

**Drugs for Neglected Diseases *initiative* and Eisai Co., Ltd. to Test Drug Candidate for Eumycetoma
Patients suffering from virtually no R&D for this neglected disease**

Drugs for Neglected Diseases *initiative*
Eisai Co., Ltd.

[Basel, Switzerland , Tokyo, Japan- 10 September 2015] The Drugs for Neglected Diseases *initiative* (DNDi) and the Japanese pharmaceutical company Eisai Co., Ltd. have signed an agreement to proceed with the clinical development of Eisai's anti-fungal drug fosravuconazole for the potential new treatment of eumycetoma, a fungal form of mycetoma, one of the world's most neglected diseases.

Most probably transmitted through pricks to the skin by walking barefoot, eumycetoma is a chronic condition that affects people in tropical and subtropical regions, in particular across Africa, with the highest burden found in Sudan. The fungus penetrates the skin and causes massive tumour-like lesions that lead to serious disability, grave socioeconomic consequences, and stigma.

There is only one current treatment option, which is expensive, toxic, and only cures about 30% of patients even after twelve months of treatment. Those who aren't cured are at risk of repeated amputations as the infection spreads throughout the body.

Fosravuconazole, an azole-class antifungal drug discovered by Eisai, has shown *in vitro* and *in vivo* to have strong antifungal activities against eumycetoma.* Under the terms of the agreement, DNDi and partners will be conducting the clinical development to assess safety and efficacy of fosravuconazole in patients with the disease, while Eisai provides DNDi with its scientific expertise as well as a supply of the drug for the clinical studies. Eisai also has the option to become DNDi's industrial partner to manufacture, register, and make available fosravuconazole at an affordable price to the public sector in endemic areas.

'We are very excited about the possibility of a new treatment against this terrible and neglected condition', said Dr Nathalie Strub-Wourgaft, Medical Director of DNDi. *'Eumycetoma patients have received little attention and virtually no research and development has addressed their needs.'*

There are major knowledge gaps about mycetoma in general, including about its transmission, prevalence, route of infection, and susceptibility. The disease was only recently added to the World Health Organization (WHO) list of neglected tropical diseases in 2013, under 'other neglected conditions'.

'Mycetoma is a serious global health issue affecting mostly young adults in developing countries, particularly those of low socioeconomic status and manual workers such as agriculturalists, labourers and herdsmen', said Takashi Owa, Ph.D., Chief Innovation Officer, Eisai Co., Ltd. *'As a human health care company, we are committed to developing a new treatment for this horrendous disease, thereby contributing to the lives of people in endemic areas.'*

Fosravuconazole will be investigated in a randomized controlled trial to study the efficacy of the drug compared to an existing therapy in moderate eumycetoma cases. This study is scheduled to start in 2016, and will be conducted by DNDi in collaboration with the Mycetoma Research Center (MRC) of the University of Khartoum, Sudan.

* PLoS Negl Trop Dis. 2014 Jun 19;8(6):e2942. doi: 10.1371/journal.pntd.0002942. eCollection 2014.

About the Drugs for Neglected Diseases *initiative* (DNDi)

A not-for-profit research and development organization, DNDi works to deliver new treatments for neglected diseases, in particular leishmaniasis, human African trypanosomiasis, Chagas disease, specific filarial infections, paediatric HIV, mycetoma, and hepatitis C. Since its inception in 2003, DNDi has delivered six treatments: two fixed-dose antimalarials (ASAQ and ASMQ), nifurtimox-eflornithine combination therapy (NECT) for late-stage sleeping sickness, sodium stibogluconate and paromomycin (SSG&PM) combination therapy for visceral leishmaniasis in Africa, a set of combination therapies for visceral leishmaniasis in Asia, and a paediatric dosage form of benznidazole for Chagas disease. DNDi has established regional disease-specific platforms, which bring together partners in disease-endemic countries to strengthen existing clinical research capacity, as well as to build new capacity where necessary. www.dndi.org

About Eisai Co., Ltd.

Eisai Co., Ltd. is a leading global research and development-based pharmaceutical company headquartered in Japan. We define our corporate mission as "giving first thought to patients and their families and to increasing the benefits health care provides," which we call our *human health care (hhc)* philosophy. With over 10,000 employees working across our global network of R&D facilities, manufacturing sites and marketing subsidiaries, we strive to realize our *hhc* philosophy by delivering innovative products in various therapeutic areas with high unmet medical needs, including Oncology and Neurology.

As a global pharmaceutical company, our mission extends to patients around the world through our investment and participation in partnership-based initiatives to improve access to medicines in developing and emerging countries.

For more information about Eisai Co., Ltd., please visit www.eisai.com.

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