

April 3, 2020

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

**The GHIT Fund Awards Grant for the Development of
a New Malaria Transmission-Blocking Vaccine
by Ehime University and Sumitomo Dainippon Pharma**

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 transmission-blocking vaccine (TBV), 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”).

This novel candidate *Plasmodium falciparum* (malaria) vaccine that incorporates an optimized immunogen, Pfs230D1+ that was discovered by Ehime University and PATH, formulated with Sumitomo Dainippon Pharma’s novel TLR7 adjuvant (DSP-0546E) could block parasite transmission from human to mosquito. When launched, the Formulation could be a transformational tool as the world’s first malaria TBV to aid the elimination of malaria.

Malaria is a parasitic, mosquito-borne disease. Although the number of deaths from the disease began to decline from around 2005, it still afflicts more than 200 million people around the world, and caused over 400,000 deaths in 2018 (World Malaria Report 2019). Efforts to develop malaria vaccines preventing infection have been ongoing for more than 40 years, however, first-generation vaccines designed to prevent the infection from mosquito to human have proved effective in only about 30 percent of cases. Thus, there is a pressing need for next-generation vaccines with higher levels of effectiveness.

Beginning April 2020, PATH will serve as Project Lead for this two-year project and will provide project management support, contribute recombinant proteins Pfs230D1+, and coordinate the design and execution of in vivo studies. PATH will also oversee regulatory filings of Investigational New Drug (IND) application for clinical study and communications. Ehime University will focus on evaluating immunogenicity of the vaccine candidates. Sumitomo Dainippon Pharma will be responsible for the generation of DSP-0546E adjuvant, and the assays to measure its stability. The three organizations intend to commence clinical studies in the United States after completion of the Project.

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

Sumitomo Dainippon Pharma is eager to advance its research and development of new malaria TBVs through collaborative innovation with Ehime University and PATH using our new ground-breaking adjuvant technology, in a bid to contribute to global health.

Reference

Pfs230D1+

In the previous GHIT Fund Project jointly conducted by Ehime University and PATH (T2016-207), they successfully identified the optimal region of Pfs230 that elicit the most potent TBV responses. They named this potential malaria TBV candidate as Pfs230D1+. For more information on the Pfs230 antigen, please visit

<https://www.ghitfund.org/investment/portfoliodetail/detail/102>.

TLR7 adjuvant (DSP-0546E)

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, 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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