



## PRESS RELEASE

# Eisai and DNDi Enter into a Collaboration and License Agreement to Develop a New Drug for Chagas Disease

**Geneva, Switzerland, September 29, 2009** – Eisai Co., Ltd. (“Eisai”) and the Drugs for Neglected Diseases *initiative* (DNDi), a non-profit independent foundation, announced today that they have signed a collaboration and license agreement for the clinical development of a promising new drug for the treatment of Chagas disease, a fatal infectious disease that threatens 100 million people in Latin America and the Caribbean.

Ravuconazole, an anti-fungal drug discovered and developed by Eisai, has been shown in *in vitro* and *in vivo* to have potent activity against the pathogen responsible for Chagas disease. Under the terms of the agreement, DNDi shall retain sole responsibility for the clinical development to assess the safety and efficacy of E1224, which is a pro-drug of ravuconazole, in patients with Chagas disease within endemic countries. Eisai shall provide DNDi with its scientific expertise in clinical development as well as supply the drug for the clinical studies. Eisai shall also have the option to become the industrial partner with DNDi to manufacture, register and make available E1224 at an affordable price to the public sector in endemic countries.

*“Since the establishment of DNDi in 2003 to develop innovative, safe, affordable and more efficacious drugs for the treatment of neglected diseases, this agreement represents a first of its kind in forging a partnership with a Japanese pharmaceutical company to bring innovation in health tools to those most in need.”* declared Dr Bernard Pécoul, Executive Director of DNDi. *“This project will give hope for the patients and the practitioners in the field.”*

*“We are extremely pleased to establish an innovative and collaborative product development partnership with DNDi to address jointly the unmet needs of patients suffering from neglected diseases”,* emphasized Mr. Haruo Naito, President and CEO of Eisai. *“In recognition of the plight of millions of Chagas patients, Eisai is stepping forward to join the quest for bringing a new, effective and affordable treatment option to them. This partnership further illustrates Eisai’s human health care (hhc) mission to satisfy unmet medical needs and increase the benefits to patients and their families.”*

Transmitted by the bite of the kissing bug or *vinchuca*, Chagas disease is a public health problem particularly in the poor areas of Latin America and the Caribbean. About 8 million people are believed to carry it<sup>[1]</sup>, and about a third of these - if left untreated - will develop serious heart or intestinal damage that could lead to death. Two drugs, discovered decades ago with limited efficacy at the chronic phase of the disease and poor tolerability profile in adults, are currently available. In this context, the development of a new treatment which could be effective for the chronic phase of the disease, particularly in adults, would represent a breakthrough.

In a collaborative effort to address unmet medical needs for neglected diseases, Eisai and DNDi will work in tandem to bring a new treatment option for patients with Chagas disease as early as possible.

## Notes for Editors

### About Chagas disease

Chagas disease is primarily transmitted by large, blood-sucking reduviid insects widely known as “the kissing bug”, Chagas disease is endemic in 21 countries across Latin America, with an average of 14,000 deaths per year, Chagas disease kills more people in the region each year than any other parasite-born disease, including malaria. These are mostly poor people who live in rural areas or migrate to the outskirts of larger urban centers. Without an adequate diagnosis and treatment, one in every three to four Chagas disease patients develops a potentially fatal form of the disease, which involves the enlargement of the heart. Often, patients will require a pace-maker, implantable defibrillators and in some cases need to undergo a heart transplant. Many patients, however, die suddenly, some without ever realizing that they had been infected. According to WHO<sup>[2]</sup>, the number of diagnosed cases has been increasing over recent years due to population mobility and shifts of existing transmission to areas classified as of nonendemic for Chagas disease, such as Australia, Canada, Europe, Japan, and the United States of America. This increase presents additional risks of transmission through blood transfusion, congenital infection and organ transplantation.

### About DNDi

**The Drugs for Neglected Diseases *initiative* (DNDi)** is a not-for-profit product development partnership working to research and develop new and improved treatments for neglected diseases such as malaria, leishmaniasis, human African trypanosomiasis, and Chagas disease. With the objective to address unmet patient needs for these diseases, DNDi was established in 2003 by the Oswaldo Cruz Foundation from Brazil, the Indian Council for Medical Research, the Kenya Medical Research Institute, the Ministry of Health of Malaysia the Pasteur Institute and Médecins sans Frontières (MSF). WHO/TDR acts as a permanent observer. Working in partnership with industry and academia, DNDi has the largest ever R&D portfolio for the kinetoplastid diseases. Since 2007, DNDi has delivered three products, fixed-dose antimalarials “ASAQ” and “ASMQ”, and a treatment for the advanced stage of sleeping sickness NECT (nifurtimox-eflornithine combination therapy). For more: [www.dndi.org](http://www.dndi.org). In July 2009, on the occasion of the centenary of the discovery of Chagas disease, DNDi has launched a worldwide campaign to draw attention to the huge gaps in treatments for Chagas patients. For more: [www.treatchagas.com](http://www.treatchagas.com).

### About Eisai Co., Ltd.

Eisai Co., Ltd. is a research-based human health care company that discovers, develops and markets products throughout the world. Eisai focuses its efforts in three therapeutic areas: Integrative Neuroscience, including neurology and psychiatric medicine; Integrative Oncology, including anticancer therapies and supportive-care treatment; and Vascular/Immunological Reaction, including acute coronary syndrome, sepsis, rheumatoid arthritis, etc. Through a global network of research facilities, manufacturing sites and marketing subsidiaries, Eisai actively participates in all aspects of the worldwide health care system. Eisai currently employs more than 10,000 people worldwide. For more information about Eisai, please visit [www.eisai.co.jp/index-e.html](http://www.eisai.co.jp/index-e.html)

[1] WHO, A62/17, Chagas disease: control and elimination, Report by the WHO Secretariat, 20 March 2009

[2] idem

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