

No.13-48

August 27, 2013
Eisai Co., Ltd.

EISAI RECEIVES PREQUALIFICATION FROM WORLD HEALTH ORGANIZATION FOR LYMPHATIC FILARIASIS MEDICINE DIETHYLCARBAMAZINE SUPPLY FROM VIZAG PLANT, INDIA TO 24 ENDEMIC COUNTRIES TO BEGIN THIS YEAR

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that it has received prequalification from the World Health Organization (WHO) for diethylcarbamazine citrate (DEC) 100 mg tablets manufactured at its Vizag Plant in India for the treatment of lymphatic filariasis, a neglected tropical disease (NTD). The approval is the first case worldwide in which a pharmaceutical company has received prequalification from WHO for a medicine used to treat an NTD.

Eisai is a signatory to the London Declaration, which is the largest global public-private partnership to date and aims to eliminate ten NTDs by 2020. The lymphatic filariasis medicine DEC is in short supply worldwide, which poses a major obstacle in eliminating the disease. As part of Eisai's commitment under the declaration, the company has agreed to produce 2.2 billion high-quality DEC tablets at the Vizag Plant and, from 2013, to work with WHO to supply the tablets at price zero to endemic countries over a seven-year period. Based on this initiative, Eisai developed the formulation and conducted bioequivalence studies before submitting its application to WHO for prequalification in October 2012. After a relatively smooth evaluation process, Eisai was able to receive prequalification for the DEC tablets less than 10 months from submission of the application. The prequalification is a crucial milestone that will see Eisai deliver "Eisai-original," high-quality DEC tablets to 250 million people living in at-risk communities in countries where lymphatic filariasis is endemic, thereby contributing to successful elimination of the disease. In 2013, Eisai will begin providing DEC tablets produced at the Vizag Plant to WHO for use in mass drug administration programs in each endemic country.

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 developing and emerging countries as a form of long-term investment for future market growth. Eisai remains actively committed to addressing issues in global health including NTDs, in order to better contribute to increasing the benefits provided to patients and their families worldwide.

[Please refer to the following notes for further information on NTDs, lymphatic filariasis, the London Declaration on NTDs, and the WHO Prequalification of Medicines Programme.]

Media Inquiries:
Public Relations Department,
Eisai Co., Ltd.
+81-(0)3-3817-5120

[Notes to editors]

1. About Neglected Tropical Diseases (NTDs)

According to the World Health Organization (WHO), 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 and territories that are endemic for 6 or more. These diseases not only survive and spread in conditions of poverty but also anchor large populations in poverty.

(NTDs designated by 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, and yaws)

2. About Lymphatic Filariasis

Lymphatic filariasis is a parasitic disease that is transmitted to humans by the bite of a mosquito. Once transmitted, it causes lymphatic dysfunction. While infection is usually acquired during childhood, symptoms often gradually appear over several years, with the most serious manifestations of the disease occurring in adulthood. One of the most serious manifestations, 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 historically has 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. Today, lymphatic filariasis affects an estimated 120 million people in 73 countries worldwide, most of whom live in developing and emerging nations in Africa, Southeast Asia and other regions. In Japan, the disease has been confirmed to have existed since the Heian period (794-1184), but was successfully eliminated in the late 1970s as a result of initiatives begun roughly ten years earlier by the Japanese government in partnership with the public-private sector, with Japan then becoming the first country in the world to demonstrate the successful achievement of lymphatic filariasis elimination.

3. About the London Declaration on Neglected Tropical Diseases (NTDs)

On January 30, 2012, the CEOs of 13 major global pharmaceutical companies^{*1}, the Bill & Melinda Gates Foundation, the U.S. Agency for International Development, the U.K. Department for International Development, the World Bank, and officials from NTD-endemic countries gathered in London to pledge their support for a coordinated effort to combat ten NTDs^{*2} over the next decade. 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 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, implementation programs, and other areas as it seeks to more effectively combat NTDs.

^{*1}Abbott, AstraZeneca, Bayer, Bristol-Myers Squibb, Eisai, GlaxoSmithKline, Gilead, Johnson & Johnson, Merck (Merck KGaA: Germany), Merck Sharp & Dhome, Novartis, Pfizer, and Sanofi

^{*2}Dracunculiasis (Guinea worm disease), lymphatic filariasis, blinding trachoma, human African trypanosomiasis, leprosy, soil-transmitted helminthiasis, schistosomiasis, onchocerciasis, Chagas disease (American trypanosomiasis), and visceral leishmaniasis

4. About the WHO Prequalification of Medicines Programme

The WHO Prequalification Medicines Programme aims to make quality medicines available for the treatment of high-priority diseases. Medicinal products submitted for prequalification are comprehensively evaluated based on information provided by the manufacturers and inspection of the corresponding manufacturing and clinical sites, with those products that are recognized as having met the WHO quality standard subsequently placed on a list of prequalified medicinal products used by United Nations agencies and other organizations to guide their procurement decisions regarding medicines being provided to the developing world.