

Press Release

Investment of Approx. USD 4.5 Million in Development of Diagnostics for Tuberculosis to Partners including Fujirebio and University Hospital Heidelberg

TOKYO, JAPAN (April 23, 2025) — The Global Health Innovative Technology (GHIT) Fund announced today an investment of approximately JPY 679 million (USD 4.5 million¹) for the development of diagnostics for tuberculosis, in addition to an investment approximately JPY 15.9 million (USD 0.1 million¹) for a drug discovery project for Chagas disease and leishmaniasis.²

Investment of approximately JPY 679 million (USD 4.5 million¹) for the development of diagnostics for tuberculosis

Tuberculosis (TB) remains a serious infectious disease, with approximately 10.8 million cases and 1.25 million deaths reported in 2023, making it the leading causes of death from a single infectious agent.³ The United Nations' Sustainable Development Goals (SDGs) set a target to end TB by 2030, but achieving this goal requires accurate and accessible diagnostic technologies. Current TB tests face challenges such as low sensitivity, high costs, complexity, and the need for specialized equipment and sputum samples, making them unsuitable for all patients. In particular, children, people with conditions who cannot produce sputum, and those in resource-limited settings often struggle to receive timely diagnoses, causing the continued spread of the disease. To address this issue, the GHIT Fund has decided to invest approximately JPY 679 million (USD 4.5 million¹) towards a new TB diagnostic development project by US-based diagnostic developer Fluxus, Inc.,⁴ in partnership with Fujirebio, Inc., a developer of clinical diagnostics in Japan,⁴ and Heidelberg University Hospital in Germany.

This project will leverage Fluxus' cutting-edge ultrasensitive detection technology to develop and validate a urine-based TB biomarker lipoarabinomannan (LAM) assay on its automated benchtop immunoassay analyzer. Additionally, the project will design and develop critical components for a portable, ultrasensitive point-of-care (PoC) system that integrates the urine LAM test. This advanced technology will enable rapid, accurate, and accessible diagnosis across a broader patient population, contributing to improved clinical outcomes and reduced transmission.

In addition, the GHIT Fund will invest approximately JPY 15.9 million (USD 0.1 million¹) in a screening project against Chagas disease and leishmaniasis by Kitasato University, Nagasaki University, University of Tokyo, and Drugs for Neglected Diseases initiative (DNDi).

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

As of March 31, 2025, the GHIT Fund has invested in 36 projects, including 15 discovery projects, 12 preclinical projects, and 9 clinical trials.⁵ The total amount of investments since 2013 is JPY 38.2 billion (USD 255 million¹) (Appendix 2).



¹ USD1 = JPY149.53, the approximate exchange rate on March 31, 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 Screening Platform, which were open for applications from June 2023 to July 2024.

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

⁴ Fluxus, Inc. and Fujirebio, Inc. are members of Fujirebio.

⁵ This number includes 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 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

ID: G2023-204

Project Title	Ultrasensitive Detection of Urine LAM for Point-of-Care Rapid Diagnosis of All Forms of Tuberculosis
Collaboration Partners	1. Fluxus, Inc. (USA) 2. Fujirebio, Inc. (Japan) 3. Heidelberg University Hospital (Germany)
Disease	Tuberculosis
Intervention	Diagnostics
Stage	Product Design, Product development
Awarded Amount	JPY 679,783,110 (USD 4.54 million)
Status	New project
Summary	<p>[Project objective] To develop a prototype portable point-of-care (PoC) system and integrated ultrasensitive assay for detection of Lipoarabinomannan (LAM) in urine. The test will be benchmarked to a fully-validated ultrasensitive urine LAM assay being developed on Fluxus' automated benchtop immunoassay analyzer.</p> <p>[Project design] The project objectives will be achieved by performing the following Specific Aims: 1) Complete development and validation of an ultrasensitive urine LAM assay on an existing benchtop immunoassay analyzer. This assay will be adapted and transferred to a stable and cost-effective PoC cartridge format. 2) Design and development of critical components for a portable, ultrasensitive PoC system, with functional cartridge and prototype PoC LAM assay.</p>
Project Detail	https://www.ghitfund.org/investment/portfoliodetail/detail/240/en

ID: S2024-122

Project Title	Searching for Chagas disease therapeutic seed compounds from microbial cultures
Collaboration Partners	1. Kitasato University (Japan) 2. Nagasaki University (Japan) 3. University of Tokyo (Japan) 4. Drugs for Neglected Diseases initiative (DNDi) (Switzerland)
Disease	Chagas disease / Leishmaniasis
Intervention	Drug
Stage	Screening
Awarded Amount	JPY 15,945,864 (USD 106,639)
Status	New project
Summary	<p>[Project objective] The main objective of our proposed project is to identify novel <i>T. cruzi</i> active scaffolds meeting GHIT/DNDi hit criteria and amenable for further development by screening microbial cultured broths with a natural product chemistry approach. We aim at characterizing at least five <i>T. cruzi</i> new chemical templates unprecedentedly associated with <i>T. cruzi</i> activity over an 18-month work period. We will also opportunistically evaluate the anti-<i>Leishmania donovani</i> activity of any antichagasic agent to be identified in the course of the project.</p> <p>[Project design] In this project, three academic institutions (Kitasato University, Nagasaki University, and the University of Tokyo) and DNDi will utilize their expertise to identify at least five seed compounds for Chagas disease therapeutics produced by microorganisms in a one-and-a-half-year research period. The seed compounds for Chagas disease therapeutics to be identified during the project will also be assessed for their activity against <i>Leishmania donovani</i>, which causes visceral leishmaniasis, to verify their drug potential.</p>
Project Detail	https://www.ghitfund.org/investment/portfoliodetail/detail/241/en

*All amounts are listed at an exchange rate of USD1 = JPY149.53, the approximate exchange rate on March 31, 2025.



Appendix 2. Investment Overview (as of March 31, 2025)

Investments to date

Total investments: 38.2 billion yen (USD 255 million¹)

Total invested projects: 136 (36 active projects and 100 completed projects)

To learn more about the 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>