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GHIT Fund invests in two innovative malaria eradication tools

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Approach shows promise for achieving malaria eradication and tackling rapidly spreading malaria drug resistance; GHIT also announces investments in malaria and tuberculosis diagnostics, and new treatments for leishmaniasis and soil-transmitted helminthiasis

The Global Health Innovative Technology Fund (GHIT Fund) announced today that it's investing US$1,383,785 in a pair of innovative malaria eradication tools—a vaccine that could block transmission of two species of the deadly disease and a rapid field test that can reveal a malaria infection in minutes.

"We will not be able to eradicate malaria if we can't interrupt disease transmission," said GHIT Fund Executive Director & CEO Dr. BT Slingsby. "And that will require two essential tools: vaccines that interrupt the parasite's constant movement between humans and mosquitos, and simple, rapid diagnostic tests that allow us to identify and treat asymptomatic persons who are silently carrying and spreading malaria parasites."

The GHIT Fund also revealed that it's investing US$2,160,577 to accelerate development of a new diagnostic test for tuberculosis (TB), which has now overtaken HIV as the leading cause of death from infectious disease. In addition, GHIT will provide US$1,690,711 to develop treatments for two neglected tropical diseases that torment billions: leishmaniasis, a parasitic disease transmitted by sand flies that, in the cutaneous forms, causes disfiguring skin ulcers, and in the visceral form can lead to fatal organ failure, and soil-transmitted helminthiasis infections, which are caused by parasitic worms that plague two billion people worldwide and routinely lead to physical and cognitive impairments in children.

"Our new investments in malaria, TB and these neglected tropical diseases send a clear message that GHIT and Japan are committed to employing the most innovative and advanced R&D tools available to save lives and improve health in the developing world," Dr. Slingsby said.

GHIT Fund Commits to Eradicating Malaria

Malaria kills hundreds of thousands of people every year—mostly young children in sub-Saharan Africa. Although the burden has decreased in recent years, the ever-evolving malaria parasite has proven to be a hardy adversary, constantly shifting to develop resistance to the world's most effective drugs and insecticides. Just last year, researchers discovered that drug-resistant malaria parasites now rapidly spreading across Southeast Asia are capable of infecting African mosquitoes. Malaria experts warn that it would be devastating if the world's best malaria drugs become useless in Africa, as it could undo decades of progress toward malaria eradication.

Alarmed by the threat of drug resistance, the malaria research community is pushing for transmission-blocking vaccines to be ready for deployment by 2030. The goal is to develop a vaccine targeting the transmission of one or both types of malaria parasites—the more deadly *Plasmodium falciparum* parasite and the more widespread *Plasmodium vivax* parasite. GHIT is supporting, with an investment of US$419,285, a collaboration between CellFree Sciences Co., Ltd., a Japan-based biotech, and the University of Florida (UF) in the United States of America (USA) to develop a malaria vaccine that would target both *P. falciparum* and *P. vivax* malaria.

Their candidate is thus far the leading mosquito-based "transmission-blocking vaccine" (TBV). Mosquito-based means that while this type of vaccine is given to humans, the target is the mosquito: when mosquitoes bite vaccinated humans, the blood they extract would contain antibodies generated by the vaccine that would interfere with the parasite's passage from human to mosquito. If the vaccine can break this cycle of transmission and enough people are inoculated, an entire community should eventually see a major drop in malaria infections.

While other TBVs are in development, the CellFree-UF TBV candidate is the only one that could potentially block both *P. falciparum* and *P. vivax* parasites. The vaccine candidate targets a protein in the mosquito's gut called AnAPN1 that plays a critical role in facilitating the transmission of both types of malaria parasites from humans to mosquitoes. The hope is that when given to humans, the vaccine would generate protection that would subsequently interfere with the parasites movement into mosquitoes.

"GHIT funding will allow us to make the experiments needed to move an AnAPN1-based vaccine candidate into the preclinical stage," said Satoshi Ozawa, president & CEO of CellFree Sciences Co., Ltd. "CFS will make the proteins for use in mice to generate antibodies against different AnAPN1 proteins, and to test whether those antibodies can block the transmission cycle of the parasites. The selection of an optimal antigen within AnAPN1 will be essential for the success of the TBV candidate."

Draining Hidden Reservoirs of Malaria Parasites

Another major obstacle to malaria eradication involves humans who carry substantial "reservoirs" of malaria parasites and regularly pass them along to mosquitoes, even as they themselves experience no outward symptoms of actual disease. GHIT is confronting this major source of malaria transmission by investing US$964,500 to develop a diagnostic system for quickly detecting asymptomatic malaria, one that would be far more sensitive than existing technology. The project involves a collaboration between Japan-based researchers and collaborators at Panasonic Corporation, Juntendo University, the National Institute of Advanced Industrial Science and Technology (AIST), Institute of Tropical Medicine, Nagasaki University, and Malaria No More Japan, along with partners at the Kenya Medical Research Institute (KEMRI-CGHR).

Their goal is to develop testing technology that could work in low-resource field settings and determine in less than 10 minutes whether an asymptomatic person is carrying parasites. The ability to quickly screen large populations for the presence of malaria parasites is considered crucial both to overall malaria eradication work and also to ongoing efforts to track drug resistance: a treated person may look like they have been cured even if the drug has actually failed to completely purge their parasites.

The team tested a prototype in a preliminary field trial in Uganda, where it performed better than current methods. GHIT's investment will allow further evaluation and validation in malaria-endemic areas.

A TB Test for HIV-Positive Patients

GHIT is also investing US$2,160,577 in a new rapid diagnostic test by Fujifilm Corporation, one of the leading healthcare companies, and Foundation for Innovative New Diagnostics (FIND) of Switzerland, which can identify active tuberculosis in HIV-positive patients. Today, one in three HIV-positive people die not of AIDS, but of TB. Thus early, affordable detection of TB is urgently needed. Existing diagnostics cannot reliably detect TB in HIV-positive patients, in part because the tests require sputum that many co-infected patients cannot produce.

Fujifilm and FIND's test would instead use urine to detect active TB infection. There is initial evidence that the test is potentially more sensitive than existing methods, while also providing results more easily and quickly. GHIT's investment would allow researchers to begin development of the test and collect samples from TB patients, especially those co-infected with HIV.

"People with HIV are uniquely vulnerable to tuberculosis, and early detection could be a life-saver," said Teiichi Goto, corporate vice president and general manager, medical systems business division of Fujifilm Corporation. "We are hopeful that our work with FIND to develop a rapid TB test that requires only a urine sample could be a significant development for millions of people around the world who must cope with both of these deadly diseases."

New Treatments for Neglected Diseases Caused by Sandflies and Worms

GHIT also awarded US$1,002,996 to an international partnership between the global health nonprofit organization PATH, Ajinomoto Co., Meiji Seika Pharma Co., Ltd., and the University of Massachusetts Medical School to develop a new treatment for soil-transmitted helminth (STH) infections that is based on a protein called Cry5B.

STH infections are transmitted by roundworm, whipworm and hookworm eggs found in human feces, which contaminate the soil in areas with poor sanitation. Among the most common infections in the world, STH infections can cause diarrhea, weakness and chronic blood loss that can lead to anemia. According to WHO, more than 880 million children need treatment for STH infections, which can lead to chronic physical and cognitive problems. Current treatments are threatened by drug-resistant strains, which have already arisen in livestock. Also, they can't be given to women in their first trimester of pregnancy, leaving both the mother and fetus vulnerable to damage from STH.

The Cry5B protein has shown efficacy in animal models. There also is evidence that resistance to the protein would

develop much more slowly compared to current treatments, which could allow for decades of intensive use. And its safety profile could permit its use in women during their first trimester of pregnancy and in young children.

Finally, GHIT awarded US$687,715 to GeneDesign, Inc., a Japan-based biotech, and the Drugs for Neglected Diseases *initiative* (DND*i*) to develop a better treatment for cutaneous leishmaniasis (CL), a disease transmitted by sandflies that counts a million new cases each year. The affliction causes painful, sometimes disfiguring skin ulcers that result in scarring, social stigma and economic loss that last a lifetime. Current drugs, which have been in use since the 1940s, are toxic, difficult to administer, expensive and often ineffective.

With GHIT's investment, GeneDesign and DND*i* would assess in an animal model the efficacy of the treatment combination of an immunomodulator with an anti-parasitic drug in order to enhance the healing and parasite clearance of skin lesions. The proposed approach shows potential to work faster than current drugs, reduce scarring and prevent relapse.

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