

September 27, 2023

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

**GHIT Fund Awards Grant for Development of
New Vaccine to Prevent Clinical Malaria by
Ehime University and Sumitomo Pharma**

The Proteo-Science Center at Ehime University (Director: Tatsuya Sawasaki, PhD, “Ehime University”) and Sumitomo Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President, and CEO: Hiroshi Nomura, “Sumitomo Pharma”) announced today that the preclinical development project for a PfRipr5 new asexual blood-stage malaria vaccine (PfRipr5-PD; the “Project”), which they are jointly developing with the European Vaccine Initiative (the “EVI”, Germany) and iBET (Portugal), has been awarded a grant from the Global Health Innovative Technology Fund (the “GHIT Fund”, Japan).

Ehime University and Sumitomo Pharma are also engaged in joint development programs for malaria infection-blocking and malaria transmission-blocking vaccines, both of which have been awarded a grant from the GHIT fund.

Consisting of a new asexual blood-stage malaria vaccine candidate antigen (PfRipr5) discovered in joint research by Ehime University and Sumitomo Pharma and Sumitomo Pharma’s new vaccine adjuvant (TLR7 adjuvant: DSP-0546E), the vaccine to be developed (“the vaccine”) is a candidate for preventing clinical malaria by inhibiting the entry of the malaria parasite *Plasmodium falciparum* into erythrocytes. When launched, this new vaccine to protect against clinical malaria could be a game-changer in the fight against malaria in areas where it is endemic.

Malaria is a mosquito-borne parasitic disease. Despite a decline in the number of patients since 2005, the COVID-19 pandemic has caused a resurgence in both malaria cases and deaths. Globally, malaria affected over 200 million people worldwide, resulting in more than 600,000 deaths (Source: World Malaria Report 2022). Although efforts to develop effective vaccines against malaria have been ongoing for at least 40 years, RTS,S/AS01—the first-generation vaccine for preventing transmission from mosquitoes to humans recommended by the World Health Organization (WHO) in 2021—has proved only about 30% efficacy. So, there is a pressing need for next-generation vaccines that are much more effective.

In the Project, the EVI, the representative, will lead the overall management of the Project as well as clinical study application procedures for two years from October 2023. The iBET will be in charge of the process development for the GMP-compliant manufacture of PfRipr5, technology transfer to CDMOs, and supervision of its GMP-compliant manufacturing. Ehime University will analyze PfRipr5 characteristics as well as the functional evaluation of the antibodies induced by the vaccine. Sumitomo

Pharma will provide the adjuvant and take charge of non-clinical assessment. Upon completion of the Project, the four organizations plan to start clinical studies in Europe.

Ehime University has high hopes that the success of the Project will accelerate the development of next-generation revolutionary vaccines to prevent clinical malaria, thereby helping combat malaria, which remains one of the highest priorities in global health.

Sumitomo Pharma is eager to create a new ground-breaking vaccine through collaborative innovation with Ehime University 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 by Ehime University and Sumitomo Pharma, please see the following press releases.

- Vaccine to prevent clinical malaria (April 9, 2019)
<https://www.sumitomo-pharma.com/news/20190409-1.html>
- Elucidating mechanism of action of PfRipr5, the vaccine to prevent clinical Plasmodium falciparum malaria – Speeding up malaria vaccine development (April 21, 2020)
<https://www.sumitomo-pharma.co.jp/news/assets/pdf/ne20200421.2.pdf>
(in Japanese only)
- Malaria transmission-blocking vaccine (April 3, 2020)
<https://www.sumitomo-pharma.com/news/200403.html>
- Malaria infection-preventing vaccine (March 31, 2021)
<https://www.sumitomo-pharma.com/news/20210331.html>

PfRipr5

The PfRipr5 discovered through research by Ehime University in collaboration with Sumitomo Pharma is a new asexual blood-stage malaria vaccine candidate antigen for protecting against clinical malaria with a partial amino acid sequence of a Rh5-interacting protein (PfRipr) expressed in the malaria parasite *Plasmodium falciparum*. Previous asexual blood-stage vaccine candidates for protecting against clinical malaria proved ineffective because of the antigen polymorphism. However, Ehime University clearly showed that PfRipr5 has the potential to be highly effective because of its highly conserved sequence in parasite isolates from malaria-endemic areas.

TLR7 adjuvant (DSP-0546E)

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

Global Health Innovative Technology Fund (GHIT Fund)

The GHIT Fund is a Japan-based international public-private partnership fund (PPP) that was formed between the Government of Japan, multiple pharmaceutical companies, the Bill & Melinda Gates Foundation, Wellcome, and the United Nations Development Programme (UNDP). The GHIT Fund invests in and manages an R&D portfolio of development partnerships aimed at addressing neglected diseases, such as malaria, tuberculosis, and neglected tropical diseases, which afflict the world's vulnerable and underserved populations. In collaboration with global partners, the GHIT Fund mobilizes Japanese industry, academia, and research institutes to create new drugs, vaccines, and diagnostics for malaria, tuberculosis, and neglected tropical diseases. For more information, please visit <https://www.ghitfund.org>.

European Vaccine Initiative (EVI)

The EVI is a non-profit organization supporting the development of vaccines for diseases of poverty and emerging infections. The EVI will be responsible for the overall management of the Project and the clinical study application procedures. For more information, please visit <http://www.euvaccine.eu>.

iBET

The iBET is a private, not-for-profit, research-intensive small and medium-sized enterprise in biotechnology and life sciences. Established in 1989, the iBET bridges university and industry research by establishing partnerships in the areas related to health and pharma and food and health. Its key areas of expertise include the production and purification of complex and functionalized biopharmaceuticals, e.g., recombinant proteins and virus-like particles for vaccine candidates, as well as the development of analytics and tools for process monitoring and control and product characterization.

In the Project, the iBET will be responsible for the process development for the GMP-compliant manufacturing of PfRipr5, technology transfer to CDMOs, and supervision of GMP-compliant manufacturing. For more information, please visit <http://www.ibet.pt>.

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