



MYCETOMA

- Chronic inflammatory disease, in a fungal (eumycetoma) and a bacterial (actinomycetoma) form. Eumycetoma, mainly endemic in Africa, is much more difficult to treat
- Attacks the skin, deep muscle structures and the bone, believed to enter the body via thorn pricks or lesions on the feet
- Affects poor people in rural areas and in particular young males aged between 15 and 30
- Causes devastating deformities, often resulting in amputation and morbidity
- No global surveillance systems exist, so epidemiological data is lacking. The Mycetoma Research Centre in Khartoum, Sudan, has recorded around 6,500 patients since 1991
- Mycetoma is endemic in tropical and subtropical regions. The 'mycetoma belt' includes Chad, Ethiopia, Mauritania, Sudan, Senegal, and Somalia, as well as India, Mexico, Venezuela, and Yemen



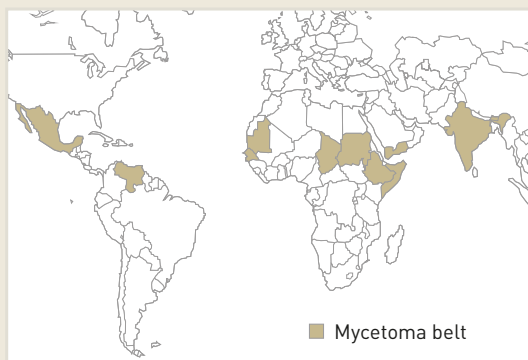
Eumycetoma treatments are extremely long, toxic, ineffective, and expensive. The disease is slow-growing and people often only seek treatment when it has reached later stages, by which time antifungal treatments are only 25-35% effective. Treatment is often followed by surgical removal of the remaining mass, leading to multiple amputations and, ultimately, the loss of entire limbs – with the risk of complications and death. An effective, safe, and affordable treatment for use in rural settings is urgently needed.

In 2016, mycetoma became the 18th disease to be added to the WHO list of NTDs, giving the disease political prominence and potentially paving the way for governments to monitor the disease, and for donors to fund research.

80% of known patients develop deformities that need to be amputated

Global burden

Unknown



“I was in excruciating pain. I had to use a lot of pain killers just to be able to walk from one point to another. At some point, I got tired and decided to have my leg amputated.”

Alsadik Mohamed Musa Omer

Infected with mycetoma 19 years ago while playing football at school in Sudan

DNDi aims to deliver:

- A new safe, effective, and affordable treatment for patients with limited eumycetoma



Fosravuconazole

OBJECTIVE: Conduct a randomized controlled clinical trial to investigate the efficacy of fosravuconazole compared to the current treatment, itraconazole.

Background: The anti-fungal drug fosravuconazole, an orally bioavailable azole discovered by Eisai and under development for Chagas disease (see p. 35 'New benzimidazole regimen +/- fosravuconazole' project), may be an effective and affordable treatment for eumycetoma. A Phase II/III randomized controlled trial will be conducted to study the efficacy of fosravuconazole in moderate lesions compared to the current treatment, itraconazole. The primary objective of this double-blind, randomized, single-centre study will be to demonstrate the superiority of fosravuconazole over itraconazole after 12 months' treatment.



Dr Haruo Naito
Representative Corporate
Officer and CEO,
Eisai Co., Ltd

“Eisai places an emphasis on initiatives that lead to increase non-financial value, including ESG (Environmental, Social and Governance). Eliminating NTDs, one of the major social issues which is affecting more than 1 billion people mainly in developing countries, is in alignment with Eisai's *hbc* philosophy, and we believe these endeavors will ultimately lead to increase our corporate value. We are proud of our collaboration with DNDi to develop treatments for Chagas disease and mycetoma, and are proactively and continuously working to solve access to medicine problems in developing countries.”

2016 Protocols were finalized. Recruitment of patients (with a target of 136 participants) started in early 2017. An interim analysis will be conducted at three months.

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➔ SPOTLIGHT

Political recognition at last: mycetoma added to WHO list of neglected tropical diseases

In 2016, mycetoma was added to WHO's official list of 'neglected tropical diseases' during the 69th World Health Assembly, making it the 18th disease in the list. By adding this devastating infection to the list, WHO Member States took an important step in boosting national and global responses to this woefully neglected disease and addressing the suffering of patients. This inclusion will give the disease the political prominence it so desperately needs to help increase donors, funders, and pharmaceutical bodies' awareness and attention leading to more research and development, health education, and advocacy programmes. This will eventually lead to better medicines and diagnostic tests ■

Dr Najwa Jouda in the laboratory of the Mycetoma Research Centre, Sudan



Prof Ahmed Hassan Fahal
Director, Mycetoma Research Centre, Sudan

“I was representing the Sudanese Government when I gave a statement to support the inclusion of mycetoma in the WHO neglected tropical diseases list that was discussed at the World Health Assembly in Geneva in May. Its adoption was a memorable event. I could not control my deep emotions and feelings and in fact I went into tears.”