

New drug candidate for Chagas disease tested in patients in Bolivia

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This photo was taken in Minsque, Bolivia. Credit: Fabio Nascimento / DNDi, 2014

The Drugs for Neglected Diseases initiative (DNDi) announced today at the International Congress of Parasitology (ICOPA), the launch of a Phase II drug trial to test fexinidazole, a drug shelved in the 1980s and 'rediscovered' by DNDi nearly a decade ago, for Chagas disease patients. The drug is also being tested in patients in Africa for two other parasitic

diseases, sleeping sickness and visceral leishmaniasis.

Chagas disease, with up to 8 million victims and 100 million at risk of infection in Latin America and increasingly elsewhere, is the number one cause of infectious heart disease in the region. Despite the vast disease burden, only two treatments exist and both are associated with side effects, notably nifurtimox, and benznidazole – which is the best available treatment option today.

'With results of recent studies on E1224 and posaconazole offering no perspective as monotherapies for Chagas disease, but providing solid data for the efficacy of benznidazole, we have two very important jobs to do with no delay: scale up treatment with benznidazole and push on with new treatment strategies including bringing new drugs into the pipeline', said Dr Bernard Pécoul, Executive Director, DNDi. 'We have no excuse not to move full speed ahead with these two strategies', he added.

The Phase II study of fexinidazole as a monotherapy for Chagas [patients](#) with indeterminate chronic disease, carried out by DNDi and its partners, has begun recruiting patients to test efficacy and safety of the new drug. The double-blind, multicentre, placebo-controlled, dose-finding and proof-of-concept trial will include 140 patients. The aim is to determine whether at least one of six dosing regimens of the orally administered drug is safer and more efficacious than placebo in clearing the *T. cruzi* parasite that causes the disease. This is the second proof-of-concept Phase II trial to be conducted in Bolivia.

'We have greatly benefited from the recent study conducted in Bolivia, which has provided the knowhow we and our partners needed to set up and launch this important clinical trial', said Dr Isabela Ribeiro, Head of the Chagas Programme, DNDi. 'Such collaborative research efforts are bringing us to a new level of science for the benefit of Chagas disease

patients, and we are doing all we can to ensure new treatments get tested and delivered.'

DNDi's clinical development programme for Chagas disease currently pursues the evaluation of fexinidazole and new regimens of benznidazole, as a monotherapy and in combination, for the treatment of adult patients with chronic indeterminate Chagas disease in order to reduce drug exposure and improve tolerability, while maintaining or improving efficacy. DNDi also undertakes early stage drug screening and lead optimization activities to ensure that back up molecules are available and advance through the drug development pipeline.

Current treatments for Chagas disease alarmingly reach only 1% of the estimated 8 million affected, highlighting the immediate need to scale up treatment today and accelerate development of entirely new drugs.

Fexinidazole for Chagas Disease Trial Partners

Platform of Integral Care for Patients with Chagas Disease, Tarija y Cochabamba (Bolivia); Universidad Mayor de San Simon, Bolivia; Universidad Autónoma Juan Misael Saracho, Bolivia; Collective of Applied Studies and Social Development (CEADES), Bolivia; Centre de Recerca en Salut Internacional de Barcelona (CRESIB), Spain; National Council of Scientific and Technological Research (INGEBI/CONICET), Argentina; JSS Medical Research, Canada; Cardiabase, France; CREAPHARMA, France.

About Chagas disease

The leading parasitic killer in the Americas, Chagas disease (American trypanosomiasis) infects an estimated 8 million people, mostly in Latin America, where it is endemic in 21 countries and kills some 12,000 people each year. The most affected people are very poor, live in

inadequate housing conditions, and often have little access to healthcare. Cases of Chagas disease are increasingly recognized in North America, Europe, Japan, and Australia. Caused by the parasite *Trypanosoma cruzi*, Chagas disease starts with an early, acute stage lasting a variable period, and is followed by a late, chronic stage lasting a lifetime, in which up to 30% of patients develop life-threatening heart damage and up to 10% may have severe damage to their digestive system. The Chagas parasite is primarily transmitted via the bite of the blood-sucking triatomine bug, sometimes called the 'kissing bug'. Chagas is also transmitted by blood transfusion, organ transplantation, oral ingestion, or during pregnancy from mother to newborn, in which an estimated 14,000 new cases occur annually. Current treatments are often limited in their broad implementation due to the duration of treatment and side effects associated with their use. DNDi is working to develop a new, safe, effective, and affordable treatment for Chagas disease.

Provided by Drugs for Neglected Diseases Initiative

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