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

Launch of Joint Research on a Novel Multi-Stage Malaria Vaccine by Ehime University and Sumitomo Pharma and Grant Award from the GHIT Fund

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: Toru Kimura, "Sumitomo Pharma") announced today that they have launched joint research on a novel multi-stage malaria vaccine. In addition, the project to develop a novel multi-stage malaria vaccine based on PfCSP and PfRipr5 (the "Project"), which they are jointly advancing with PATH (USA), Statens Serum Institut ("SSI", Denmark), and the University of Copenhagen (Denmark), has been awarded a grant under the Target Research Platform of the Global Health Innovative Technology Fund (the "GHIT Fund", Japan). Ehime University and Sumitomo Pharma are also conducting joint research on a malaria infection-preventing vaccine, a malaria transmission-blocking vaccine, and a vaccine to prevent clinical malaria, each of which has been awarded a grant from the GHIT Fund based on their respective development stages and research objectives.

The vaccine candidate targeted in the Project (the "Vaccine") consists of a nanoparticle presenting both PfCSP, the liver-stage malaria antigen identified by SSI and PfRipr5, a new asexual blood-stage malaria vaccine candidate antigen discovered through joint research between Ehime University and Sumitomo Pharma, combined with Sumitomo Pharma's new vaccine adjuvant (TLR7 adjuvant: DSP-0546E). The Vaccine is expected to prevent infection with *Plasmodium falciparum* transmitted by mosquitoes, as well as subsequent erythrocyte invasion (onset of disease), through a multi-stage mechanism. If successfully commercialized, it has the potential to contribute to malaria control in endemic regions as a new multi-stage malaria vaccine. The Project aims to produce the Vaccine and obtain non-clinical proof of concept (POC) over a two-year period starting in October 2025.

Malaria is a mosquito-borne parasitic disease. Despite a decline in the number of cases around 2005, it began to rise again around 2015, and has continued to increase year by year since the COVID-19 pandemic. Globally, malaria affects more than 260 million people, resulting in approximately 600,000 deaths (Source: World Malaria Report 2025). 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 demonstrated an efficacy of only about 30%. In 2023, WHO also recommended the similar R21/Matrix-M vaccine, however, there

remains a pressing need for next-generation vaccines that are much more effective.

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 to combat malaria, which remains one of the highest priorities in global health.

Sumitomo Pharma is eager to create a novel multi-stage malaria vaccine through collaborative innovation with Ehime University using its 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/20200403-1.html
- Malaria infection-preventing vaccine(March 31, 2021)
  https://www.sumitomo-pharma.com/news/20210331.html
- Vaccine to protect against clinical malaria (September 27, 2023)
  https://www.sumitomo-pharma.com/news/20230927.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 (PPP) that was formed between the Government of Japan, multiple pharmaceutical companies, the 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/.

PATH
PATH is an international organization that collaborates with public institutions, companies, and investors to address the world's most urgent health challenges and advance health equity. Leveraging diverse expertise—including science, health, economics, technology, and patient support—PATH works to accelerate the development of innovative solutions such as vaccines, medicines, medical devices, and diagnostics that strengthen health systems around the world.
For more information, please visit https://www.path.org/.

Statens Serum Institut (SSI)
SSI is under the auspices of the Danish Ministry of Health. Its main duty is to ensure preparedness against infectious diseases and biological threats as well as control of congenital disorders. For more information, please visit https://en.ssi.dk/.

University of Copenhagen
Founded in 1479, the University of Copenhagen is the largest institution of education and research in Denmark. It has approximately 36,500 students and around 5,000 researchers. The University offers an international research and learning environment, and its researchers have been awarded a total of ten Nobel Prizes to date.

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