



Press Release

Total Investment of Approx. USD 7.3 Million in Malaria and TB R&D projects with Partners including European Vaccine Initiative, University of Copenhagen, and University of Tübingen

TOKYO, JAPAN (July 17, 2025) — The Global Health Innovative Technology (GHIT) Fund announced today a total investment of approximately JPY 1 billion (USD 7.3 million¹) in four R&D projects for the development of vaccine, drug, and diagnostics for malaria and tuberculosis (TB).²

Investment of JPY 800 million (USD 5.5 million¹) in malaria vaccine project

Malaria is a serious infectious disease that affects more than 260 million people and claims approximately 600,000 lives worldwide each year. Over 90% of all malaria cases occur in Africa, with more than 70% of those affected being children under the age of five.³ Malaria is transmitted to humans by mosquitoes. While prevention and treatment methods are available, the efficacy of currently available vaccines remains limited, highlighting the urgent need for the development of vaccines with higher efficacy and longer-lasting protection.

To address this challenge, the GHIT Fund has decided to invest JPY 800 million (USD 5.5 million¹) in a malaria vaccine development project currently in the preclinical stage. This project is being led by the European Vaccine Initiative, the Research Institute for Microbial Diseases (RIMD) at Osaka University, the University of Copenhagen, the University of Tübingen, Danish biotechnology company AdaptVac, Ajinomoto Co., Inc., and Nobelpharma Co., Ltd.

This investment is a continuation of previous projects supported by GHIT, which has invested a total of approximately JPY 630 million (USD 4.3 million¹) from 2013 to 2022. The present project aims to develop a vaccine that prevents the proliferation of malaria parasites during the blood-stage of infection. The vaccine is designed to achieve higher efficacy and longer-lasting protection with fewer doses. By reducing manufacturing costs, the project also aims to improve access to vaccines in malaria-endemic regions.

In addition, the GHIT Fund will invest for a total of approximately JPY 260 million (USD 1.8 million¹) in the following three R&D projects:

(1) Target research project for malaria diagnostics by Ehime University and Universiti Malaysia Sabah

(2) Target research project for TB drug by the University of Auckland and the University of Tokyo

(3) Target research project for malaria drug by Medicines for Malaria Venture (MMV), LPIXEL Inc., and University of Dundee

This investment brings four new companies and universities on board. Through collaborations with 190 partners across 39 countries — including 64 Japanese and 126 non-Japanese institutions — we aim to contribute to solving global health challenges and accelerating product development.





Please refer to Appendix 1 for detailed descriptions on these projects and their development stages.

As of July 17, 2025, the GHIT Fund has invested in 37 projects, including 15 discovery projects, 13 preclinical projects, and 9 clinical trials.⁴ The total amount of investments since 2013 is JPY 39.3 billion (USD 271 million¹) (Appendix 2).

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The GHIT Fund is a Japan-based international public-private partnership (PPP) fund 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.

https://www.ghitfund.org/en

 $^{^{1}}$ USD1 = JPY144.81, the approximate exchange rate on June 30, 2025.

² These awarded projects were selected and approved as new investments from among proposals to RFP2023-002 and RFP2024-001 for the Product Development Platform and the Target Research Platform, which were open for applications from June 2023 to July 2024.

³ WHO: <u>https://www.who.int/news-room/fact-sheets/detail/malaria</u>

⁴ This number includes projects in the registration phase.





Appendix 1. Project Details

ID: G2024-201

Project Title	Biomanufacture and preclinical development of the blood-stage malaria vaccine candidate SE36/cVLP
Collaboration Partners	 European Vaccine Initiative (Germany) RIMD, Osaka University (Japan) University of Copenhagen (Denmark) AdaptVac (Denmark) University of Tübingen (Germany) Ajinomoto Co., Inc. (Japan) Nobelpharma Co., Ltd. (Japan)
Disease	Malaria
Intervention	Vaccine
Stage	Preclinical
Awarded Amount	JPY 800,715,002 (USD 5.5 million)
Status	Continued project
Summary	 [Project objective] This team's goal is to fast-track the clinical development of the SE36/cVLP vaccine candidate and obtain supporting evidence for a safe and efficacious blood-stage vaccine that could be deployed as a stand-alone or potentially combined in a second-generation multi-stage malaria vaccine. The main objectives are to: Manufacture a large GMP batch of SE36 Produce a GMP batch of SE36/cVLP Conduct a GLP-compliant nonclinical toxicology study for SE36/cVLP + Sepivac SWE adjuvant Prepare clinical trial documentation for the conduct of a phase I/IIa (CHMI) trial for SE36/cVLP (+/- Sepivac SWE) to assess safety, immunogenicity, and time-to-first episode of clinical malaria in malaria-naïve vaccinated subjects [Project design] The previous GMP manufacturing process for SE36 was largely based on the <i>E. coli</i> expression system with modest yield after several chromatography steps. Benefiting from recent collaborations and new adaptive vaccine technologies, the project team now proposes to manufacture a larger batch of SE36 antigens will be displayed on capsid virus-like particles (cVLP) ensuring unidirectional and high-density display. A previously manufactured small lab-scale batch of SE36/cVLP showed that coupling was stable and that coupled SE36 was highly immunogenic in the mouse model. Armed with this success, the project team now expands its efforts to manufacture a larger GMP batch of SE36/cVLP, conduct a GLP-compliant nonclinical toxicology study and prepare trial documentation to conduct a phase I/IIa trial with this newly optimised formulation of the SE36 vaccine candidate. A successful completion of these activities will set the stage for a first-in-human safety, immunogenicity and efficacy trial.
Project Detail	https://www.ghitfund.org/investment/portfoliodetail/detail/242/en

Fight Neglected Diseases through Partnerships



ID: T2024-153

Project Title	ZOO-RDT: Validating a novel biomarker and associated reagents for diagnosis of acute zoonotic malaria in southeast Asia
Collaboration Partners	1. Ehime University (Japan) 2. Universiti Malaysia Sabah (Malaysia)
Disease	Malaria
Intervention	Diagnostics
Stage	Target Research
Awarded Amount	JPY 64,693,198 (USD 0.4 million)
Status	New project
Summary	 [Project objective] There are no <i>P. knowlesi</i>-specific point-of-care (PoC) tests. Rapid diagnostic tests based on the pLDH biomarker show high cross-reactivity between <i>P. vivax</i> and <i>P. knowlesi</i> making them impossible to distinguish. Current diagnostic practices take time and delay patient access to treatment. Simple, accessible PoC tools are urgently required. Identification of <i>P. knowlesi</i>-specific diagnostic markers has been largely neglected. The serine repeat antigen (sera) multigene family has been extensively studied in <i>P. falciparum</i> and rodent parasite lines and plays critical roles across the parasite life cycle. The <i>P. knowlesi</i>-specific exposure marker, with laboratory and population-level evaluations showing no cross-reactivity with <i>P. vivax</i>, a phylogenetically closely related species. The project team will use this antigen to develop reagents for a <i>P. knowlesi</i> PoC diagnostic test. [Project design] Overall aim: Validate novel biomarker(s) and associated monoclonal antibodies for lateral flow assay development for the diagnosis of acute infections. Objective 1: Reagent optimisation: the optimised PkSERA3 ag 2 protein plus two variants will be used in the generation of monoclonal antibodies (mAbs). Objective 2: Analytical and clinical validation of PkSERA3 Ag2 and variants as species-specific indicators of acute <i>P. knowlesi</i> infection across epidemiological zones. Objective 3: Assessment of Technical Feasibility in the lateral flow system. The best performing mAbs will be assayed by ELISA, and further down-selection will lead to selected mAbs being printed onto test strips. Antibody reagents will be provided to a diagnostic test developer Contract Research Organization (CRO) to validate the technical feasibility of integrating the developed mAbs into a lateral-flow RDT. Objective 4: Stakeholder consultation to understand the preferred test design, and to inform Product Design and generate evidence for a busin
Project Detail	https://www.ghitfund.org/investment/portfoliodetail/detail/243/en





ID: T2024-253





ID: T2024-268

Machine learning-based deconvolution of antimalarial drug mechanisms of action through cell painting of compound-treated <i>Plasmodium falciparum</i> -infected erythrocytes
 Medicines for Malaria Venture (MMV) (Switzerland) LPIXEL Inc. (Japan) University of Dundee (UK)
Malaria
Drug
Target Research
JPY 99,628,772 (USD 0.6 million)
New project
 [Project objective] The project ultimately aims to deliver a new high-throughput and information-rich platform for informing and classifying antimalarial modes of action (MoA), and highlighting novel compound-induced phenotypes. This proposal seeks to leverage advances in cellular imaging and machine learning-led pattern recognition. The final goal is to develop a robust, reproducible method to deliver information on a compound's biological impact (whether its MoA or pathway is novel or known) in synchrony with the confirmation of growth inhibition and thus allow clustering on both chemistry and biology, potentially saving months in the context of Hit Generation. [Project design] The project relies on high-content imaging and subsequent analysis of drug-treated <i>Plasmodium falciparum</i> parasites. The initial assay development phase will optimise methodologies for staining, fixation and imaging of parasite-infected red blood cells, including both healthy untreated parasites and those treated with a pilot set of compounds with defined MoA. This will allow preliminary development of artificial intelligence (AI) models to classify parasite morphology across the 48 hour lifecycle, as well as the phenotypic impact of drug-treatment. Once treatment and imaging parameters have been optimised, data collection will be performed with an expanded set of compounds covering a diverse range of MoA, in order to refine and validate the development of AI models for pattern recognition. AI models will ultimately be packaged into a cloud-based, user-friendly application so that images generated by researchers can be analysed without specialist AI knowledge.
https://www.ghitfund.org/investment/portfoliodetail/detail/245/en

*All amounts are listed at an exchange rate of USD1 = JPY144.81, the approximate exchange rate on June 30, 2025.





Appendix 2. Investment Overview (as of July 17, 2025)

Investments to date

Total investments: 39.3 billion yen (USD 271 million¹) Total invested projects: 139 (37 active projects and 102 completed projects)

To learn more about the GHIT Fund's investments, please visit Investment Overview: <u>https://www.ghitfund.org/investment/overview/en</u> Portfolio: <u>https://www.ghitfund.org/investment/portfolio/en</u> Advancing Portfolio: <u>https://www.ghitfund.org/investment/advancingportfolio/en</u> Clinical Candidates: <u>https://www.ghitfund.org/investment/clinicalcandidates/en</u>