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Eisai Co., Ltd.

INITIATIVES FOR DEVELOPING NEW MEDICINES FOR NEGLECTED TROPICAL DISEASES AND MALARIA

EISAI COMMITS FUNDING TO THE 2ND PHASE OF GLOBAL HEALTH INNOVATIVE TECHNOLOGY FUND ACTIVITIES

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") has announced that it will grant a total of 500 million yen to the Global Health Innovative Technology Fund ("GHIT Fund") to fund the second phase of its activities, which will take place in the five-year period from FY 2018 to FY 2022. The GHIT Fund is a public-private partnership, co-established in April 2013 by multiple Japanese pharmaceutical companies (including Eisai), the Japanese government, and the Bill & Melinda Gates Foundation, for the purpose of accelerating development of new medicines to cure infectious diseases in developing and emerging countries by facilitating collaboration between research organizations in Japan and overseas.

In order to develop treatments for the numerous people suffering from infectious diseases such as Neglected Tropical Diseases (NTDs) and malaria in developing and emerging countries, there are disease-specific development and marketability issues to overcome. It is also necessary to establish local supply systems and help patients secure access to diagnosis and treatments. The key to overcoming these challenges are industry-government-academia partnerships which transcend the usual sector boundaries.

Eisai is proactively collaborating with academia and research organizations and has participated in 11 joint research projects to develop new medicines and vaccines for malaria, Chagas disease, leishmaniasis, and filariasis, with the support of the GHIT Fund.
Currently, Eisai is conducting a Phase II clinical trial of its in-house developed agent E1224 (generic name: fosravuconazole) for the treatment of Chagas disease in partnership with the non-profit organization Drugs for Neglected Diseases *initiative* (DND*i*). Eisai is also conducting a Phase I clinical trial of antimalarial agent SJ733 in collaboration with non-profit public-private partnership Medicines for Malaria Venture (MMV) and the University of Kentucky. Furthermore, several pre-clinical stage projects are underway, including joint research with the Broad Institute and MMV to develop an antimalarial agent with a new mechanism of action, which has been newly adopted by the GHIT Fund this year.

In accordance with its *human health care* (*hhc*) philosophy, Eisai will continue to proactively engage in initiatives which contribute to improving the health and welfare of people in developing and emerging countries. Eisai considers this to be a long term investment in economic growth and the expansion of the middle-income class.

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[Notes to editors]

1. About the Global Health Innovative Technology Fund (GHIT Fund)

The first of its kind in Japan, the GHIT Fund is a public-private partnership between the Japanese government, multiple pharmaceutical companies, the Bill & Melinda Gates Foundation, the Wellcome Trust, and UNDP. Launched in April 2013 with an initial commitment of more than US$100 million and now with capital of US$145 million, the organization taps Japanese research and development (R&D) to fight neglected diseases. GHIT Fund invests and manages a portfolio of development partnerships aimed at neglected diseases that afflict the world's poorest people. GHIT Fund mobilizes Japanese pharmaceutical companies and academic and research organizations to engage in the effort to get new medicines, vaccines, and diagnostic tools to people who need them most, with Japan quickly becoming a game-changer in global health. www.ghitfund.org

2. About Neglected Tropical Diseases (NTDs)

According to the World Health Organization (WHO), NTDs blight the lives of more than 1 billion people in 149 countries, the majority of which are living in poverty.[1] These diseases not only survive and spread in conditions of poverty but are also a cause of poverty in many countries and regions. NTDs can cause blindness and deform in ways that hinder economic productivity and prevent a normal social life. In serious cases, they may lead to death. The consequences are costly for societies and for health care.

The following 18 NTDs have been designated by WHO for control or elimination: dengue and chikungunya, rabies, trachoma, buruli ulcer, yaws [endemic treponematoses], leprosy [Hansen's disease], Chagas disease, human African trypanosomiasis [sleeping sickness], leishmaniasis, taeniasis / cysticercosis, dracunculiasis [guinea-worm disease], echinococcosis, food-borne trematodiases, lymphatic filariasis, onchocerciasis [river blindness], schistosomiasis, soil-transmitted helminthiases, and mycetoma.

3. About Chagas disease

Transmitted by the bite of the assassin bug or vinchuca, Chagas disease is a public health problem, particularly in poorer areas of Latin America and the Caribbean. About 6-7 million people are believed to carry the disease and 75 million people are estimated to be at risk of infection.[2] Chagas disease has acute, asymptomatic and chronic phases, and it sometimes takes several decades to reach the chronic phase. In the chronic phase, the central nervous, gastrointestinal, and cardiovascular systems are affected in 10% to 30% of infected people, and peripheral neuropathy, cardiomyopathy, megacolon, or megaesophagus may be observed. If infected people are left untreated, about a third of them will develop serious heart or intestinal damage that could lead to death.

4. About Malaria

Malaria, one of the three major infectious diseases, is caused by malaria parasites that are transmitted to people through the bite of an infected mosquito. According to the WHO, malaria is responsible for about 430,000 deaths per year, mostly among African children.[3]

Recently, strains of malaria which are resistant to existing medicines have been reported, and the development of a new medicine with a novel mechanism of action is an urgent priority. The majority of available antimalarial medicines target the blood-stage, in which the parasites replicate within erythrocytes, but are ineffective against the liver and transmission stages. In order to completely cure malaria, prevent relapse, and prevent malaria being spread via mosquitoes, it is necessary to develop a new antimalarial medicine which targets all stages of the parasite lifecycle.

5. About Filariasis

Filariasis, a disease caused by thread-like worms called filariae, is broadly divided into lymphatic filariasis and Onchocerciasis.

Lymphatic filariasis, which is estimated to have infected approximately 67 million people worldwide[2], is a parasitic

disease that is transmitted to humans by the bite of a mosquito. Once transmitted, it causes lymphatic dysfunction. The most serious manifestation, known as elephantiasis, is a permanent physical disability in which a patient's lower extremities swell to resemble those of an elephant. In addition to impacting a patient's ability to perform everyday tasks, it has historically led to many patients falling victim to social persecution due to biases against the disease. The disease also causes patients and their families much emotional distress.

Onchocerciasis, or river blindness, is an infectious disease endemic in 31 sub-Saharan African countries, which is estimated to have infected 26 million people.[2] It is caused by the parasitic worm Onchocerca volvulus. It is transmitted through repeated bites by black flies of the genus Simulium. Adult worms live in fibrous nodules under the skin. An infection causes intense itching and other symptoms. When it progresses, Onchocerca volvulus microfilariae concentrate on eyeballs, which can lead to eye lesions, and if left untreated, may result in blindness.

6. About Leishmaniasis

Leishmaniasis, a disease caused by protozoan parasites of the genus Leishmania, is transmitted by the bite of a species of sand fly. More than 12 million people are currently infected in over 90 countries worldwide, while an additional 0.9-1.3 million are estimated to be infected every year. Leishmaniasis is divided into cutaneous leishmaniasis, which causes skin ulcers, and visceral leishmaniasis, which causes fever and anemia. Visceral leishmaniasis invades bone marrow, the liver, the spleen, lymph nodes and other organs, and if left untreated, may result in death.

1 WHO Neglected Tropical Diseases http://www.who.int/neglected_diseases/diseases/en/

2 WHO Integrating neglected tropical diseases in global health and development: Fourth WHO report on neglected tropical diseases, 2017 http://www.who.int/neglected_diseases/resources/9789241565448/en/

3 WHO World Malaria Report 2016 http://www.who.int/malaria/publications/world-malaria-report-2016/report/en/