

GHIT Fund Announces New Investments: A Total of 790 Million Yen for Product Development of Neglected Tropical Diseases

TOKYO, JAPAN (November 11, 2022)—The Global Health Innovative Technology (GHIT) Fund announced today a total of approximately 790 million yen (US\$5.3 million*) to invest in product development for lymphatic filariasis and onchocerciasis, two neglected tropical diseases (NTDs).** (Appendix 1)

"Even in the midst of a pandemic, GHIT Fund is committed to advancing product development to contribute to global health with Japanese technologies and innovation for patients suffering from neglected diseases by strengthening partnerships with product development partners and funding partners." said Dr. Osamu Kunii, CEO of GHIT Fund.

Neglected tropical diseases caused by parasitic infection: New drug development for lymphatic filariasis and onchocerciasis

Lymphatic filariasis (elephantiasis) and onchocerciasis (river blindness) are two neglected tropical diseases that are caused by parasitic worms. These diseases affect more than 86 million people globally. Existing drugs principally target the young worms and not the adult worms. This means that sustained and prolonged delivery with high treatment coverage to endemic communities is required to break the transmission cycle of the long-living adult worms.

Through an investment project by the GHIT Fund, which started in 2013, the project team has already demonstrated that adult worms can be killed by eliminating a symbiotic bacterium that they contain, called Wolbachia.

This time, approximately 790 million yen (US\$5.3 million*) will be invested to continue the development of the new drug through a Phase II clinical trial to evaluate its efficacy in patients suffering from onchocerciasis.

As of November 11, there are 61 ongoing projects, including 28 discovery, 20 preclinical and 13 clinical trials in the GHIT portfolio (Appendix 2). The total amount of investments since 2013 is 28.4 billion yen (US\$191 million).

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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

^{*} USD1 = JPY¥148.28, the approximate exchange rate on October 31, 2022.

^{**} These awarded projects were selected from a number of proposals to the RFP2022-001 for Target Research Platform, Screening Platform, Hit-to-Lead Platform, and Product Development Platform, which was open for applications from November 2021 to July 2022. The GHIT board conducted in July 2022 approved these new investments.



Global Health Innovative Technology Fund

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

G2022-102

Project Title	Phase II Clinical Development of AWZ1066S, a Small Molecule anti-Wolbachia Candidate Macrofilaricide Drug
Collaboration Partners	Eisai Co. Ltd., Liverpool School of Tropical Medicine (LSTM), University of Liverpool (UoL), University Hospital of Bonn (UKB), University of Buea (UoB)
Disease	Lymphatic filariasis/Onchocerciasis
Intervention	Drug
Stage	Clinical Development (Phase II)
Awarded Amount	¥796,004,431 (US\$5,368,252)
Status	Continued project
Summary	 [Project objective] The objective of this project is to continue the development of this drug candidate further by completing a Phase II clinical trial to assess its effectiveness in patients suffering with onchocerciasis. This is an essential step in the development of a new drug and brings us closer to a new treatment for these diseases. [Project design] The project will involve: Completion of essential preclinical safety studies prior to the start of the clinical trial Completion and registration of the clinical trial protocol Completion of the Phase II trial in line with international requirement for the licensing of new drugs.
Project Detail	https://www.ghitfund.org/investment/portfoliodetail/detail/203/en

*All amounts are listed at the exchange rate of USD1 = JPY¥148.28, the approximate exchange rate on October 31, 2022.



Appendix.2 Investment Overview (As of November 11, 2022)

1. Investment to date

Total investments 28.4 billion yen (US\$191 million*)

Total invested projects 114 (active projects 61, completed projects 53)

2. Portfolio analysis (active projects + completed projects)



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To know more about GHIT 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>