutical companies, the Bill & Melinda Gates Foundation, the Wellcome Trust, and the United Nations Development Programme

(UNDP). The GHIT Fund invests and manages an R&D portfolio of development partnerships aimed at neglected diseases, such as malaria, tuberculosis and neglected tropical diseases that afflict the world's vulnerable and underserved populations. The GHIT Fund mobilizes the Japanese industry, academia, and research institutes to create new drugs, vaccines, and diagnostics for malaria, tuberculosis, and neglected tropical diseases, in collaboration with global partners. For more information, please visit <https://www.ghitfund.org>.

PATH

PATH is a global organization that works to accelerate health equity by bringing together public institutions, businesses, social enterprises, and investors to solve the world's most pressing health challenges. With expertise in science, health, economics, technology, advocacy, and dozens of other specialties, PATH develops and scales solutions—including vaccines, drugs, devices, diagnostics, and innovative approaches to strengthening health systems worldwide. For more information, please visit <https://www.path.org/>.

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Evaluation of a malaria vaccine candidate comprised of full-length recombinant CSP formulated with DSP-0546 adjuvant, using RTS,S/AS01 as a benchmark



- Experience: Malaria vaccine research
- Role: Evaluating function of the vaccine candidates



- Experience: Adjuvant R&D
- Role: Providing DSP-0546E adjuvant and immunopharmacology study

Preclinical development of malaria pre-erythrocytic Vaccine candidate

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- Experience: Malaria vaccine clinical development
- Role: Project management/leadership, fCSP production, providing RTS,S/AS01 and Data analyses

GHIT Fund

Global Health Innovative Technology Fund

(Grant of Approx. ¥100M)