

Researchers to test drug candidate for eumycetoma

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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 <u>chronic condition</u> that affects people in tropical and <u>subtropical regions</u>, 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 <u>stigma</u>.

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 <u>clinical development</u> 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.

Provided by Drugs for Neglected Diseases Initiative

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