



Drugs for Neglected Diseases *initiative*

FOR IMMEDIATE RELEASE

New Child-Adapted Chagas Disease Treatment Approved for Registration

[Rio de Janeiro and Recife, Brazil, and Geneva, Switzerland – 2 December 2011] Today, at the occasion of the 4th DNDi Partners' Meeting in Rio de Janeiro, Brazil, Dr Carlos Gadelha, Secretary of Science, Technology and Strategic Products, Brazilian Ministry of Health, announced that Brazil's National Health Surveillance Agency (ANVISA) granted registration of a new paediatric dosage form of benznidazole, developed through a partnership between the Pernambuco State Pharmaceutical Laboratory (LAFEPE) of Brazil and the Drugs for Neglected Diseases *initiative* (DNDi). Registration of this child-adapted formulation of benznidazole will be published on 12 December 2011.

This new tablet means easier-to-administer and safer treatment of Chagas disease in infants and young children under the age of two, as they will receive accurate dosage.

Until today, benznidazole was available only as a 100-mg tablet for adults. Treatment for young children required cutting adult pills into tiny slivers – up to 12 pieces depending on the child's weight – and crushing and mixing them with water or juice, to be administered twice a day for 60 days. This difficult and inefficient method often results in improper dosing, risks of increased side-effects or ineffective treatment, and treatment stoppages.

Chagas disease infects an estimated 8 to 10 million people, mostly in Latin America, and kills some 12,000 people each year, making it the leading parasitic killer in the Americas, where it causes more deaths than malaria. The Chagas parasite is primarily transmitted via the bite of the blood-sucking triatome bug, widely known as the 'kissing bug', which is often found in poor housing conditions. In addition to blood transfusion, organ transplant, or ingesting infected food, the parasite is also transmitted during pregnancy from mother to child.

This new dosage form for children represents real progress for several reasons. Children are at especially high risk of infection, with a majority of them born from infected mothers. It is known that early treatment using benznidazole in the first year of life can eliminate the parasite in more than 90% of infected newborns. Thus, babies infected with Chagas disease will benefit the most from this new paediatric tablet.

'Thousands of mothers with Chagas disease-infected babies will welcome this as more than just a pill', says Manuel Gutiérrez, President of the International Federation of Chagas Patients. 'Their voices have finally been heard.'

The new 12.5-mg tablet is easily dispersible (disintegrated) and adapted for babies and children up to two years of age (20 kg body weight). Treatment is designed to use one, two, or three tablets, depending on weight (recommended dosage, 5-10 mg/kg bodyweight/day).

'The presentation of this paediatric dosage form of benznidazole, as a final result of the collaborative project between DNDi and LAFEPE, opens possibilities for effective treatment [...] for thousands of children', says Dr Mirta Roses Periago, Director of the Pan American Health Organization (PAHO). 'From now on, hope of an early cure for infection of the parasite that causes Chagas disease is a wonderful reality.'

Tools to facilitate implementation of and access to the new treatment include a Demand Forecast, a Procurement Guide, and a Tool Box providing training and educational materials for doctors, other health professionals, mothers, and caregivers regarding appropriate use of the treatment.

In 2008, DNDi and LAFEPE entered a joint development agreement for this dosage form. The new tablet will be produced by LAFEPE, a public pharmaceutical manufacturer run by the State of Pernambuco in Brazil and the sole global producer of benznidazole.

'We will exert all efforts, regarding commercial aspects, towards rapid patient access of this drug', says Luciano Vasquez, President of LAFEPE. 'It will be offered at cost to all public health institutions, including the Ministry of Health of Brazil.' Indeed, the paediatric dosage form will also be made available at cost to non-governmental organizations and philanthropic institutions.

The new paediatric dosage form has been granted registration from Brazil's National Health Surveillance Agency (ANVISA), and DNDi is collaborating with LAFEPE to make the drug widely available, notably by working to register the drug in Argentina, Bolivia, Colombia, and Paraguay – priority countries where Chagas disease prevalence is high and treatment is urgently needed.

'At a time when efforts are being made to secure production of benznidazole, we must ensure that this new product is made available in all endemic areas and that treatment of children is rapidly expanded, in addition to the treatment of adults', says Dr Bernard Pécoul, Executive Director of DNDi. 'With this new tablet, we can reach a turning point for the treatment of children infected with Chagas disease and we have to move rapidly to get the drug to them.'

The project received funding support from the Department for International Development (DFID), UK; the Dutch Ministry of Foreign Affairs (DGIS), The Netherlands; Médecins Sans Frontières/Doctors without Borders (International, Italy, Brazil); the Spanish Agency for International Development Cooperation (AECID), Spain; the Swiss Agency for Development and Cooperation (SDC), Switzerland; the United States Agency for International Development, via the 4th Sector Health Project implemented by Abt Associates, Inc.; Swiss private foundations and individual donors.

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About Chagas Disease

Chagas disease (American trypanosomiasis) infects an estimated 8 to 10 million people, mostly in Latin America, where it is endemic in 21 countries. It kills some 12,000 people each year, making it the leading parasitic killer in the Americas. The people most affected by the disease are very poor and live in inadequate housing conditions and often have little access to healthcare. Cases are also rising in North America, Europe, Japan, and Australia. Caused by the parasite *Trypanosoma cruzi*, Chagas disease starts with an early, acute stage lasting about two months, and is followed by a late, chronic stage lasting through lifetime, in which up to 30% of patients develop heart damage and up to 10% may have severe damage to their digestive system. In early adulthood, patients with these symptoms ultimately die, usually from heart damage. The Chagas parasite is primarily transmitted via the bite of the blood-sucking triatome bug, sometimes called the 'kissing bug'. Chagas is also transmitted by blood transfusion, organ transplantation, oral ingestion, or during pregnancy from mother to newborn. The latter, congenital Chagas disease, is considered to represent the most important mode of transmission of the coming years, and it is estimated that over 14,000 new such cases occur annually.

About LAFEPE

Pernambuco State Pharmaceutical Laboratory (Laboratório Farmacêutico do Estado de Pernambuco; LAFEPE) is the second largest public laboratory in Brazil. LAFEPE was created in 1966 to produce medicines at low cost for people with limited purchasing power. Based in Recife, the capital of the state of Pernambuco in northeastern Brazil, LAFEPE focuses on developing, producing, and marketing drugs to support the needs of public health policy. For example, in 1994, it became the first official laboratory in Brazil to produce the antiretroviral

zidovudine (AZT). The Pernambuco laboratory invests in the modernization of its facilities, with high-tech industrial equipment. Its pioneering programme, 'Popular Pharmacy', set up in popular market areas in different regions of the state, serves as a model for the federal government. www.lafepe.pe.gov.br

About DNDi

The Drugs for Neglected Diseases *initiative* (DNDi) is a not-for-profit research and development organization working to deliver new treatments for neglected diseases, in particular sleeping sickness (human African trypanosomiasis), Chagas disease, leishmaniasis, specific helminth infections, and paediatric HIV. DNDi was established in 2003 by Médecins Sans Frontières/Doctors Without Borders (MSF), Oswaldo Cruz Foundation (FIOCRUZ) from Brazil, Indian Council for Medical Research (ICMR), Kenya Medical Research Institute (KEMRI), Ministry of Health of Malaysia, and Pasteur Institute of France. The Special Programme for Tropical Disease Research (TDR) serves as a permanent observer. Since 2003, DNDi has delivered five new treatments for neglected patients: 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, and a set of combination therapies for visceral leishmaniasis in Asia. The new paediatric dosage form of benznidazole is now the sixth treatment delivered by DNDi since its inception eight years ago. www.dndi.org

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