

# The GHIT fund shows its cards

Japan's biggest pharmaceutical companies, the Bill and Melinda Gates Foundation, and the Japanese government have awarded their first round of global health research grants.

David Holmes

The Global Health Innovative Technology (GHIT) fund launched in May to bring the expertise and capacity of the Japanese pharmaceutical industry to bear on the infectious diseases that disproportionately afflict the world's poor. In a three-way fund-matching partnership, a consortium of five of Japan's biggest pharmaceutical companies, the Japanese government and the Bill and Melinda Gates Foundation committed US\$100 million, for 5 years, to malaria, tuberculosis, neglected tropical diseases (NTDs) and HIV research. The fund has now announced its first tranche of grants, showcasing the type of research it plans to support.

GHIT whittled down 28 proposals to award \$5.7 million to six product-development partnerships (PDPs) between Japanese companies or institutes and international collaborators. The biggest winner was malaria research.

The largest award, of US\$2.6 million, was granted to a partnership between the not-for-profit foundation Medicines for Malaria Venture (MMV) and Takeda to support the clinical testing of a new antimalarial drug candidate, DSM265. The small molecule, which could become the first antimalarial dihydroorotate dehydrogenase inhibitor, has just entered Phase I studies. The same partnership also scooped a \$575,000 award to continue the preclinical development and formulation of a potential antimalarial prophylactic quinolone derivative, ELQ300.

A partnership between the Research Institute for Microbial Diseases at Osaka University, Japan, and Gulu University, Uganda, was awarded \$735,000 to assess whether the BK-SE36 malaria vaccine can be improved by adding an adjuvant. BK-SE36, a recombinant blood-stage vaccine, showed promise in clinical trials, but needs reformulations because seroconversion was low when it was tested in malaria-endemic areas. Finally, \$600,000 will go to Japan's Ehime University, the biotechnology company CellFree Sciences and the non-profit organization PATH to leverage Ehime University's wheat-germ

cell-free protein synthesis technology to identify antigens for malaria vaccine development.

Two grants were awarded for research into other infectious diseases. The National Institute of Biomedical Innovation, Japan, and Aeras received \$720,000 for preclinical evaluation of a mucosal tuberculosis vaccine. The Broad Institute of MIT and Harvard University, USA, and Eisai received \$510,000 to optimize the ML341 scaffold for treating Chagas disease.

While these first grants are for work on drugs and vaccines in preclinical and clinical stages of development, the fund is also supporting discovery, licensing and diagnostic work. GHIT has already financed a screening platform that enables the Global Alliance for TB Drug Development, the MMV and the Drugs for Neglected Diseases Initiative to screen for drug candidates from the compound libraries of the Japanese pharmaceutical consortium members, Astellas Pharma, Daiichi Sankyo, Eisai, Shionogi and Takeda. A second call for proposed screening partnerships was announced in November, with all screening costs to be reimbursed by the fund. Meanwhile, proposals for the fund's second round of PDP grants are already under review, with awards likely to be announced by March 2014.

With these funding announcements, GHIT joins a bewildering number of governmental, non-governmental, unilateral, bilateral and multilateral organizations, such as the UK government's Department for International Development and the Wellcome Trust, who have been funding similar initiatives for decades. So what will set GHIT apart? "The fund-matching approach itself is not innovative, it's an established approach that's been used before for malaria and NTDs," says Simon Croft, Dean of the Faculty of Infectious and Tropical Diseases at the London School of Hygiene and Tropical Medicine, UK. What is new, says Croft, is that the fund is "trying to bring Japanese research scientists into developing products for non-profit diseases, and they've got a lot of hidden skills there. They're the late arrivals to the ball, but very welcome".

And B. T. Slingsby, Executive Director of GHIT, is confident that the fund will be

able to make its mark. "If you just look at the number of drugs that are produced by Japanese pharmaceutical companies in general, Japan is number three behind the US and UK. There is an enormous capacity and culture of innovation here in Japan. It's just a matter of how to bring that into global health," he says.

Any products that eventually arise from GHIT will be made available to disease-endemic low-income and middle-income countries on a non-profit basis, either through royalty-free licensing arrangements or through direct manufacturing and distribution at cost price. "That way we can ensure access and affordability of our funded products going forward," says Slingsby.

The PDPs will retain rights over any intellectual property that arises from their GHIT grants, so there may still be a profit opportunity. "You may see drugs that have no commercial market in the endemic countries that have a small viable market in higher income countries," explains John-Arne Røttingen, a visiting professor of Global Health and Population at Harvard University.

## Japan's upside

The GHIT fund is part of a renewed phase of engagement with global health by Japan, which has lagged behind many Western economies when it comes to contributing to global health research and development (R&D). Japan spends 100-times less, as a percentage of its gross domestic product, on publicly funded NTD R&D than does the USA (*Lancet* 382, 1286–1307; 2013).

For the Japanese government, the fund fits into a wider diplomatic policy of "smart power" (*Lancet* 382, 915–916; 2013), but is also an important strand of the revitalization plan for Japan's domestic economy. Economic strategists have identified pharmaceuticals, health care and medical technology as important sectors for growth in the coming decades, and the GHIT fund should help Japanese companies establish a more global presence.

For a start, the Japanese pharmaceutical partners in the fund are gaining visibility, contacts, relationships and experience in international markets. And forging new relationships is particularly important for Japanese pharmaceutical companies, who were slow moving into the developing markets that are due to provide most of the sector's growth. With GHIT, that could start to change. "Becoming engaged on that global level as a pharmaceutical company in drug development and in vaccine development is a core strategy for doing business in the developing world," says Slingsby.