

# GHIT Fund ANNUAL REPORT 2018











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# Reaching New Heights

The 2018 fiscal year begins GHIT's second five-year phase of operations after our successful replenishment in 2017. We are pleased to report on our progress and performance, made possible by our partner's unwavering efforts and commitment toward developing game-changing innovations for global health. We are thrilled to be closer than ever to graduating innovative clinical candidates from our portfolio and putting them into the hands of those who need them most.

Since its 2013 establishment, GHIT has catalyzed the research and development (R&D) of new global health innovations for neglected patients by facilitating cross-sector partnerships between Japanese and non-Japanese entities. GHIT has invested USD 170M in 80 projects to date; currently, 22 discovery projects, 14 preclinical projects, and 8 clinical trials are under way in low- and middle-income countries (LMICs). Our most advanced clinical candidates include a urine-based rapid tuberculosis (TB) diagnostic kit (P.09-10), a pediatric formulation

of the gold-standard drug for schistosomiasis (P.11-12), and a long-lasting mycetoma drug (P.13-14). It is consistently clear to us that our development partners and co-investors share our mission, passion, and sense of urgency to progress. We are committed to the registration of two products from our portfolio by 2022.

Because we recognize that innovation is valueless without access, we also remain committed to the integration of access at every step of the R&D process. In keeping with this core piece of our institutional DNA, this past year we co-launched—together with the Government of Japan and the Access Delivery Partnership led and coordinated by the United Nations Development Programme (UNDP)—“Uniting Efforts for Innovation, Access and Delivery,” a platform for dialogue and collaboration among key stakeholders involved in innovation, access, and delivery of health technologies for unmet health needs in LMICs (P.17-18).



All of these achievements build important momentum for the year ahead. In 2019, Japan will host its first G20 Summit, including the first-ever meeting between health and finance ministers, as well as the Tokyo International Conference on African Development VII. Both convenings represent critical milestones for Japan's and GHIT's leadership in global health and significant opportunities to further strengthen and expand R&D and access partnerships. The UN High-Level Meeting on Universal Health Coverage (UHC) in September 2019 also provides a critical opportunity for Japan to show its leadership in this area and increase momentum toward attaining UHC across the globe.

We are so grateful for the skill, passion, and steadfast commitment that every single one of our governors, funding partners, and development/access partners actively brings to the table every day. They motivate us to reach higher, work better, and keep pushing toward our vision.



中谷 比呂樹

Hiroki Nakatani

Board Chair & Representative Director



BT Slingsby

CEO & Executive Director  
(through March 31, 2019)

# Advancing Portfolio

## Discovery

## Preclinical

Drugs / Vaccines

Target Research

Screening

Hit-to-Lead

Preclinical

Diagnostics

Target Research

Product Design



Malaria



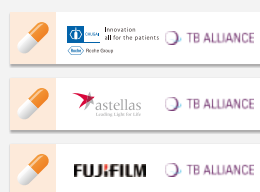
▶P16



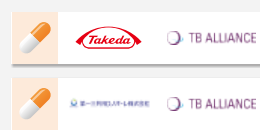
Tuberculosis



▶P15



▶P15



Neglected Tropical Diseases

Chagas disease, Leishmaniasis



Dengue fever



Leishmaniasis



▶P16

Chagas disease



Leishmaniasis



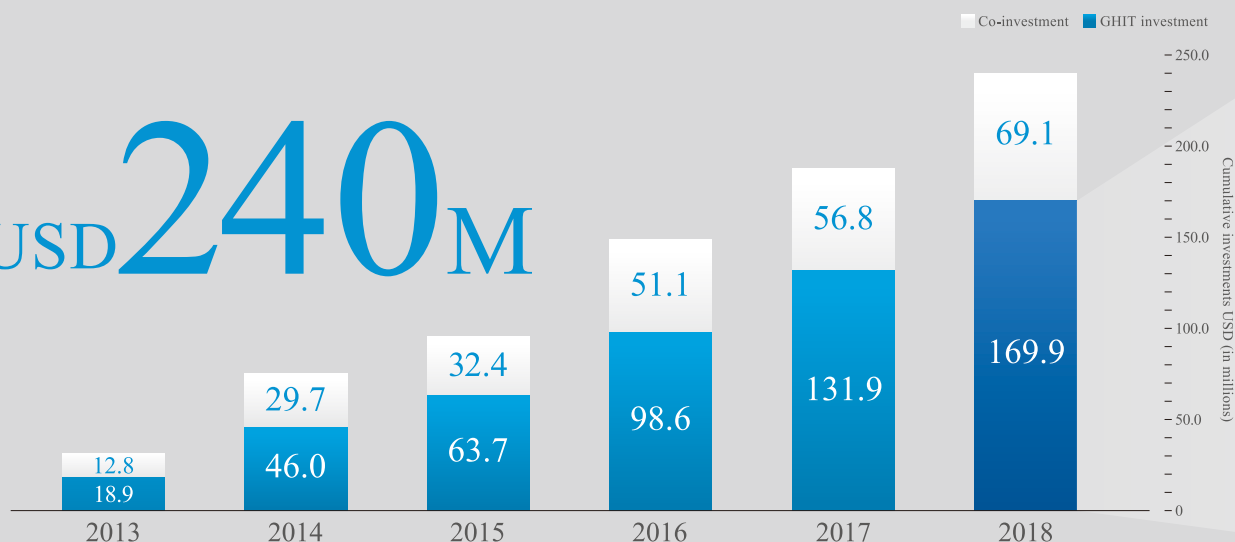
Schistosomiasis



Soil-transmitted helminthiasis




















































USD 240M



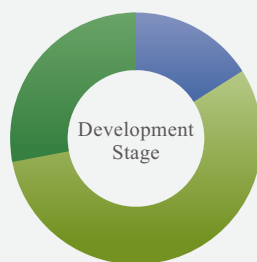
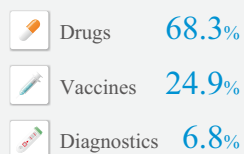
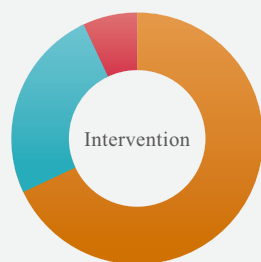
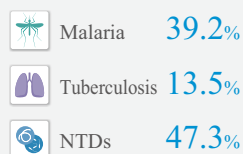
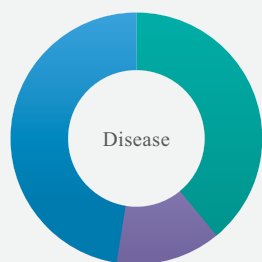
US dollar amounts represent conversions from Japanese yen, solely for the reader's convenience, at JPY 100 = USD 1.

As of March 2019

## Clinical

	Phase I	Phase II	Phase III	Registration
	Product Development	Product Validation	Product Validation	Registration
     	     	     		
		     		   <a href="#">▶ P09-10</a>
        		<p>Chagas disease</p>    <p>Mycetoma</p>    <a href="#">▶ P13-14</a>	<p>Schistosomiasis</p>        <a href="#">▶ P11-12</a>	

## Investment Overview FY2013-FY2018



80

Total invested partnerships

44 Active investments  
36 Completed investments

114

Total product development partners

43 Japanese partners  
71 Non-Japanese partners



# Clinical Candidates



## SJ733

Disease: Malaria  
Intervention: Drug  
Development Stage: Phase IIa  
Country: To be determined

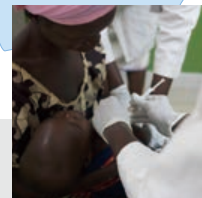
SJ733 is a chemically novel and potent antimalarial candidate, based on a dihydroisoquinolone platform and featuring good oral availability, excellent safety tolerability, and a low propensity for resistance. The trial plans to test SJ733 in combination therapy to target special needs groups (children and pregnant women).



## BK-SE36/CpG

Disease: Malaria  
Intervention: Vaccine  
Development Stage: Phase Ib  
Country: Burkina Faso

This trial will assess the safety and reactogenicity of three doses of malaria vaccine candidate BK-SE36, formulated with TLR9 ligand adjuvants K3 CpG oligodeoxyribonucleotides (K3 CpG-ODN) in healthy African adults and children exposed to the Plasmodium falciparum parasite.



## DSM265

Disease: Malaria  
Intervention: Drug  
Development Stage: Phase IIb  
Country: To be determined

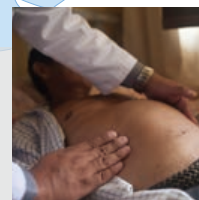
DSM 265 is a novel antimalarial candidate anticipated to become a single exposure radical cure and prophylaxis (SERCaP) product. The trial aims to optimize oral formulation and lower the administration volume for pediatric use.



## E1224

Disease: Chagas disease  
Intervention: Drug  
Development Stage: Phase IIb  
Country: Bolivia

This trial compares the safety and efficacy of oral Fosravuconazole (E1224, a water-soluble ravuconazole prodrug) regimens with benznidazole in adults with chronic, indeterminate Chagas disease. The novel candidate treatment regimen is oral, easy to use, safe, and affordable.



## Bolivia

E1224 Chagas disease/Drug





## E1224

Disease: Mycetoma  
Intervention: Drug  
Development Stage: Phase IIb  
Country: Sudan

This trial tests whether Fosravuconazole (E1224), an azole-class antifungal drug discovered by Eisai, may also be an effective and affordable treatment for mycetoma. The trial is being conducted with the WHO Collaborating Center on Mycetoma in Khartoum.



►P13-14



## PZQ

Disease: Schistosomiasis  
Intervention: Pediatric Drug  
Development Stage: Phase III  
Countries: Côte d'Ivoire, Kenya, Zimbabwe

The Pediatric Praziquantel Consortium developed the pediatric formulation of the gold-standard drug for schistosomiasis to address the unmet medical needs of infected preschool-age children. The formulation under investigation is smaller, exhibits an improved palatability, and is orally dispersible, in contrast to the current commercial formulation.



►P11-12

## Burkina Faso

BK-SE36/CpG Malaria/Vaccine

## Sudan

E1224 Mycetoma/Drug

## Côte d'Ivoire

PZQ Schistosomiasis/Pediatric Drug

## Kenya

PZQ Schistosomiasis/Pediatric Drug

## Tanzania

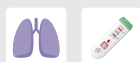
DAR-901 TB/Vaccine

## Zimbabwe

PZQ Schistosomiasis/Pediatric Drug

## South Africa

TB-LAM TB/Diagnostic



## TB-LAM

Disease: Tuberculosis  
Intervention: Diagnostic  
Development Stage: Product validation  
Country: South Africa

This project aims to develop a highly sensitive, rapid point-of-care TB test to diagnose the disease from urine in high-risk, HIV-infected individuals. Product validation studies based on samples from South African townships are under way.



►P09-10



## DAR-901

Disease: Tuberculosis  
Intervention: Vaccine  
Development Stage: Phase IIb  
Country: Tanzania

DAR-901 is the only novel TB booster vaccine candidate based on inactivated whole cell derived from Mycobacterium obuense that has shown efficacy in humans. The DAR-PIA trial will be a Phase II study of the DAR-901 booster conducted among 13-15 year old adolescents in Tanzania.



# SILVAMP™ TB-LAM

Novel, urine-based, point-of-care TB test for people living with HIV in low-resource settings

## One of the three most deadly infectious diseases the world has ever known

TB infects 10 million people and kills 1.6 million annually.<sup>1</sup> The dire socioeconomic consequences of this disease can drive entire countries into poverty. Patients and their families endure severe stigma, and many are unable to work. This, coupled with the significant cost of treatment, contributes to a vicious circle for millions across the globe. 87% of all TB patients live in Africa and Southeast Asia, but the disease affects every country in the world. Drug-resistant TB is a major global public health threat.

The combination of HIV and TB is particularly lethal, with each speeding the other's progress. People living with HIV are up to 30 times more likely to develop TB than those who are HIV negative. The World Health Organization (WHO) estimates that 57% of TB cases among people living with HIV are not diagnosed or treated.<sup>2</sup>

## Need for diagnostic innovation

Currently, TB diagnosis is made primarily based on sputum analysis. However, because 20–60% of HIV-positive patients presenting for TB diagnosis are unable to produce a sputum sample, many patients cannot be diagnosed in time, which results in high morbidity and high mortality. The United Nations' Sustainable Development Goals (SDGs) and End TB Strategy call for reducing TB mortality rates by 90% and infection rates by 80% by 2030. To do this, the world needs a non-sputum based, rapid diagnostic tool that can be used in LMICs and is effective for use with HIV-positive patients.

## Leveraging Japanese photograph processing technology to transform diagnosis

GHIT has since 2016 invested in a partnership between FUJIFILM Corporation and the Foundation for Innovative New Diagnostics (FIND) to develop the SILVAMP™ TB-LAM, a rapid, low-cost TB diagnostic with high sensitivity and specificity. Instead of sputum, the

SILVAMP™ TB-LAM uses patients' urine to diagnose TB, detecting low concentrations of LAM (lipoarabinomannan), which is found in the cell walls of mycobacterium tuberculosis.<sup>3</sup> The partnership successfully leverages FUJIFILM's proprietary silver halide amplification technology, originally developed for processing photographs, to create highly sensitive immunochromatography, which is capable of detecting viruses and bacteria. The SILVAMP™ TB-LAM is simple to use and does not depend on special equipment or require a stable power source. Therefore, this innovative diagnostic kit has the potential to be a game-changing solution for detecting TB in endemic areas.

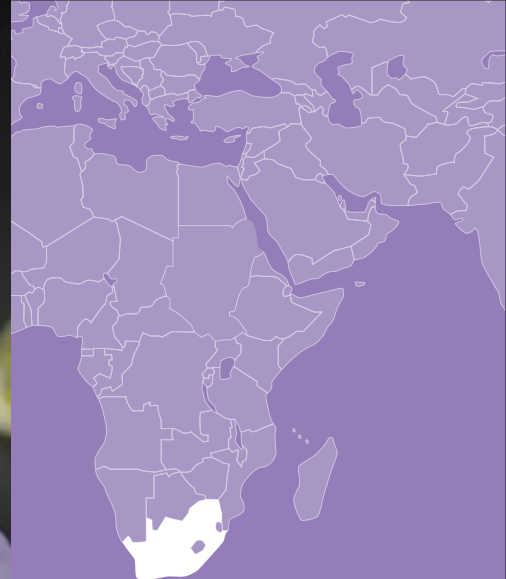
## Clinical and regulatory progress

The SILVAMP™ TB-LAM complies with health, safety, and environmental protection standards for products sold in the European Economic Area and was CE marked in November 2018. To obtain WHO endorsement to use the test for TB diagnosis in HIV-positive patients in LMICs, the product is undergoing a validation studies to perform prospective evaluations in settings of intended use and to generate the required evidence for WHO policy development. The partnership has also facilitated the SILVAMP™ TB-LAM's transition to volume manufacturing.

### References

1. [https://www.who.int/gho/tb/epidemic/cases\\_deaths/en/](https://www.who.int/gho/tb/epidemic/cases_deaths/en/)
2. [https://www.who.int/hiv/topics/tb/about\\_tb/en/](https://www.who.int/hiv/topics/tb/about_tb/en/)
3. [http://www.fujifilm.com/news/n180927\\_02.html](http://www.fujifilm.com/news/n180927_02.html)





## South Africa



Disease: Tuberculosis

Intervention: Diagnostic

Development Stage: Product validation

Country: South Africa

*"FUJIFILM has applied its technology and knowledge originally developed for photograph processing into problem solving in health and medicine. the SILVAMP™ TB-LAM is suitable for resource-limited countries with unreliable power, and it delivers rapid and accurate results by simply placing a urine sample into a cartridge that does not require electricity. We believe this will be a game-changing tool for the patients and healthcare professionals who fight against tuberculosis."*



### **Kaoru Terashima**

Corporate Vice President, In Vitro Diagnostics, FUJIFILM Corporation

*"We are proactively working on R&D and access issues every day to develop better innovations and deliver to those who are in need. There's nothing that could make us happier than knowing that our diagnostics are being utilized in the clinical settings in LMICs and are contributing to health for as many people as possible."*



### **Junichi Katada**

Manager, Research & Development Management Headquarters,  
Medical Systems Research & Development Center, FUJIFILM Corporation

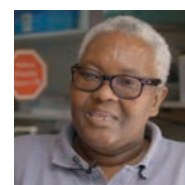
*"The SILVAMP™ TB-LAM has already shown great potential in identifying TB in people who are HIV positive – this could be the first of a new generation of rapid tests that could transform TB diagnosis for all. Early diagnosis enables faster linkage to treatment, which positively impacts patients, their families, and everyone around them. Simply speaking, lives are saved."*



### **Catharina Boehme**

CEO, FIND

*"Currently, diagnostic testing is not easily accessible, sometimes not affordable, and results often takes too long. Results from sputum-based TB diagnoses take labs several days to turn around. On the other hand, the SILVAMP™ TB-LAM uses patient urine samples and is very easy to use; results are ready within one hour. If a test result is positive, patients can receive lifesaving treatment that same day."*



### **Caroline Mateben**

Research Nurse, Medical Microbiology, University of Cape Town

## Product Development Partners



# Pediatric Praziquantel (PZQ)

## A new pediatric formulation of the gold-standard drug for schistosomiasis

### Schistosomiasis: the pediatric challenge

Endemic in 78 countries, schistosomiasis, also known as "bilharzia and snail fever," is a water-borne disease that affects nearly 240 million people and carries a debilitating health, economic, and social footprint, particularly for children and their families. Exposure leaves these children vulnerable to increased risk for anaemia, stunting, and a reduced ability to learn, although the effects are usually reversible with treatment.<sup>4</sup> Praziquantel (PZQ), the affordable, gold-standard drug, has existed for more than 30 years and transformed the lives of millions of adults and school-aged children.

Treatment for preschool-aged children has not been implemented due to several key obstacles: difficulty in swallowing and risk of choking give the large-sized commercially available tablets; high rejection rates due to bitter taste when pills are crushed and dispersed in liquids; and potential of under-dosing, which leads to lower effectiveness of crushed tablet suspensions.<sup>5</sup>

### Pediatric PZQ consortium

In response to this unmet need, since 2014 GHIT has invested in a catalytic global public-private consortium of eight partners to develop, register, and provide access to the first pediatric PZQ formulation for schistosomiasis in preschool-aged children. Current partners include Astellas Pharma Inc., Farmanguinhos, Kenya Medical Research Institute, Lygature, Merck KGaA, the Schistosomiasis Control Initiative, the Swiss Tropical and Public Health Institute, and Université Félix Houphouët-Boigny.

### Formulation innovation

Astellas led the initial formulation development during preclinical phases. The resulting pediatric tablets developed by Astellas are about a quarter of the size of the existing commercial PZQ tablets and are orally dispersible (can be taken with or without water). This, together with agents that minimize the bitterness caused by PZQ and improve the taste

of the tablets, helps children swallow more easily, which facilitates compliance and efficacy. After a successful technology transfer from Astellas in Japan to Merck KGaA in Germany and Farmanguinhos in Brazil, and successful clinical trials in South Africa, Tanzania, and Côte d'Ivoire, further formulation development and production process optimization activities were conducted to develop better tablets for the Phase III trials in Kenya and Côte d'Ivoire and future launch. Compared to the PZQ tablets available today, the new formulation contains only levopraziquantel (R-(-)-PZQ) as an active pharmaceutical ingredient. Dextropraziquantel (S-(+)-PZQ), the inactive isomer that contributes to the severe bitter taste, has been removed.

### Clinical progress

In 2019, the Consortium will initiate Phase III trials in preschool-aged children in Côte d'Ivoire, Kenya, and Zimbabwe to test the safety, effectiveness, and acceptability of the new formulation. At the same time, the Consortium is solidifying regulatory, access, and delivery strategies, including incorporation of feedback from regulatory authorities, such as the European Medical Agency and key stakeholders from WHO, and planning for long-term financing and supply chain mechanism to ensure timely and sustainable roll out.

#### References

4. <https://www.who.int/schistosomiasis/disease/en/>
5. World Health Organization. Report of a meeting to review the results of studies on the treatment of schistosomiasis in preschool-age children. Geneva: World Health Organization; 2011.







Côte d'Ivoire

Kenya

Zimbabwe



Disease: Schistosomiasis

Intervention: Pediatric Drug

Development Stage: Phase III

Countries: Côte d'Ivoire, Kenya, Zimbabwe

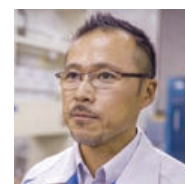
*"Consortium partners, which hail from across sectors and countries, are so committed. No one person or partner could do this alone. We are all experts in drug development but not necessarily in delivering medications to remote parts of Sub-Saharan Africa. Thus, the global community will play a critical role in helping us provide the new drug to the vulnerable children who need it most. We will facilitate a dialogue with the global community to guarantee sustainable access and delivery."*



**Elly Kourany-Lefoll**

Head of Neglected Tropical Diseases Drug Development, Merck KGaA

*"The first time I heard about the project in 2012, I asked myself what I could do for small children as a formulation expert to address the size and bitterness of the existing PZQ tablet. We are proud that Astellas's technology successfully solved these problems. Thinking about the future, and the smiles of the children in Africa who will be impacted by this innovation, we are highly motivated to deliver the product as soon as possible, in partnership with members of the Consortium."*



**Hiroyuki Kojima**

Senior Director, Drug Product Development, Technical Operations, Astellas Institute for Regenerative Medicine

*"This clinical trial is very important. Pediatric PZQ will solve a major problem we have had for a long time; we will finally be able to reach children under 5 years of age. As a government and as a Ministry of Health, we made the policy decision to lend our full support to this trial because it will not only provide a national solution for our country, but also a global solution for the world."*



**Sultani Hadley Matendechero**

Head, Kenya National Neglected Tropical Diseases Program, Ministry of Health

*"Thanks to pediatric PZQ, it will soon be possible to expand schistosomiasis treatment to preschool-aged children – a critical part of the long-term process of eliminating the disease and progressing in line with WHO's NTD roadmap for 2020 and beyond."*



**Amadou Garba**

Scientist, Schistosomiasis Control Programme, WHO Department of Control of Neglected Tropical Diseases

## Product Development Partners



# Fosravuconazole (E1224)

## First-ever double-blind, randomized control trial for mycetoma drug

### One of the most neglected of all tropical diseases

Endemic in numerous tropical and subtropical countries, mycetoma's main victims are poor teenagers and young adults in rural areas. Most cases of mycetoma are reported from the so-called "mycetoma belt," which includes Brazil, Mexico, and Venezuela in Latin America; Chad, Ethiopia, Mauritania, Senegal, Somalia, and Sudan in sub-Saharan Africa; Yemen in the Middle East; and India in Asia, among others.<sup>6</sup> Though cases date back more than 300 years, mycetoma was only added to the WHO's official list of Neglected Tropical Diseases in 2016.

Mycetoma slowly and progressively destroys soft tissue, particularly on the feet. The disease has two forms: Actinomycetoma, caused by bacteria, and Eumycetoma, caused by a fungal infection. Eumycetoma has no effective treatment and is currently managed with sub-optimal, expensive drugs carrying strong side effects and often requiring surgery, including amputation of affected limbs. In rare cases, it affects the lungs or brain and can be fatal. In all cases, patients are unable to work and face severe social stigma. An effective, affordable, and easy-to-administer treatment is urgently needed.

### Clinical Progress

GHIT has invested in a partnership between Eisai Co., Ltd., and the Drugs for Neglected Diseases *initiative* (DNDi), together with the Mycetoma Research Center (MRC), a WHO Collaborating Center in Khartoum, Sudan. This partnership is conducting the world's first double-blind, randomized control Phase IIb Proof of Concept clinical trial in mycetoma, comparing Eisai's Fosravuconazole, originally developed to treat other fungal infections, with the current treatment, itraconazole. Eisai supplied the drug for the clinical study. The trial is taking place in Sudan, the country where the disease is most prevalent and where the government is uniquely committed at the highest levels to addressing this scourge. Fosravuconazole has a proven safety profile and shows strong antifungal activity against mycetoma. This drug, if successful,

would drastically improve patient compliance and reduce costs for individuals and health systems alike.

By January 2019, 84 patients had been enrolled, reaching the threshold for interim analysis to determine the weekly dosage (200mg or 300mg) of Fosravuconazole. Once the analysis has been completed, patient enrollment in the trial is expected to conclude by the end of 2019. Follow-up should conclude in early 2021 to assess the effectiveness of Fosravuconazole as compared to itraconazole.<sup>7</sup>

### Khartoum Call to Action

Working closely with WHO, Sudan's Federal Ministry of Health has led the way in fighting mycetoma internationally. In October 2018, WHO Director-General Tedros Adhanom Ghebreyesus visited the MRC, where he pledged to support more research into mycetoma epidemiology and diagnostics to produce a simple point-of-care test, and called for new, cost-effective medicines and disease control.<sup>8</sup>

At the 6th International Conference on Mycetoma in Khartoum in February 2019, WHO and the MRC launched the Khartoum Call for Action, which was signed by governments of endemic countries and organizations—including GHIT—engaged in mycetoma research and advocacy. The call to action will lead to a greater commitment of support for mycetoma research, diagnosis, treatment, and care.<sup>9</sup>

#### References

6. <https://www.who.int/news-room/fact-sheets/detail/mycetoma>
7. [https://www.dndi.org/wp-content/uploads/2019/02/DNDi\\_Mycetoma\\_2019.pdf](https://www.dndi.org/wp-content/uploads/2019/02/DNDi_Mycetoma_2019.pdf)
8. <http://www.mycetoma.edu.sd/index.php/archive-mrc/146-director-general-of-who-calls-for-more-mycetoma-research-during-visit-to-mycetoma-research-centre>
9. [https://www.who.int/neglected\\_diseases/news/The-Khartoum-Call-for-Action.pdf?ua=1](https://www.who.int/neglected_diseases/news/The-Khartoum-Call-for-Action.pdf?ua=1)





Disease: Mycetoma  
Intervention: Drug  
Development Stage: Phase IIb  
Country: Sudan

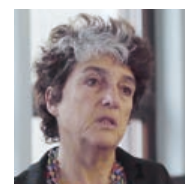
*"Mycetoma patients are the poorest of the poor in the most remote areas. People of low socioeconomic status and manual workers such as agriculturalists, laborers, and herdsmen bear the brunt of the burden. Health and socioeconomic impacts are severe, including significant disability and pain, as well as financial burden, preventing patients and their families from going to school and finding employment. The disease can devastate entire communities. I dream of a world free of mycetoma and the suffering it causes; good solutions for treatment and diagnosis would get us closer."*



#### Ahmed Hassan Fahal

Professor of Surgery, University of Khartoum and Director, MRC

*"There is so much need for funding for R&D for diagnosis and treatment, for epidemiological studies, and for better access to affordable treatment for immediate usage. Partnerships are what is needed to provide solutions and bring patients hope. If we can show good efficacy of fosravuconazole in this clinical trial, that would be a great hope for the patients. It would transform their quality of life."*



#### Nathalie Strub Wourgaft

NTD Director, DNDi

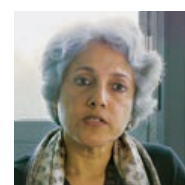
*"As I learned more about mycetoma patients in Sudan, I came to truly recognize the devastating effects of this disease on their daily lives. As a scientist and with these patients—who travel very far and with great difficulty from rural areas to the capital city to receive treatment—top of mind, I re-committed to do whatever I possibly do to deliver a safe, effective drug for them as soon as possible."*



#### Katsura Hata

Senior Director, Global Health Research Section,  
hhc Data Creation Center, Eisai & Co., Ltd.

*"Adding mycetoma to WHO list of NTDs in 2016 helped bring more attention to the disease. It also made us realize how much we still don't know. WHO supports and encourages partners, especially funders, to address mycetoma's root causes and use the modern tools of science to find solutions to this problem."*



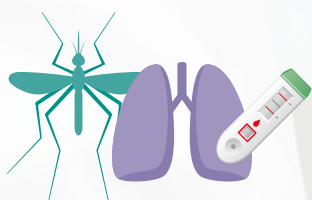
#### Soumya Swaminathan

Chief Scientific Officer, WHO

## Product Development Partners



# New Partnerships FY2018



## Malaria Tuberculosis Diagnostic

### Development of Lateral Flow Assay platform for improving sensitivity of point-of-care assays for malaria and tuberculosis

Asahi Kasei Corporation (Japan) & Biopromic AB (Sweden)



According to the WHO's target product profile for infectious disease diagnostics, a limited number of point-of-care tests are available, meeting a fraction of the demand. This is due to the very low concentration of easily accessible antigens in point-of-care samples. Current Lateral Flow Assay (LFA) devices offer analytical sensitivity above 1-5ng/ml while the concentration of antigens in TB and malaria patients' samples is usually below 100pg/ml. To address the clear need for more sensitive LFA systems, Asahi Kasei and Biopromic AB's project aims to develop a new LFA platform with antigen detection 50 times the current industry standard. Achieving such a high analytical LFA test sensitivity requires significant improvement and integration of multiple components of the LFA system.

<https://www.ghitfund.org/investment/portfoliodetail/detail/140/en>



## Tuberculosis Drug

### Hit-to-Lead development of novel anti-TB natural products

Daiichi Sankyo RD Novare (Japan) & TB Alliance (USA)



This project is the result of a GHIT-funded screening effort by Daiichi Sankyo RD Novare, TB Alliance, and the Research Institute of Tuberculosis at the Japan Anti-tuberculosis Association (RIT/JATA). RIT/JATA evaluated bactericidal activity against TB using Daiichi Sankyo RD Novare's original natural product library, created from microorganisms such as actinomycetes and fungi and consisting of 30,000 extracts and 600 purified natural compounds. After close collaboration, the partners identified a group of hit compounds and subsequently determined the structures of the active components. The active components were further studied for their biological properties, and partners developed a research plan to generate additional fermentation products for structural modifications and biological evaluations. Today, the partners seek to identify lead compounds that can result in effective new TB drugs that feature shorter treatments and cures for both drug-sensitive and drug-resistant TB.

<https://www.ghitfund.org/investment/portfoliodetail/detail/142/en>





## Malaria Drug

### Lead optimization of antimalarials

Mitsubishi Tanabe Pharma Corporation (Japan) & Medicines for Malaria Venture (Switzerland)



Several antimalarial hits from a diverse series of molecules resulted from the screening of Mitsubishi Tanabe Pharma Corporation's approximately 50,000-member library of unique compounds. Development of structure-activity relationships for three series of focus in a hit-to-lead project revealed that one of those series is appropriate for lead optimization. The series is fast-killing, exhibits high antimalarial potency across the lifecycle, and has good physicochemical and pharmacokinetic properties. It also shows efficacy in the mouse model for malaria. The primary objective of this project is to identify between one and three late leads within 18 months, as defined by Medicines for Malaria Venture's progression criteria, and to further profile them in the final six months to select a preclinical candidate capable of progression to first-in-human clinical trials. The second objective is to confirm the proposed mode of action to assess the likelihood that these compounds will have the ability to treat malaria safely in areas of emerging drug resistance.

<https://www.ghitfund.org/investment/portfoliodetail/detail/136/en>



## Leishmaniasis Vaccine

### Immune therapy to prevent visceral leishmaniasis complications

University of Tokyo (Japan), International Center for Diarrheal Disease Research (Bangladesh), and Infectious Disease Research Institute (USA)



Intervention in visceral leishmaniasis (VL; Kala-azar) patients at greatest risk of treatment failure, relapse, or subsequent development of post-Kala azar dermal leishmaniasis (PKDL) is critical for effective disease management. Published data has identified vaccine candidates that are as effective as a prophylaxis in advanced animal models. Project partners will build upon this data to determine the candidate antigen best suited for use in Bangladesh. They will also use a long-term preclinical model of the *L. donovani* infection to develop immune/chemotherapeutic approaches to prevent complications of VL. To develop an effective therapeutic vaccine for VL, selecting the right antigen(s) and adjuvant is important. It is also key that the vaccine does not compromise the effects of chemotherapy. Therefore, this project will comprise three major activities: patient-instructed selection of a vaccine antigen for prevention of PKDL; evaluation of compatibility of vaccines with amphotericin B treatment; and evaluation of immune therapy efficacy in the long-term VL model.

<https://www.ghitfund.org/investment/portfoliodetail/detail/130/en>

# UNITING EFFORTS FOR HEALTH

## INNOVATION – ACCESS – DELIVERY

### A new convening and communication platform

R&D and access are inextricably linked. Yet few opportunities exist for biomedical R&D funders, innovators, and access stakeholders to discuss the common challenges they face and to jointly identify solutions. To address this gap, in January 2019 the Ministry of Foreign Affairs of Japan, UNDP-administered Access and Delivery Partnership (ADP), and GHIT co-hosted the conference entitled “Uniting Efforts for Innovation, Access and Delivery: A Global Dialogue in Bangkok”. The conference engaged more than 100 carefully selected R&D funders, research organizations, product development partnerships, research institutes, and access platforms to discuss challenges and opportunities around the innovation, access, and delivery of health technologies. The dialogue represented a rare and much-needed opportunity for partners across the R&D spectrum, each with essential perspectives and roles.

The event also marked the launch of Uniting Efforts for Innovation, Access, and Delivery—a convening and communication platform to help improve the impact and efficiency of current and future R&D investments and priorities, increase efficiencies and the integration of access considerations into R&D plans at an earlier stage, and



optimize the introduction of new treatments to those most in need.<sup>10</sup> Participants in this inaugural meeting identified numerous specific possibilities for future actions at the global, regional, and national levels.

Thanks to the support of the Government of Japan, GHIT and ADP have been grappling with these issues since 2013, on the one hand driving health technology innovation for malaria, TB, and Neglected Tropical Diseases and on the other strengthening policies, human capacities, systems, and regulations to promote access and delivery. Yet increased R&D





# Uniting Efforts for Innovation, Access and Delivery: A Global Dialogue

30-31 January 2019

WiFi  
Username: UNDP  
Password: UNDP



*“No single country, sector, or organization can solve this problem. Let’s work together, so that patients can access innovative health products as soon as possible. Everyone is part of the solution.”*

**Manabu Sumi**

Director, Global Health Policy Division  
Ministry of Foreign Affairs of Japan

efficiencies do not, on their own, lead to the introduction and use of new health technologies. Greater progress toward Universal Health Coverage and the Sustainable Development Goal targets also require stakeholders across the globe to tackle critical bottlenecks in LMIC health systems and enhance access and delivery mechanisms.

In its first year, the platform is focusing on bringing together key partners to define a common agenda for health technology access and delivery preparedness in LMICs. Over the long term, the aim is to establish a global network of R&D funders, innovators, product development partnerships, and delivery-focused organizations and to evolve this network into a major platform for learning, information exchange, and coordination and collaboration.

Reference  
10. <https://www.unitingeffortsforhealth.org/>



# Co-Investment: Amplifying Impact for Patients

In the same way that successful global health R&D is built on partnership, so, too, is effective funding for that innovation. Indeed, co-investment, where multiple funders and partners collaborate to advance R&D, is a critical approach to amplifying the impact of individual investments.

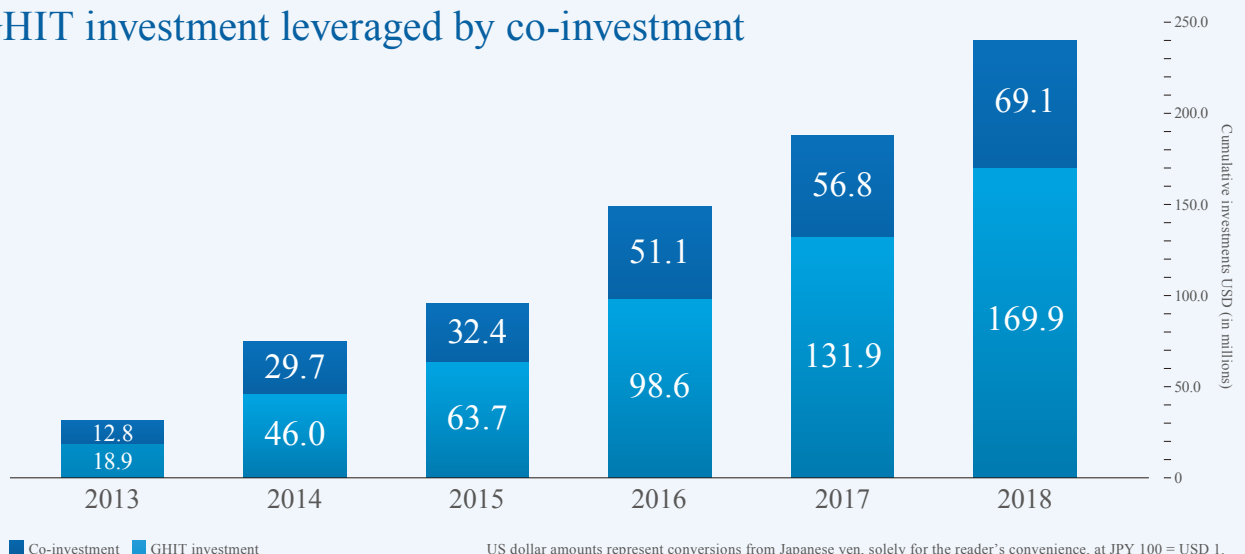
GHIT is a proud co-investor in many partnerships alongside multiple funders around the world. For example, GHIT co-invests with the European & Developing Countries Clinical Trials Partnership (EDCTP) in the pediatric PZQ phase III trial, which is providing clinical data and support for registration of a new praziquantel tablet formulation to treat schistosomiasis in preschool-aged children. Other examples include The Republic and Canton of Geneva through its International Solidarity Office, which has committed to support mycetoma activities in Sudan with the overall goal of developing a new safe, effective, affordable and field-adapted treatment for patients affected by mycetoma. GHIT has worked with multiple funders and



partners domestically and internationally to find opportunities for co-investment and align investment strategy so that promising innovations can be developed and delivered to patients faster.

By co-investing, funders decrease the risk associated with individual investment and amplify their impact exponentially. Moreover, by partnering with multiple funders, product development partners can accelerate

## GHIT investment leveraged by co-investment







progress by leveraging each funder's unique networks and resources. Finally, co-investment helps ensure that products are part of the global product development portfolio.

Importantly, co-investment is not restricted only to financial investments; in-kind donations and services can also be critically important contributions. For example, private companies sometimes contribute human, technical, and other internal resources, each of which plays an essential

role in advancing product development.

GHIT aims to increase co-investment in its development partnerships so that by the end of FY2022 its own contributions are matched by outside funding including in-kind contributions. In keeping with this goal, we are actively exploring opportunities to join forces with other co-investors and partners to leverage investment impact for patients.

## How Co-Investment Works



# FINANCES

\*\*\*For Translation Purposes Only\*\*\*

## Independent Auditor's Report

To the Board of Directors, Global Health Innovative Technology Fund.

### <Audit of the Financial Statements>

We have audited the accompanying financial statements, which comprise the balance sheet, the statement of income, the notes to the financial statements, and the related supplementary schedules of the Public Interest Incorporated Association Global Health Innovative Technology Fund ("the Organization") applicable to the seventh fiscal year from April 1, 2018, through March 31, 2019. We conducted our audit in accordance with the rules and regulations concerning the Act on the Authorization, etc. of Public Interest Incorporated Associations and Public Interest Incorporated Foundations in Japan, under Article 23.

### Directors' Responsibility for the Financial Statements and the Related Supplementary Schedules

Directors need to ensure that the financial statements and related supplementary schedules were prepared and fairly presented in accordance with accounting principles generally accepted in Japan. Among others, directors are responsible for designing and operating such internal control as directors determine is necessary to enable the preparation and fair presentation of the financial statements and the related supplementary schedules that are free from material misstatement, whether due to fraud or error.

### Auditor's Responsibility

Our responsibility is to express an opinion on these financial statements and the related supplementary schedules based on our audit. We conducted our audit in accordance with auditing standards generally accepted in Japan. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements and the related supplementary schedules are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements and the related supplementary schedules. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the financial statements and the related supplementary schedules, whether due to fraud or error. The purpose of an audit of the financial statements is not to express an opinion on the effectiveness of the Organization's internal control, but in making these risk assessments, the auditor considers internal controls relevant to the Organization's preparation and fair presentation of the financial statements in order to design audit procedures that are appropriate for the circumstances. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by directors, as well as evaluating the overall presentation of the financial statements and the related supplementary schedules.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

### Opinion

In our opinion, the financial statements and the related supplementary schedules referred to above present fairly, in all material respects, the financial position and results of operations of the Organization applicable to the seventh fiscal year ended March 31, 2019, in conformity with accounting principles generally accepted in Japan for Public Interest Incorporated Associations (similar to a 501(c)(3) in the United States).

### <Opinion on the List of Assets and Liabilities>

We have audited the accompanying list of assets and liabilities for the seventh fiscal year of the Public Interest Incorporated Association Global Health Innovative Technology Fund at March 31, 2019. We conducted our audit in accordance with the rules and regulations concerning the Act on the Authorization, etc. of Public Interest Incorporated Associations and Public Interest Incorporated Foundations in Japan, under Article 23.

### Directors' Responsibility for the List of Assets and Liabilities

Directors need to ensure that the list of assets and liabilities was prepared and fairly presented in accordance with accounting principles generally accepted in Japan and also in conformity with the public-interest certification documents.

\*\*\*For Translation Purposes Only\*\*\*

### Auditor's Responsibility

Our responsibility is to express an opinion on the said list of assets and liabilities which was prepared and fairly presented in accordance with auditing standards generally accepted in Japan and also in conformity with the public-interest certification documents.

### Opinion

In our opinion, the list of assets and liabilities referred to above present fairly, in all material respects, in accordance with auditing standards generally accepted in Japan and also in conformity with the public-interest certification documents.

### <Conflicts of Interest>

We have no interest in the Organization which should be disclosed in compliance with the Certified Public Accountants Act.

Ernst & Young ShinNihon LLC.

May 8, 2019

End-of-Document

## 独立監査人の監査報告書

令和元年5月8日

公益社団法人グローバルヘルス技術振興基金

理 事 会 御 中

### EY新日本有限責任監査法人

指定有限責任社員 公認会計士 矢崎 弘 直 郎  
業 務 執 行 社 員

### <財務諸表監査>

当監査法人は、公益社団法人及び公益財団法人の認定等に関する法律第23条の規定に基づき、公益社団法人グローバルヘルス技術振興基金の平成30年4月1日から平成31年3月31日までの第7期の貸借対照表及び損益計算書（公益認定等ガイドライン1-5 (I)の定めによる「正味財産増減計算書」をいう。）並びにその附属明細書並びに財務諸表に対する注記について監査し、併せて、正味財産増減計算書内訳表（以下、これらの監査の対象書類を「財務諸表等」という。）について監査を行った。

### 財務諸表等に対する理事者の責任

理事者の責任は、我が国において一般に公正妥当と認められる公益法人会計の基準に準拠して財務諸表等を作成し適正に表示することにある。これには、不正又は誤謬による重要な虚偽表示のない財務諸表等を作成し適正に表示するために理事者が必要と判断した内部統制を整備及び運用することが含まれる。

### 監査人の責任

当監査法人の責任は、当監査法人が実施した監査に基づいて、独立の立場から財務諸表等に対する意見を表明することにある。当監査法人は、我が国において一般に公正妥当と認められる監査の基準に準拠して監査を行った。監査の基準は、当監査法人に財務諸表等に関する重要な虚偽表示がないかどうかについて合理的な保証を得るために、監査計画を策定し、これに基づき監査を実施することを求めている。

監査においては、財務諸表等の金額及び開示について監査証拠を入手するための手続が実施される。監査手続は、当監査法人の判断により、不正又は誤謬による財務諸表等の重要な虚偽表示のリスクの評価に基づいて選択及び適用される。財務諸表監査の目的は、内部統制の有効性について意見表明するためのものではないが、当監査法人は、リスク評価の実施に際して、状況に応じた適切な監査手続を立案するために、財務諸表等の作成と適正な表示に関連する内部統制を検討する。また、監査には、理事者が採用した会計方針及びその適用方法並びに理事者によって行われた見積りの評価も含め全体としての財務諸表等の表示を検討することが含まれる。

当監査法人は、意見表明の基礎となる十分かつ適切な監査証拠を入手したと判断している。

### 監査意見

当監査法人は、上記の財務諸表等が、我が国において一般に公正妥当と認められる公益法人会計の基準に準拠して、当該財務諸表等に係る期間の財産及び損益（正味財産増減）の状況をすべての重要な点において適正に表示しているものと認める。

### <財産目録に対する意見>

当監査法人は、公益社団法人及び公益財団法人の認定等に関する法律第23条の規定に基づき、公益社団法人グローバルヘルス技術振興基金の平成31年3月31日現在の第7期の財産目録（「貸借対照表科目」、「金額」及び「使用目的等」の欄に限る。以下同じ。）について監査を行った。

### 財産目録に対する理事者の責任

理事者の責任は、財産目録を、我が国において一般に公正妥当と認められる公益法人会計の基準に準拠するとともに、公益認定関係書類と整合して作成することにある。

### 監査人の責任

当監査法人の責任は、財産目録が、我が国において一般に公正妥当と認められる公益法人会計の基準に準拠しており、公益認定関係書類と整合して作成されているかについて意見を表明することにある。

### 財産目録に対する監査意見

当監査法人は、上記の財産目録が、我が国において一般に公正妥当と認められる公益法人会計の基準に準拠しており、公益認定関係書類と整合して作成されているものと認める。

### 利害関係

公益社団法人グローバルヘルス技術振興基金と当監査法人又は業務執行社員との間には、公認会計士の規定により記載すべき利害関係はない。

以 上



# 2018 Financial Summary (Audited)

## Balance Sheet

Assets (in million)	JPY	USD
Current Assets	1,156.2	10.4
Fixed Assets	4,097.8	36.9
<b>Total Assets</b>	<b>5,254.0</b>	<b>47.3</b>
Liabilities (in million)	JPY	USD
Current Liabilities	935.6	8.4
Non-current Liabilities	292.4	2.6
<b>Total Liabilities</b>	<b>1,228.0</b>	<b>11.0</b>
Net Assets (in million)	JPY	USD
Designated Net Assets	4,026.0	36.3
General Net Assets	-	-
<b>Total Net Assets</b>	<b>4,026.0</b>	<b>36.3</b>
<b>Total Liabilities and Net Assets</b>	<b>5,254.0</b>	<b>47.3</b>

## Net Assets Variation Statement

Change in General Net Assets (in million)	JPY	USD
Ordinary Income		
Grants Received	3,296.0	29.7
Contribution Received	764.2	6.9
Misc. Income	2.8	0.0
<b>Total Ordinary Income</b>	<b>4,063.0</b>	<b>36.6</b>
Ordinary Expenses		
Operating Expenses	3,865.8	34.8
Management Expenses	197.2	1.8
<b>Total Ordinary Expenses</b>	<b>4,063.0</b>	<b>36.6</b>
Change in Designated Net Assets (in million)	JPY	USD
Grants Received and Others		
Governments, NGOs, Multilateral Organizations	3,338.6	30.1
Foundations	1,629.6	14.7
Contributions Received	834.4	7.5
<b>Total Grants and Contributions Received</b>	<b>5,802.6</b>	<b>52.3</b>

The US dollar amounts in this section represent translations of Japanese yen, solely for the reader's convenience, at PY 111 = USD 1, the exchange rate as of March 31, 2019.

This financial summary is an excerpt from the GHIT Fund's audited financial statements, which are audited by Ernst & Young ShinNihon LLC.. The GHIT Fund is a Public Interest Incorporated Association and is registered in Japan.

# LEADERSHIP

## COUNCIL

The Council consists of the Japanese government, various foundations, and private companies that provide funding to GHIT. The Council resolves important matters as provided by applicable laws and regulations or the Articles of Incorporation including appointment and dismissal of members of the Council and the Board of Directors, amendment of the Articles of Incorporation, and approval of financial statements.



**Hideo Suzuki**

Ambassador, Director-General for Global Issues  
Ministry of Foreign Affairs



**Chieko Ikeda, MD, MPH, MS**

Senior Assistant Minister for Global Health  
Minister's Secretariat  
Ministry of Health, Labour and Welfare



**Trevor Mundel, MD, PhD**

President, Global Health  
Bill & Melinda Gates Foundation



**Jeremy Farrar, MD, PhD, FRCP**

Director  
Wellcome



**Astellas Pharma Inc.**

Yoshihiko Hatanaka  
Representative Director  
Chairman of the Board



**Chugai Pharmaceutical Co., Ltd.**

Tatsuro Kosaka  
Representative Director  
President and CEO



**Daiichi Sankyo Company, Limited**

George Nakayama  
Representative Director  
Chairman and CEO



**Eisai Co., Ltd.**

Haruo Naito  
Representative Corporate Officer  
and CEO



**Shionogi & Co., Ltd.**

Isao Teshirogi, PhD  
President and CEO



**Takeda Pharmaceutical Company Limited**

Christophe Weber  
Representative Director  
President and CEO

## BOARD OF DIRECTORS

The Board of Directors consists of global health experts and management professionals. In addition to overseeing operations by the Leadership Team, it also resolves important business matters including approval of major rules, strategic plans, annual operational plans/budget, and funding decisions based on recommendations from the Selection Committee.



**Chair & Representative Director  
Hiroki Nakatani, MD, PhD, MHPED**

Project Professor  
Global Research Institute  
Keio University



**Vice Chair  
Peter Piot, MD, PhD**

Director and Professor of Global Health  
London School of Hygiene and Tropical Medicine  
Former Executive Director, UNAIDS



**BT Slingsby, MD, PhD, MPH**

CEO & Executive Director  
Global Health Innovative Technology Fund  
\*Through March 31, 2019



**Catherine K. Ohura, MS, PMP**

CEO & Executive Director  
Global Health Innovative Technology Fund  
\*From April 1, 2019



**Mahima Datla**

Managing Director  
Biological E. Limited



**Toru Kajiwara**

Director, Office of Global Health Cooperation  
Ministry of Health, Labour and Welfare



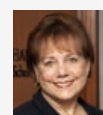
**Daikichi Momma**

Former Director-General, International Bureau  
Ministry of Finance  
Former Executive Director  
International Monetary Fund representing Japan



**Manabu Sumi, MD, PhD, MPH**

Director, Global Health Policy Division  
International Cooperation Bureau  
Ministry of Foreign Affairs



**Ann M. Veneman, JD**

Former Executive Director, UNICEF  
Former Secretary  
United States Department of Agriculture



**Supervisory Board Member  
Hikaru Ishiguro, LLM**

Statutory Auditor  
INSPIRE Corporation



**Supervisory Board Member  
Ko-Yung Tung, JD**

Lecturer at Law, Harvard Law School  
Former Senior Vice President  
and General Counsel, World Bank



**Ex-Officio  
Stephen Caddick, PhD**

Director, Innovations Division  
Wellcome



**Ex-Officio  
Andrin Oswald, MD**

Director, Life Sciences Partnerships  
Bill & Melinda Gates Foundation



## SELECTION COMMITTEE

The Selection Committee consists of domestic and international experts who have extensive knowledge and experience in research and development of drugs, vaccines and diagnostics. This committee evaluates investment proposals and reports from development partners and recommends the investments to the Board of Directors. This committee includes no private company representatives to avoid any Conflicts of Interest between our backers and development partners.



Co-Chair  
**Kiyoshi Kita, PhD**  
Professor Emeritus, The University of Tokyo  
Professor and Dean, Nagasaki University School of Tropical Medicine and Global Health



Co-Chair  
**Dennis Schmatz, PhD**  
Former Head, Infectious Diseases Research  
Merck Research Labs, USA  
Former Head, Research, MSD-Japan



**Ralf Clemens, MD, PhD**  
Independent Vaccine Expert



**Ann Mills-Duggan, PhD**  
Head, Seeding Drug Discovery Fund  
Business Development, Innovations  
Wellcome



**Ken Duncan, PhD**  
Deputy Director  
Discovery & Translational Sciences  
Bill & Melinda Gates Foundation



**Ken Ishii, MD, PhD**  
Professor, Institute of Medical Science  
University of Tokyo  
Professor, the Laboratory of Vaccine Science  
at the Immunology Frontier Research Center  
(IFReC), Osaka University



**Gerd Michel, PhD**  
Chief Scientific Officer  
Vela Diagnostics



**Naoto Uemura, MD, PhD**  
Professor, Department of Clinical Pharmacology  
and Therapeutics  
Oita University Faculty of Medicine

## ADVISORY PANEL

Members provide strategic advice to the Board of Directors and to the Leadership Team.



**Harvey V. Fineberg, MD, PhD**  
President, Gordon and Betty Moore Foundation  
Former President  
Institute of Medicine of the National Academies



**Dai Hozumi, MD, MSM, MPH**  
Chief Technical Officer  
VP for Center for Technical Excellence  
IntraHealth International



**Michael R. Reich, PhD**  
Taro Takemi Professor  
International Health Policy  
Harvard School of Public Health



**Kumi Sato**  
President and CEO  
Cosmo Public Relations Corporation



**Lorenzo Savioli, MD, DTM&H, MSc**  
Former Director, Department of  
Neglected Tropical Diseases  
World Health Organization

## LEADERSHIP TEAM

Leadership Team is responsible for the design and development of business and investment strategies and, upon Board approval, the execution of strategies, administrative operations, and organizational growth of GHIT.



**BT Slingsby, MD, PhD, MPH**  
CEO  
\*Through March 31, 2019



**Catherine K. Ohura, MS, PMP**  
CEO  
\*From April 1, 2019



**Kio Yamabe, MBA**  
Chief Operating Officer



**Masayuki Sato, MBA**  
Vice President, External Engagement



**Kei Katsuno, MD, MPH**  
Senior Director, Investment Strategy  
& Government Relations



**Bumpei Tamamura, MPH**  
Senior Director, Brand Communications



**Miho Takazawa, MBA**  
Director, Finance



**Hayato Urabe, PhD, MPIA**  
Director, Investment Strategy  
Planning & Management

# LEADERSHIP

## EXTERNAL REVIEWERS

The work of the GHIT community could not progress without vital support from these experts and their institutions.

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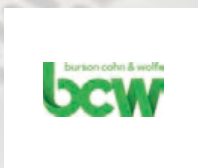
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TEL:+81-36441-2032 FAX:+81-36441-2031  
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