

**GHIT Fund Announces New Investments:  
A Total of Approximately 260 Million Yen in Shionogi,  
Takeda Pharmaceutical for New Malaria Drug Development**

**TOKYO, JAPAN** (March 13, 2023) — The Global Health Innovative Technology (GHIT) Fund announced today an investment totaling approximately 260 million yen (US\$1.9 million<sup>1</sup>) for the research and development of a new malaria drug. This investment will help identify multiple promising compounds in the early stages of research and development. (Appendix 1)

Malaria is an infectious parasitic disease that affects approximately 250 million people annually and was responsible for approximately 620,000 deaths in 2021. The World Health Organization (WHO) has set the target for reducing global malaria infections and deaths by at least 90% from 2015 levels by 2030<sup>2</sup> with a goal to ultimately eliminate malaria. However, recent progress in reducing annual deaths has stalled due to complications caused by the COVID-19 pandemic.

GHIT Fund will invest approximately 130 million yen (US\$0.97 million<sup>1</sup>) in Shionogi & Co., Ltd (Shionogi), Nagasaki University, and Medicines for Malaria Venture (MMV) for a project to develop new antimalarial drugs, along with approximately another 130 million yen (US\$X0.96million<sup>1</sup>) in Takeda Pharmaceutical Company Limited (Takeda Pharmaceutical) and MMV's synthetic research on novel antimalarial drugs.

“GHIT Fund supports the research and development of new drugs, vaccines and diagnostics to contribute to efforts to control and eradicate malaria” said Dr. Osamu Kunii, GHIT Fund CEO. “We hope that Japanese pharmaceutical companies along with research institutes will progress in the development of new drugs together with overseas partners. In particular, GHIT Fund has high expectations for the highly unique industry-academia collaboration between Shionogi and Nagasaki University aimed at developing a new antimalarial drug, a partnership based on the ‘comprehensive collaboration in the field of infectious diseases centered on malaria’ which was launched in February, 2019.”

Also, at the same time, GHIT Fund invested approximately 15 million yen (US\$0.1 million<sup>1</sup>) in Daiichi Sankyo RD Novare Co., Ltd. and the Global Alliance for TB Drug Development (TB Alliance) for a tuberculosis screening program.

As of March 13, 2023, there are 51 ongoing projects, including 25 discovery, 14 preclinical and 12 clinical trials<sup>3</sup> in the GHIT portfolio. The total amount of investments since 2013 is 28.7 billion yen (US\$210 million).

<sup>1</sup> USD1 = JPY136.34, the approximate exchange rate on February 28, 2023.

<sup>2</sup> WHO (World Health Organization): <https://www.who.int/news-room/fact-sheets/detail/malaria>

<sup>3</sup> These awarded projects were selected and approved as new investments from a number of proposals to the RFP2022-002 for Screening Platform and Hit-to-Lead Platform, which was open for applications from July 2022 to January 2023.

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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.

## Appendix.1 Project Details

### H2022-202

<b>Project Title</b>	A Hit-to-Lead study of screening hits for novel antimalarial compounds
<b>Collaboration Partners</b>	Shionogi & Co., Ltd., Nagasaki University, Medicines for Malaria Venture (MMV)
<b>Disease</b>	Malaria
<b>Intervention</b>	Drug
<b>Stage</b>	Lead Identification
<b>Awarded Amount</b>	¥132,318,400 (US\$0.97million)
<b>Status</b>	New project
<b>Summary</b>	<p>[Project objective] The objective of this project is to identify a novel lead series that could overcome the drug resistance issues and satisfy the MMV's early lead criteria by conducting structure activity relationship (SAR) study for five novel hit series.</p> <p>[Project design] This project will be divided into two parts. In the first part, all 5 hit series will be explored to understand their potential for higher potency, safety and the activity on known drug resistance strains within 6 months. In the second part, one or two series will be prioritized, and we will continue the SAR study for further potency and characterization of the series. A promising series will be subjected to <i>in vivo</i> efficacy study in mice.</p>
<b>Project Detail</b>	<a href="https://www.ghitfund.org/investment/portfoliodetail/detail/205/en">https://www.ghitfund.org/investment/portfoliodetail/detail/205/en</a>

### H2022-201

<b>Project Title</b>	Irresistible series as anti-malarial agent
<b>Collaboration Partners</b>	Takeda Pharmaceutical Company Limited, Medicines for Malaria Venture (MMV)
<b>Disease</b>	Malaria
<b>Intervention</b>	Drug
<b>Stage</b>	Lead Identification
<b>Awarded Amount</b>	¥130,723,344 (US\$0.96 million)
<b>Status</b>	Continued project
<b>Summary</b>	<p>[Project objective]</p> <p>The objective will be to perform Hit-to-Lead studies to deliver a compound from this series which meets MMV's Early Lead criteria, and which has the potential to enter lead optimization to ultimately deliver a preclinical candidate suitable for treatment of malaria (TCP-1) as a component of a drug combination.</p> <p>[Project design]</p> <ul style="list-style-type: none"> <li>● Establish structure activity relationships to demonstrate improved potency is possible (3D7 EC50 &lt; 100nM), while maintaining a good selectivity window against human cell lines (HepG2 EC50 &gt;10 uM) and good lead-like qualities for an oral agent: Mwt &lt;500 and good solubility and permeability.</li> <li>● Profile in-vitro ADMET properties and identify potential liabilities e.g hERG inhibition, metabolism and CYP inhibition. Apply appropriate MedChem risk mitigation strategies as required.</li> <li>● Conduct pharmacokinetic experiments on representative compounds to investigate IVIVC and provide support for a reasonable expectation of achieving robust oral bioavailability (demonstrate F &gt; 50% in Rat) and long half-life in human (target for Rat t1/2 &gt;8h).</li> <li>● Conduct all necessary studies required to profile one or more frontrunners against the MMV Early Lead criteria, including oral efficacy in an in-vivo model of malaria.</li> <li>● Establish a clear path for IP.</li> </ul>
<b>Project Detail</b>	<a href="https://www.ghitfund.org/investment/portfoliodetail/detail/204/en">https://www.ghitfund.org/investment/portfoliodetail/detail/204/en</a>

S2022-231

<b>Project Title</b>	Screening project between Daiichi Sankyo RD Novare and TB Alliance
<b>Collaboration Partners</b>	Daiichi Sankyo RD Novare Co., Ltd. and The Global Alliance for TB Drug Development (TB Alliance)
<b>Disease</b>	Tuberculosis
<b>Intervention</b>	Drug

<b>Stage</b>	Hit Identification
<b>Awarded Amount</b>	¥15,297,090 (US\$0.1 million)
<b>Status</b>	New project
<b>Summary</b>	Screening project between Daiichi Sankyo RD Novare and TB Alliance
<b>Project Detail</b>	<a href="https://www.ghitfund.org/investment/portfoliodetail/detail/206/en">https://www.ghitfund.org/investment/portfoliodetail/detail/206/en</a>

\*All amounts are listed at the exchange rate of USD1 = JPY136.34, the approximate exchange rate on February 28, 2023.

#### Appendix.2 Investment Overview (As of March 13, 2023)

##### Investment to date

Total investments 28.7 billion yen (US\$210 million<sup>1</sup>)

Total invested projects 116 (active projects 51 completed projects 65)

To know more about GHIT 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>