

Press Release

Investment of Approximately USD 8.8 Million for New Drug Development against Malaria in Partners including Marubeni and Eisai

- **First investment in a Japanese trading company and a Chinese pharma company**
- **Accelerating new drug development by investing in late-phase clinical trials**

TOKYO, JAPAN (December 14, 2023) — The Global Health Innovative Technology (GHIT) Fund announced today an investment of approximately 1.3 billion yen (US\$8.8 million¹) for the development of new drugs for malaria and Chagas disease.²

Malaria is an infectious parasitic disease transmitted by mosquitos that affects approximately 250 million people annually and was responsible for approximately 620,000 deaths in 2021³. The African region constitutes a staggering 95% of global malaria cases, and children under the age of 5 account for 80% of all malaria deaths in this region.

The GHIT Fund invests in new product development with the aim of contributing to global health by facilitating collaborations between Japanese technology and innovation and global institutions to address these neglected infectious diseases. This is the first investment by the GHIT Fund in a general trading company, Marubeni Corporation (Marubeni), and a pharmaceutical company in China, Shanghai Fosun Pharmaceutical Industrial Development Co., Ltd. (FOSUN PHARMA), with the aim of accelerating the development of new drugs by focusing on investments in late-phase clinical trials.

First investment in a Japanese trading company and a Chinese pharma company - new malaria drug in a Phase III trial by Marubeni, Fosun Pharma, MORU, and MMV

The GHIT Fund will invest approximately 500 million yen (US\$3.3 million¹) in a clinical phase III trial for a triple artemisinin combination drug against malaria, in partnership with a leading Japanese integrated trading and investment business conglomerate, Marubeni, a major Chinese pharmaceutical and healthcare company, FOSUN PHARMA, a Thailand-based research collaboration of universities, Mahidol-Oxford Tropical Medicine Research Unit (MORU), and the product development partnership Medicines for Malaria Venture (MMV), which provides technical support and market access expertise.

This drug candidate should have a significant public health benefit as it is expected to play an important role in the fight against artemisinin partial resistance (ART-R) which is now observed widely in the Greater Mekong Subregion (GMS) of Southeast Asia⁴ and to some extent in several African countries, including Rwanda and Uganda. Importantly, the project includes the

development of a co-formulated child-friendly version, given that most malaria cases are in children³.

800 million yen investment in a Phase IIb study of the new anti-malarial drug candidate SJ733 as a radical cure for *P. vivax*

The GHIT Fund will also invest approximately 800 million yen (US\$5.4 million¹) in the anti-malarial drug project by Eisai Co., Ltd. and the University of Kentucky to develop a radical cure for *P. vivax* malaria. SJ733, an antimalarial drug candidate, has completed a Phase IIa trial for single administration and has shown efficacy and tolerability against *P. vivax* malaria. With this new investment, the project aims to shorten the treatment period by using SJ733 in combination with the existing drug tafenoquine.

Dr. Osamu Kunii, CEO of the GHIT Fund, said “We are very excited to have Marubeni and FOSUN PHARMA as our new product development partners. It is an important step forward to invest in the development of antimalarial drugs in late-phase clinical trials to advance commercialization. The number of malaria cases and deaths in children under 5 years old is an urgent issue. This investment will make a significant contribution to reducing the burden of malaria globally, especially among young children.”

In addition, the GHIT Fund will invest approximately 16 million yen (US\$0.1 million¹) in Nagasaki University and Drugs for Neglected Diseases initiative (DNDi) for a screening project against Chagas disease, which is one of the neglected tropical diseases.

As of December 14, 2023, there are 50 ongoing projects, including 19 discovery projects, 18 preclinical projects, and 13 clinical trials⁵ in the GHIT Fund’s portfolio. The total amount of investments since 2013 is 31.6 billion yen (US\$211 million).

¹ USD1 = JPY149.52, the approximate exchange rate on October 31, 2023.

² These awarded projects were selected and approved as new investments from among proposals to RFP2023-001 for the Product Development Platform, which was open for applications from November 2022 to July 2023.

³ WHO (World Health Organization): <https://www.who.int/news-room/fact-sheets/detail/malaria>

⁴ GMS comprises Cambodia, Lao People's Democratic Republic (Lao PDR), Myanmar, Vietnam, Thailand, and the People's Republic of China (PRC, specifically Yunnan Province and Guangxi Zhuang Autonomous Region).

⁵ This number includes the projects in the registration phase.

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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 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.

<https://www.ghitfund.org/en>

Appendix 1. Project Details

G2022-205

Project Title	Evaluation and preparation for deployment of an Artemether-Lumefantrine-Amodiaquine Fixed-Dose Combination to counter antimalarial drug resistance in <i>Plasmodium falciparum</i> malaria
Collaboration Partners	1. Marubeni Corporation 2. Shanghai Fosun Pharmaceutical Industrial Development Co., Ltd. (FOSUN PHARMA) 3. Mahidol-Oxford Tropical Medicine Research Unit (MORU) 4. Medicines for Malaria Venture (MMV)
Disease	Malaria
Intervention	Drug
Stage	Clinical Phase III, Licensure
Awarded Amount	¥504,325,357 (US\$3.3million)
Status	New project
Summary	<p>[Project objective]</p> <ol style="list-style-type: none"> 1. Evaluate the safety, tolerability and efficacy of ALAQ-FDC developed and produced by FOSUN PHARMA compared to the current first-line treatments AL and ASAQ, in areas with different patterns of antimalarial drug resistance. 2. Compare the post-treatment prophylactic effect of ALAQ-FDC with AL and ASAQ. 3. Assess potential drug-drug interactions in ALAQ-FDC in clinical use. 4. Explore potential strategies for the successful registration, deployment and commercialization of ALAQ-FDC in participating countries. 5. Explore the marketing positioning of ALAQ-FDC to facilitate the introduction of ALAQ-FDC in malaria endemic countries <p>[Project design]</p> <p>The safety, tolerability, efficacy and pharmacokinetic/dynamic aspects of ALAQ-FDC will be studied in a randomized controlled non-inferiority trial comparing ALAQ-FDC to the ACTs artemether-lumefantrine (AL) and artesunate-amodiaquine (ASAQ) (with single-low dose primaquine in some sites) for the treatment of uncomplicated <i>Plasmodium falciparum</i> malaria. The study will be conducted at sites in Rwanda, Uganda, Angola, Nigeria and Thailand.</p>
Project Detail	https://www.ghitfund.org/investment/portfoliodetail/detail/215/en

G2022-218

Project Title	Combination of SJ733 with Tafenoquine as a Possible Radical Cure for <i>P. vivax</i> Malaria.
Collaboration Partners	1. Eisai Co., Ltd. 2. University of Kentucky
Disease	Malaria
Intervention	Drug
Stage	Clinical Phase IIb
Awarded Amount	¥807,182,400 (US\$5.4 million)
Status	Continued project
Summary	<p>[Project objective] The overall objective of this project is to examine the clinical safety and efficacy of the combination of SJ733 and TQ for radical cure of <i>P. vivax</i> malaria. The purpose is to develop an SJ733-TQ combination drug suitable for treatment of all patients with uncomplicated <i>P. vivax</i> malaria. The targeted results for this study are data that support 1 to 3 doses of an SJ733-TQ fixed dose combination for radical cure of <i>P. vivax</i> mono-infected patients.</p> <p>[Project design] First, we will consider toxicology associated with administration of the combination of SJ733 and TQ to support the proposed Phase IIb studies. Next, we will carry out a clinical trial to establish safety and efficacy of a fixed-dose combination of SJ733-TQ in adults with <i>P. vivax</i> malaria mono-infection to examine the safety and efficacy of the combination of SJ733 and TQ in uncomplicated <i>P. vivax</i> malaria mono-infection in Peruvian adult patients. The primary objectives are to assess the safety, tolerability, efficacy, and pharmacokinetics of an orally administered combination of SJ733 and TQ. Concurrently, we will explore options to reduce the overall cost of goods of SJ733.</p>
Project Detail	https://www.ghitfund.org/investment/portfoliodetail/detail/216/en

S2023-121

Project Title	HTS for discovery of new drugs for Chagas disease
Collaboration Partners	1. Nagasaki University 2. Drugs for Neglected Diseases initiative (DNDi)
Disease	Chagas disease
Intervention	Drug
Stage	Screening
Awarded Amount	¥16,089,533 (US\$0.1 million)
Status	New project
Summary	<p>[Project objective] The main objective of this research project is to identify novel and potent antichagasic compounds from selected chemical library subsets from the Center for Supporting Drug Discovery and Life Science Research, Osaka University that meets the GHIT/DNDi criteria.</p> <p>[Project design] A total of seven chemical library subsets from the Center for Supporting Drug Discovery and Life Science Research, Osaka University (Osaka Library, total number 62,029 compounds) will be tested in a cell-based high-throughput screening system against intracellular amastigote stage of a <i>T. cruzi</i> strain that were genetically engineered to express the firefly luciferase gene. The cytotoxicity against human cell lines as well as the biological activity against four major <i>T. cruzi</i> strains of the primary hits will be evaluated.</p>
Project Detail	https://www.ghitfund.org/investment/portfoliodetail/detail/217/en

*All amounts are listed at an exchange rate of USD1 = JPY149.52, the approximate exchange rate on October 31, 2023.

Appendix 2. Investment Overview (as of December 14, 2023)

Investments to date

Total investments: 31.6 billion yen (US\$211 million¹)

Total invested projects: 123 (50 active projects and 73 completed projects)

To learn more about GHIT Fund's investments, please visit

Investment Overview: <https://www.ghitfund.org/investment/overview/en>

Portfolio: <https://www.ghitfund.org/investment/portfolio/en>

Advancing Portfolio: <https://www.ghitfund.org/investment/advancingportfolio/en>

Clinical Candidates: <https://www.ghitfund.org/investment/clinicalcandidates/en>