Fight Neglected Diseases through Partnerships

GHIT Fund

Global Health Innovative Technology Fund

Appendix 1. Project Details

ID: G2025-217

Project Title	Preclinical studies of a novel long-acting injectable which targets malarial electron transport chain for malaria chemoprevention.
Collaboration Partners	1. Shionogi & Co., Ltd. (Japan) 2. Nagasaki University (Japan) 3. Medicines for Malaria Venture (MMV/Switzerland)
Disease	Malaria
Intervention	Drug
Stage	Preclinical
Awarded Amount	JPY 909,639,207 (USD 5.7 million)
Status	Continued project
Summary	[Project objective] A promising preclinical candidate that target malarial electron transport chain was identified in the collaboration among Nagasaki University, Japan Institute for Health Security, Shionogi and Medicines for Malaria Venture (MMV) under the GHIT Fund financial support. The candidate showed promising broad malaria lifecycle intervening activities, useful for prophylaxis and transmission block as well as treatment. This project aims to conduct the CMC (Chemistry, Manufacturing, and Controls) research and development, manufacturing of API and investigational drug product, preclinical development of the candidate, and complete the Clinical Trial Application (CTA) for Phase 1. [Project design] This project aims to complete the CTA for Phase 1 in 2 years. The activities will include the Active Pharmaceutical Ingredient (API) and the formulation research and development, manufacturing of API and investigational drug product, and non-clinical studies to enable CTA.
Project Detail	https://www.ghitfund.org/investment/portfoliodetail/detail/273/en

ID: G2025-213

Project Title	Advancing a NCE with an innovative mode of action to support WHO's Visceral Leishmaniasis (VL) Elimination Strategy in Eastern Africa and Cutaneous Leishmaniasis (CL) globally
Collaboration Partners	1. Drugs for Neglected Diseases initiative (DNDi/Switzerland) 2. Eisai Co., Ltd. (Japan)
Disease	Leishmaniasis
Intervention	Drug
Stage	Clinical Phase I
Awarded Amount	JPY 778,354,588 (USD 4.8 million)

Status	Continued project
Summary	[Project objective] The goal of this project is to advance DNDI-6174, a novel, oral therapeutic compound for the treatment of VL, with a unique mode of action and pan-kinetoplastid profile targeting VL, CL, and Chagas disease through a first-in-human clinical trial. [Project design] Pharmaceutical development efforts will focus manufacturing of the drug products and delivering the clinical trial material (CTM) for the Phase I study. Stability studies for the GMP-1 Drug Substance and the Drug Products will also be continued. The first-in-human Phase I trial will assess the safety and pharmacokinetics of DNDI-6174 through a single ascending dose (SAD) design. The study will begin once all regulatory and ethics approvals in Malaysia have been obtained and will follow international clinical research and data protection standards. The Phase I trial is proposed to take place at Ampang Hospital, Selangor, Malaysia. The SAD study will be randomized, double-blind, and placebo-controlled, enrolling healthy adult men and women. Seven dose-escalating cohorts are planned, starting at 5 mg. Each cohort will begin with sentinel dosing. Participants will undergo intensive safety monitoring, including laboratory tests, vital signs, ECG, Holter monitoring, and assessment of adverse events. A specialized committee will review blinded safety and pharmacokinetic data to determine whether dose escalation can proceed based on predefined stopping rules. DNDi will use dried blood spot (DBS) as a validated and efficient bioanalytical method well suited for future clinical trials in the field. The development of a skin microdialysis method to assess skin drug exposure will support future therapeutic response assessment for CL and post-kala-azar dermal leishmaniasis (PKDL). Population pharmacokinetic modeling will guide dose selection for later study phases. DNDi clinical and safety staff will be based in Malaysia to support trial oversight and ensure high-quality implementation. Early foetal development studies and initiation of PBPK modelling are included to rapidly allow a go/no-go decision for the inclusion of pregnant women and possibly relax constraints on contraception later in the clinical development and guide combination therapy and co-medication strategies.
Project Detail	https://www.ghitfund.org/investment/portfoliodetail/detail/274/en

ID: G2025-216

Project Title	A Phase 1 Clinical Trial Assessing the Safety and Pharmacokinetics of a *Plasmodium falciparum* Circumsporozoite Protein (CSP) Monoclonal Antibody in Healthy Malaria-Naïve Adults
Collaboration Partners	1. PATH (USA) 2. Ehime University (Japan) 3. GlaxoSmithKline (GSK/UK)
Disease	Malaria
Intervention	Drug
Stage	Clinical Phase1

Awarded Amount	JPY 584,238,711 (USD 3.6 million)
Status	Continued project
Summary	[Project objective] The goal of this project is to secure a WHO policy recommendation and financing for a mAb that prevents *P. falciparum* malaria in children younger than 3 years of age living in sub-Saharan Africa. The use of this intervention could be expanded to 6–10-year-old children and pregnant women, the other two target populations with the greatest morbidity and mortality from malaria. Our initial use-case is induction of high-level protection with a single SC dose prior to the rainy season in regions with seasonal malaria transmission. Following completion of G2021-111 and G2023-219 grants, the Partners are now progressing to perform a first-in-human (FIH) Phase 1 clinical study to evaluate the safety and pharmacokinetics (PK) profile of the mAb in healthy adults. The GSK-TC-001 mAb, the precursor of which was isolated from an RTS,S/AS01 vaccinated and protected clinical study volunteer, has been engineered to confer half-life extension and enhanced Fragment crystallizable (Fc) receptor function, and has undergone a selection process for safety and biological activity. With GHIT support (G2021-111 and G2023-219), we have manufactured a pre-master cell bank, developed upstream and downstream processes, manufactured a lot suitable for toxicological evaluations, and successfully conducted a good laboratory practice toxicology study. With the subsequent funding (G2023-219), we manufactured drug substance and drug product lots, prepared reagents for human PK and anti-drug antibody (ADA) assays needed in clinical studies and are currently preparing the application to seek competent regulatory authorities' approval for the FIH study. [Project design] This project will advance the clinical development of the monoclonal antibody GSK-TC-001 through completion of a first-in-human (FIH) Phase 1 study, development of exploratory functional assays, and preparation for subsequent Phase 2 clinical evaluation. Objective 1: Complete a Phase 1 safety, tolerability, and PK study. A FIH Phase 1a clinical trial will evaluate the safety, tolerability, PK, and immunogenicity of GSK-TC-001 in healthy, malaria-naïve adults. Regulatory, ethics, and site preparation activities will be completed in advance to minimize delays. Participants will be enrolled into sequential dose-escalation cohorts receiving single SC or IV doses, with placebo controls. Participants will be followed for up to 52 weeks following dosing. PK and ADA analyses will inform dose selection and feasibility of a subsequent Phase 2) study. Successful completion will support a Phase 1 go/no-go decision. Objective 2: Develop exploratory functional assays to support the clinical program. Feasibility of functional assays aligned with the mechanism of action of GSK-TC-001 will be assessed, including reagent sourcing and pilot testing. Selected assays will undergo development and qualification to support future clinical sample testing, with the goal of identifying at least one assay fit for purpose. Objective 3: Prepare for subsequent Phase 2 clinical development. Preparatory activities will assess Phase 2 development pathways, including the potential role of CHMI studies, selection of study populations, availability of reagents, and alignment with the evolving malaria intervention landscape. This work will culminate in a draft protocol synopsis, partner shortlist, and updated integrated

	Product Development Plan (iPDP) to enable rapid progression to the next clinical stage.
Project Detail	https://www.ghitfund.org/investment/portfoliodetail/detail/275/en

ID: G2025-113

Project Title	Integrated Diagnostic Enabled by Artificial Intelligence Digital Pathology for Soil-Transmitted Helminths and Schistosomiasis (IDxAID)
Collaboration Partners	1. Enaiblers AB (Sweden) 2. Niigata University of Pharmacy and Medical and Life Sciences (Japan) 3. Niigata University (Japan) 4. Asahikawa Medical University (Japan) 5. QIMR Berghofer Medical Research Institute (Australia)
Disease	Soil-Transmitted Helminths and Schistosomiasis
Intervention	Diagnostics
Stage	Product development
Awarded Amount	JPY 349,778,099 (USD 2.1 million)
Status	New project
Summary	[Project objective] Deliver and validate a field-ready diagnostic platform for parasitic worm infections (soil-transmitted helminths and schistosomiasis) that is accurate, fast, and affordable, and aligned with WHO guidance for monitoring, evaluation, and surveillance. The project will generate the clinical, analytical, and operational evidence required to progress toward regulated medical device status and responsible, wide-scale adoption. [Project design] The platform centers on a rugged, portable digital microscope built for places with limited or no electricity, and scans standard stool and urine slides and uses AI to highlight likely parasite eggs so a trained user can quickly confirm them on screen. The end-to-end workflow supports monitoring programs: start a survey, enter participant details, track samples, verify AI findings, automatically calculate how heavy the infection is, and share clear dashboard summaries with health teams. Over the project, we will finalize the design, refine hardware and software, train and validate AI models to identify target schistosome and soil-transmitted helminth species, set up certified quality processes, obtain manufacturing approvals, and produce pilot units. IDxAID will then run real-world field studies in Zanzibar (Tanzania), Lao PDR, Cambodia, The Philippines, Brazil, and Peru.
Project Detail	https://www.ghitfund.org/investment/portfoliodetail/detail/276/en

ID: H2025-204

Project Title	A Hit-to-Lead Optimization of Novel Antiviral Compounds for Flavivirus Infections

Collaboration Partners	1. Eisai Co., Ltd. (Japan) 2. Drugs for Neglected Diseases Initiative (DNDi/Switzerland) 3. Japan Institute for Health Security (JIHS/Japan)
Disease	Dengue /Zika
Intervention	Drug
Stage	Lead Identification
Awarded Amount	JPY154,868,833 (USD 0.9 million)
Status	Continued project
Summary	[Project objective] The goal of this project is to develop lead compounds that can reduce replication of dengue and Zika viruses using hit compounds identified in the earlier screening project as a starting point. We aim to improve the antiviral activity of the hit compounds and refine important drug-like properties such as solubility, lipophilicity, metabolic stability, and safety. By the end of the project, we aim to have identified compounds that lower the viral load in pre-clinical models and show enough promise to move forward to the next stage of drug development. [Project design] To improve the efficiency of compound optimization, we will use an AI-supported medicinal chemistry approach that enables rapid and iterative cycles of compound design, synthesis, evaluation, and AI model refinement. In each cycle, biochemical and cell-based antiviral activities, and data on solubility, lipophilicity, and metabolic stability will be used to guide the next round of compound design. As we accumulate more data, AI modelling will improve accuracy and support the identification of more promising compounds to synthesize. In addition, Drugs for Neglected Diseases initiative (DNDi) will perform advanced antiviral evaluations and early safety assessments, while Japan Institute for Health Security (JIHS) will evaluate compound efficacy against different viral strains and host cell-lines. These studies will help us assess the consistency and reliability of the efficacy of each compound as potential treatments for flavivirus infection. Promising compounds will be further evaluated in pre-clinical models, and these studies will assist in identifying lead compounds for further development.
Project Detail	https://www.ghitfund.org/investment/portfoliodetail/detail/277/en

ID: H2025-202

Project Title	Lead development of a novel anti-tuberculosis agent with activity against drug-resistant TB and potential to shorten treatment by targeting mycobacterial dormancy
Collaboration Partners	1. Niigata University (Japan) 2. The Global Alliance for TB Drug Development, Inc. (TB Alliance/USA)
Disease	Tuberculosis
Intervention	Drug
Stage	Lead Identification

Awarded Amount	JPY 87,594,013 (USD 0.5 million)
Status	New project
Summary	[Project objective] The team discovered a protein capable of inducing bacterial dormancy and subsequently identified novel compounds through a search for molecules that strongly bind to the protein. Compounds were effective against actively growing *M. tuberculosis*, and its activity was further enhanced under conditions in which many *M. tuberculosis* enter the dormant state. If a therapeutic agent can be developed that acts on both actively replicating and *M. tuberculosis* bacilli, it should contribute not only to the treatment of drug-resistant tuberculosis but also to shorter treatment durations and prevention of disease relapse, ultimately leading to the fundamental control of tuberculosis. Previous research for this study was supported by AMED under Grant Number JP16nk0101351 and 23gm1610009h. In this project, we aim to scientifically and comprehensively evaluate whether this newly identified compound has sufficient potential to serve as a future lead compound for tuberculosis drug development. [Project design] In this project, we will conduct a series of stepwise evaluations to assess the drug discovery potential of candidate compounds. First, compounds produced by actinomycetes will be purified, and their derivatives will be chemically synthesized. Physicochemical properties of the compounds will then be evaluated, including solubility and lipophilicity under physiological conditions. In addition, membrane permeability and the presence of efflux will be examined. Next, pharmacokinetic-related properties will be assessed by measuring plasma protein binding and determining the unbound fraction. Metabolic stability studies will be performed using liver microsomes and hepatocytes to evaluate fundamental in vivo disposition characteristics. For safety assessment, potential off-target inhibitory effects will be examined, together with cardiac safety evaluation using hERG inhibition assays. Genotoxicity will also be assessed through Ames tests and in vitro micronucleus assays. Based on these fundamental evaluations, promising compounds will be advanced to efficacy studies using a mouse tuberculosis infection model to verify in vivo anti-tuberculosis activity.
Project Detail	https://www.ghitfund.org/investment/portfoliodetail/detail/278/en

*All amounts are listed at an exchange rate of USD 1 = JPY 159.38, the approximate exchange rate on May 29, 2026.