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Eisai Co., Ltd.

## **EISAI PARTNERS WITH THE SABIN VACCINE INSTITUTE IN AN EFFORT TO DEVELOP VACCINES FOR NEGLECTED TROPICAL DISEASES**

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that it has entered into a partnership agreement to supply the Sabin Vaccine Institute (Headquarters: Washington D.C., President: Dr. Peter Hotez, "Sabin") with E6020, an in-house developed adjuvant that enhances the immune effects of vaccines, as well as all relevant information pertaining to the compound free of charge, to support the development of vaccines for two neglected tropical diseases (NTDs)—Chagas disease and leishmaniasis. E6020 stimulates the body's immune system via TLR4 (Toll-like receptor 4), a receptor that plays a key role in the body's innate immune system., and is expected to be used in a broad range of antigen vaccines to enhance vaccine efficacy.

Sabin is a non-profit organization dedicated to conducting research into therapeutic vaccines and NTDs. The institute works with governments, leading public and private organizations, and academic institutions on the research and development of innovative vaccines for vaccine preventable and NTDs, while at the same time advocating increased access to medical treatments.

Chagas disease and leishmaniasis are classified as diseases requiring innovative and intensified disease management (IDM) given their difficulty to diagnose and treat compared to other NTDs. This partnership is a new Product Development Partnership which integrates Sabin's strengths in the research and development of vaccines for NTDs and Eisai's compound and knowledge as a research and development-based pharmaceutical company, and which will seek to develop vaccines for these diseases as early and efficiently as possible.

Eisai is a signatory to the London Declaration, a coordinated effort to eliminate 10 NTDs by 2020 through the largest global public-private partnership to date. As part of its commitment under the Declaration, Eisai has entered into this partnership with Sabin, and has also agreed to produce at its Vizag Plant in India 2.2 billion tablets of DEC (diethylcarbamazine), a lymphatic filariasis medicine currently in short supply globally, and supply it to the World Health Organization (WHO) free of charge from 2013.

As it expands its business in both emerging and developing nations in this era of great globalization, Eisai considers its contributions to the economic development and expansion of the middle-income class through the enhancement of health and welfare in these countries as a form of long-term investment for future growth. Going forward, Eisai is committed to taking proactive steps to address issues related to access to medicines, including NTDs, as it seeks to make further contributions to increase the benefits provided to patients and their families worldwide.

**[Please refer to the following notes for a glossary of terms and further information on Neglected Tropical Diseases, the Sabin Vaccine Institute, the London Declaration, and Eisai's Commitment to Improving Global Access to Medicines]**

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## **[Notes to editors]**

### **1. Glossary of Terms**

#### 1) Adjuvant (Immunopotentiating agent)

An adjuvant, or immunopotentiating agent, is a substance that enhances the immune effects of vaccines. Basically, adjuvant means "to enhance," and when given in combination with an antigen, the adjuvant increases antibody production and augments the recipient's immune response to the vaccine. An adjuvant is added to a vaccine prior to administration.

#### 2) TLR4 (Toll-like receptor 4)

TLR is a receptor that plays a key role in the body's innate immune system, recognizing pathogenic agents such as bacteria. There are more than 10 types of TLR that have been reported to date. TLR4 is known as a receptor that recognizes endotoxin.

### **2. About Neglected Tropical diseases**

According to the World Health Organization (WHO), neglected tropical diseases (NTDs)\* blight the lives of more than 1 billion of the world's poorest 2.7 billion people. There are 149 countries and territories where NTDs are endemic, at least 100 of which are endemic for 2 or more of these diseases, and 30 countries that are endemic for 6 or more. These diseases not only survive and spread in conditions of poverty, they also anchor large populations in poverty.

(\*NTDs designated by the WHO for control or elimination: Buruli Ulcer, Chagas disease (American trypanosomiasis), Cysticercosis/Taeniasis, Dengue/Severe dengue, Dracunculiasis (guinea-worm disease), Echinococcosis, Fascioliasis, Human African trypanosomiasis, Leishmaniasis, Leprosy, Lymphatic filariasis, Onchocerciasis, Rabies, Schistosomiasis, Soil transmitted helminthiasis, Trachoma, Yaws)

#### 1) About Chagas Disease

Chagas disease is a disease transmitted by large blood-sucking triatomine bugs commonly known as "kissing bugs." Although Chagas disease mainly occurs in Latin America, it is also endemic in other regions such as Europe. An estimated 10 million people are infected worldwide, with a further 25 million at risk of the disease. Up to 30% of infected people develop cardiac disorders and up to 10% develop digestive, neurological or mixed alterations, while approximately 14,000 people lose their lives to the disease each year.

#### 2) About Leishmaniasis

Leishmaniasis is a disease caused by protozoan parasites that belong to the genus *Leishmania*. An estimated 120 million people in more than 90 countries around the world are infected with the disease, with a further 350 million at risk of infection. Approximately 2 million people are newly infected with the disease each year. There are two types of leishmaniasis—cutaneous leishmaniasis, which causes skin ulcers, and visceral leishmaniasis, which is characterized by high fever and anemia. Visceral leishmaniasis invades the bone marrow, liver, spleen, lymph nodes, as well as other organs. Left untreated, it can lead to death.

### **3. About the Sabin Vaccine Institute**

The Sabin Vaccine Institute, established in 1993 in honor of the oral polio vaccine developer, Dr. Albert B. Sabin, a non-profit organization dedicated to conducting research into therapeutic vaccines and NTDs. The institute works with governments, leading public and private organizations, and academic institutions on the research and development of innovative vaccines for vaccine preventable and neglected tropical diseases, while at the same time advocating increased access to medical treatments. For more information please visit <http://www.sabin.org>.

#### 4. About the “London Declaration on Neglected Tropical Diseases”

On January 30, 2012, the CEOs of 13 major global pharmaceutical companies\*, the Bill & Melinda Gates Foundation, the U.S. Agency for International Development (USAID), the U.K. Department For International Development (DFID), the World Bank, and officials from NTD-endemic countries gathered in London to pledge their support for a coordinated effort to combat 10 Neglected Tropical Diseases (NTDs)\*\* over the next ten years. In signing the “London Declaration on Neglected Tropical Diseases,” each of the partner companies and organizations also pledged new levels of commitment to defeating these diseases.

The London Declaration represents the largest coordinated effort to date, and unlike past approaches undertaken on by an individual organization or for a single disease, the group has committed itself to working collaboratively in an effort to comprehensively tackle issues pertaining to drug supply, distribution, development, and implementation programs as it seeks to more effectively combat NTDs.

\*Abbott, AstraZeneca, Bayer, Bristol-Myers Squibb, Eisai, GlaxoSmithKline, Gilead, Johnson & Johnson, Merck (Merck KGaA: Germany), Merck Sharp & Dhome, Novartis, Pfizer, Sanofi

\*\*Dracunculiasis (guinea worm disease), lymphatic filariasis, blinding trachoma, Human African trypanosomiasis, leprosy, soil-transmitted helminthiasis, schistosomiasis, onchocerciasis, Chagas disease, and visceral leishmaniasis.

#### 5. Eisai’s Commitment to Improving Global Access to Medicines

Today, it is estimated that some 2.7 billion\* people around the world live on US\$ 2 or less per day. Most of these 2.7 billion people do not have access to essential health care and treatment despite the availability of effective medicines. This is an international challenge that needs to be solved through collaborations among governments, international organizations such as the WHO, non-governmental organizations, and pharmaceutical companies.

In line with its *human health care (hhc)* mission, Eisai is committed to improving global access to medicines over the medium-to-long term through partnership strategies that involve working with governments, international organizations, private entities and non-profit organizations. As part of these efforts, the company has agreed to provide the medicine diethylcarbamazine (DEC) free of charge to the WHO in support of its program to eliminate the neglected tropical disease lymphatic filariasis, and is also engaged in a research collaboration with an international non-profit foundation to develop the new drug E1224 (prodrug of ravuconazole) for the treatment of Chagas disease.

For further information on Eisai’s Access to Medicines initiatives, please visit the Access to Medicines page on the Eisai Global website: <http://www.eisai.com/company/atm/index.html>