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EISAI'S INITIATIVES FOR DEVELOPING NEW MEDICINES FOR NEGLECTED TROPICAL DISEASES AND MALARIA AND COMMITMENT FOR FUNDING TO THE 3RD 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 625 million yen to the Global Health Innovative Technology Fund ("GHIT Fund") to fund the third phase of its activities, which will take place in the five-year period from FY2023 to FY2027. The GHIT Fund is a public-private partnership, co-established in April 2013 by partners such as 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. Eisai has provided a total of 1 billion yen to the first phase (FY2013 – FY2017) and the second phase (FY2018 – FY2022) of the GHIT Fund.

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 considers making efforts to resolve the global issue of access to medicines to be its duty. Under a public-private partnership including governments, international organizations, and private non-profit organizations, Eisai has participated in 23 joint research projects to develop new medicines and vaccines for mycetoma, malaria and filariasis, with the support of the GHIT Fund.

Eisai has conducted a Phase II clinical trial of its in-house developed agent E1224 (generic name: fosravuconazole) in Sudan for the treatment of mycetoma in partnership with the non-profit organization Drugs for Neglected Diseases initiative (DNDi). Eisai is also conducting a Phase II clinical trial of antimalarial agent SJ733 in collaboration with the University of Kentucky.

Eisai considers efforts for improving access to medicines, such as the elimination of NTDs and malaria, as activities aimed at creating long-term corporate value and social impact based on its corporate concept of *human health care* (*hhc*). We will continue to strengthen cooperation with our global partners and contribute to "relieving anxiety over health" and "reducing health disparities" for people at risk of infection with NTDs and those suffering from theses diseases.

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[Notes to editors]

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

The GHIT Fund is a Japan-based international public-private partnership fund (PPP) that was formed between the Government of Japan, multiple pharmaceutical companies, the Bill & Melinda Gates Foundation, Wellcome, and the United Nations Development Programme (UNDP). The GHIT Fund invests in and manages an R&D portfolio of development partnerships aimed at addressing neglected diseases, such as malaria, tuberculosis, and neglected tropical diseases, which afflict the world's vulnerable and underserved populations. In collaboration with global partners, the GHIT Fund mobilizes Japanese industry, academia, and research institutes to create new drugs, vaccines, and diagnostics for malaria, tuberculosis, and neglected tropical diseases.

https://www.ghitfund.org/en

2. About Neglected Tropical Diseases (NTDs)

Neglected Tropic Diseases (NTDs) include 20 diseases that the World Health Organization (WHO) identifies as tropical diseases which human race must overcome. More than 1.7 billion people living in the poorest and most marginalized communities worldwide are exposed to the risk of NTD infection. The spread of NTDs is mainly caused by poor hygienic conditions associated with poverty. Infections from these diseases may result in serious physical impairment and this often results in normal economic and social activities becoming highly challenging to the individual. In the worst cases, NTDs may also result in death. The prevalence of NTDs is a stumbling block to economic growth for developing and emerging countries.

The following 20 NTDs have been designated by the WHO for control or elimination: dengue fever and chikungunya, rabies, trachoma, buruli ulcer, endemic treponematoses (yaws), leprosy (Hansen's disease), Chagas disease, African sleeping sickness (Human African trypanosomiasis), leishmaniasis, taeniasis/cysticercosis, dracunculiasis (guinea worm disease], echinococcosis, food-borne trematode infections, lymphatic filariasis, onchocerciasis, schistosomiasis, soil-transmitted helminthiasis, mycetoma, scabies and snakebite envenoming.

3. About Mycetoma

Mycetoma was officially recognized as the 18th NTD by the WHO in 2016. It is considered to be one of the most neglected tropical diseases since there is a lack of basic information including its transmission pathway and incidence. Mycetoma is a progressive, chronic subcutaneous infectious disease. While most commonly seen in the feet, it can also occur in other parts of the body. It is caused by bacteria or fungus entering the body through a cut or wound and infecting the tissue beneath the skin.¹

Mycetoma is divided into two subtypes: Actinomycetoma (caused by bacterial infection) and Eumycetoma (caused by fungal infection). Actinomycetoma can be treated with antibiotics, with more than 90% success rate. On the other hand, while azole anti-fungal drugs can be used to treat Eumycetoma, the effectiveness is limited often resulting in recurrence and surgery or amputation of limbs.

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, about the half of the world's population is exposed to the risk of malaria, and there were an estimated 247 million malaria cases in 85 countries in 2021, of which about 620,000 lost their life. In particular, infants, children under the age of five, and pregnant women are more likely to develop serious illness and are always at risk of life-threatening conditions.²

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 medicines for the liver and transmission stages are limited. 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.

¹ WHO Mycetoma http://www.who.int/buruli/mycetoma/en/

² WHO Malaria https://www.who.int/news-room/fact-sheets/detail/malaria