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GHIT Fund invests $10.7 million to fight malaria, TB, leishmaniasis and dengue

Published on November 5, 2015 at 5:00 AM

The Global Health Innovative Technology Fund (GHIT Fund), which in the last two years has invested US$43 million to develop innovative tools for fighting diseases worldwide, today announced it is investing $10.7 million at multiple points in the product development pipeline to seek new interventions for malaria, tuberculosis (TB), leishmaniasis and dengue.

The projects come at a crucial time for all four diseases: new drugs and vaccines for TB and malaria are desperately needed to fight rising resistance to existing therapies, while dengue infections continue to mount worldwide—and with no drugs or vaccines yet on the market to treat or prevent them. Meanwhile, disease experts fear the chaos caused by the war in Syria and neighboring Iraq could greatly intensify infections with leishmaniasis, a dangerous and potentially deadly disease spread by sandflies.

"We are excited about this latest round of investments as they showcase our aggressive 'Hit-to-Lead Platform' (HTLP) for advancing potentially promising new interventions that have been identified through our Screening Platform," said GHIT Fund's CEO Dr. BT Slingsby. "We're also funding five new projects through our Product Development Platform and rolling out our inaugural investments in our Grand Challenges program," he added. "Through these distinctly different initiatives, GHIT is establishing an effective, efficient and multifaceted process for harnessing Japanese innovation to fight diseases that are a major source of illness in the developing world."

GHIT's new Grand Challenges Targeted Research Platform initiative is expanding the scope of GHIT's work to early-phase R&D investigating new approaches, concepts and constructs for fighting neglected infectious diseases. It's modeled after, and run in coordination with, the Grand Challenges initiative launched by the Bill & Melinda Gates Foundation 10 years ago to foster creative and bold breakthroughs targeting significant global health and development problems.

One of the GHIT Grand Challenges is awarding $297,133 to support a partnership between the Takeda Pharmaceutical Company Limited, Medicines for Malaria Venture (MMV), and the University of Melbourne. The three organizations are working together to develop tests or "assays" that would enable them to find a way to overcome the parasite's drug resistance. They will work to identify compounds capable of inhibiting proteasome activity within the cells of malaria parasites, the action that is so critical to the parasite's survival.

Preliminary evidence suggests that proteasome inhibitors, a class of drugs currently used as anticancer agents, might have the potential to restore the effectiveness of the world's leading malaria drug, artemisinin, and its derivatives. In parts of Southeast Asia, malaria drugs are losing their effectiveness, as parasites develop resistance to both artemisinin medications and the "partner" drugs administered alongside them. Taken together they are known as "artemisinin combination therapies" (or ACTs) and are the current gold standard for malaria care.

"These projects are early stage, but build on Takeda's work with proteasome inhibitors, which has already led to new medicines for other diseases, including certain types of cancer," said Dr. Timothy Wells, chief scientific officer at Medicines for Malaria Venture. "Combining proteasome expertise with malaria expertise represents a very innovative approach."

Meanwhile, GHIT's HTLP approach is deepening relationships established through GHIT between product development partnerships fighting neglected diseases and Japanese companies and academic organizations that may have relevant compounds. And GHIT's Product Development Platform is funding later-stage development work for drugs, vaccines and diagnostics.

Hit-to-Lead Platform: Interest Grows as Promising Projects Advance

GHIT awarded the following four projects a total of $3.5 million as part of its HTLP program. All the projects originated from collaborations established through GHIT's Screening Platform, which funded efforts to screen the diverse and target-rich compound libraries curated by Japanese pharmaceutical companies for potentially promising therapies.

- An HTLP partnership between Eisai Co., Ltd. and MMV will further explore the potential of a series of "hits"

that emerged from screening 20,000 compounds in Eisai's library or the target-based screening in Eisai's original project. MMV and Eisai will assess their potential activity against different stages of the malaria parasite. One of the "hits" has a well-understood and promising mode of action against malaria, another has activity against the liver, blood and gametocyte stages of malaria, and a third comes from an innovative structural class of compounds that thus far has not been explored for its anti-malarial properties.

- An HTLP partnership between Daiichi Sankyo Company, Limited and the TB Alliance will focus on prospects identified from screening 70,000 compounds in Daiichi Sankyo's proprietary "Pharma Space Library (PSL)." PSL is Daiichi Sankyo's proprietary lead-like library, which contains over 1,000 pharmacologically relevant fragments and enables researchers to conduct a comprehensive exploration of their potential structure-activity relationships. The screening work initially identified 2,420 compounds, with further screening narrowing that to 148. All of the compounds screened were designed and synthesized internally at Daiichi Sankyo. And the compounds selected for their potential to fight TB are drug-like molecules. Further work will be carried out by the Daiichi Sankyo Life Science Research Centre in India (RCI). GHIT will invest $908,231 in the development partnership between Daiichi Sankyo and TB Alliance.

This round of HTLP investments also includes targeted investments from GHIT's new partner, the Wellcome Trust, the world's second highest spending charitable foundation and a global leader in funding of innovative biomedical research. Specifically, Wellcome Trust will support two innovative partnerships aimed at developing new drug candidates for malaria and tuberculosis.

- An HTLP partnership between Takeda and MMV will consider hits selected from screening 20,000 compounds in Takeda's library. Of the three series of compounds identified, two are novel for malaria and could hold promise for both treating the disease and reducing transmission. The third series appears to be very potent against the liver stage of a malaria infection and could also have potential to protect people from getting a malaria infection.
- An HTLP partnership between Shionogi & Company, Limited, the Japan Anti-Tuberculosis Association (JATA), and the Global Alliance for TB Drug Development (TB Alliance) will explore candidates that emerged from screening 40,000 compounds maintained by Shionogi. Shionogi is one of the few pharmaceutical companies in the world actively involved in antibacterial work. JATA conducted the screening work and among the promising hits are compounds that, while not in the antibacterial class, were already under assessment in Shionogi's internal programs, which means there is already in-depth knowledge of their chemistry and safety.

Product Development Platform: Accelerating Vaccine and Drug Development

In its fifth round of awards, GHIT's Product Development Platform is funding work on vaccines for leishmaniasis, dengue and TB, along with research into two malaria drug candidates.

- GHIT awarded $1.83 million to researchers at Ohio State University, Nagasaki University and McGill University for development and preclinical testing of the safety and efficacy of two vaccine candidates against cutaneous and visceral leishmaniasis. As part of this investment, researchers at the US Food and Drug Administration's (FDA's) Center for Biologics Evaluation and Research will participate in the assessment of the vaccine candidates. Leishmaniasis infects two million people worldwide every year, causing painful, sometimes disfiguring, skin ulcers in its cutaneous form and affecting vital organs in its visceral form, which is fatal if left untreated. Nagasaki University's participation in this project, as well as the following partnership with European Vaccine Initiative (EVI) and the Institute Pasteur, is part of its expanding role in global health R&D.
- GHIT awarded $612,902 to the European Vaccine Initiative (EVI), Nagasaki University, and the Institut Pasteur to manufacture a clinical grade formulation and conduct preclinical testing of a dengue vaccine candidate that is intended to provide protection against all four serotypes of the dengue virus. The project is the second dengue vaccine project to join GHIT's portfolio.
- GHIT awarded $1.4 million to Dartmouth College (US), Tanzania's Muhimbili University of Health and Allied Sciences (MUHAS), and Tokyo Medical and Dental University (TMDU) to conduct a randomized clinical trial in Tanzania aimed at evaluating the safety and efficacy of a booster TB vaccine known as DAR-901. DAR-901 will be administered to 13-15-year-old participants who received the standard TB vaccine at birth, known as the Bacillus Calmette-Guérin or BCG vaccine. Newborn immunization with BCG is generally only effective for 10-15 years and DAR-901 is designed to boost and prolong this protection against TB. The study is currently

undergoing appropriate regulatory and ethical evaluations in Tanzania. This is the second TB vaccine in the GHIT portfolio.

- GHIT awarded $207,753 to the Liverpool School of Tropical Medicine, the University of Liverpool, and Eisai to support their continued preclinical work on a malaria drug candidate intended to provide an alternative to existing therapies, many of which are losing their efficacy as the malaria parasite develops resistance.
- GHIT awarded an additional $1.9 million to a malaria project already in its portfolio: a collaboration between MMV and Takeda to develop a malaria drug that progressed to Phase 2 clinical trials earlier this year.

Launching GHIT's Targeted Research Platform in Partnership with Grand Challenges

GHIT is funding two early-stage malaria R&D projects as it moves forward with its first projects under its new Grand Challenges partnership.

In addition to the aforementioned partnership between MMV, Takeda, and the University of Melbourne, GHIT awarded $993,030 to Australia's Walter and Eliza Hall Institute of Medical Research, Japan's Ehime University, Switzerland's Foundation for Innovative New Diagnostics (FIND), and the Japanese biotech firm CellFree Sciences Co., Ltd. to develop biomarkers for malaria that could drive the development of new diagnostic tools. This is the second diagnostic project in the GHIT portfolio.

Source:
Global Health Innovative Technology Fund (GHIT Fund)
