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News Release

Not intended for U.S. and UK Media

1st World Neglected Tropical Diseases Day

Bayer application for nifurtimox to treat pediatric patients with Chagas disease submitted for approval in US

- New formulation for weight-adjusted treatment of pediatric Chagas patients age 0-18 targets most vulnerable patient group
 - Submission based on results of CHICO (**CH**agas disease **I**n **C**hildren treated with Nifurtim**O**x) phase III clinical study of nifurtimox in pediatric patients with Chagas disease as well as pre-clinical data
 - Fight against Neglected Tropical Diseases part of Bayer's Sustainability Strategy
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Berlin, January 30, 2020 – On the occasion of the first “World Neglected Tropical Diseases (NTDs) Day”, Bayer reiterates its commitment to contribute to fight these diseases that still threaten 1.5 billion people worldwide. In addition to supporting the World Health Organization with medicines for African sleeping sickness and Chagas disease free of charge, Bayer developed a new formulation of its medication nifurtimox in order to improve the body-weight adjusted dosing in pediatric Chagas patients. The application to the U.S. Food and Drug Administration (FDA) builds on the positive results from the CHICO phase III clinical study, the largest clinical study to date in pediatric patients with Chagas disease.

“The new formulation of nifurtimox will improve dosing for newborns, infants, and children, the most vulnerable patient group suffering from Chagas disease and will be a significant contribution to control the disease,” said Stefan Oelrich, Member of the Board of Management of Bayer AG and President of Bayer's Pharmaceuticals Division. “We will improve access to nifurtimox through new applications for registrations in countries with a high disease burden. The fight against NTDs is part of Bayer's Sustainability Strategy, launched in December 2019.”

The potentially life-threatening Chagas disease is caused by the protozoan parasite *Trypanosoma cruzi*. In endemic countries, transmission of the disease most commonly occurs through the bite of triatomines or kissing bugs and the parasites contained in the excreta of the insect penetrate the bite wound. Children are especially vulnerable due to their relatively thin skin and their exposure to such insects. The disease can also be transmitted through infected blood transfusions, organ transplantation, or by the congenital route from an infected mother to her unborn child.

“In fact, the younger the patient, the better the chances of recovery,” said Dr. Jaime Altcheh, Head of the Department of Parasitology and Chagas disease at the Ricardo Gutierrez Children’s Hospital in Buenos Aires and coordinating investigator of CHICO. “With the new pediatric formulation, we can more accurately treat newborn and infants. The tablets can be broken to divide the dose. Equally as important, the tablet dissolves quickly in water, which is particularly significant because these very young children are not able to swallow solid tablets – and they have to receive the medication three times a day for 60 days.”

CHICO is a prospective, randomized, double-blind, historically controlled phase III trial to evaluate the efficacy, safety, and pharmacokinetics of nifurtimox in 330 pediatric patients with acute or chronic Chagas disease. It was conducted at 25 investigational sites in Argentina, Bolivia, and Colombia between 2016 and 2018. With the CHICO SECURE program all patients who were enrolled in CHICO for additional three years are further followed-up.

About Bayer

Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. Its products and services are designed to benefit people by supporting efforts to overcome the major challenges presented by a growing and aging global population. At the same time, the Group aims to increase its earning power and create value through innovation and growth. Bayer is committed to the principles of sustainable development, and the Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2018, the Group employed around 117,000 people and had sales of 39.6 billion euros. Capital expenditures amounted to 2.6 billion euros, R&D expenses to 5.2 billion euros. For more information, go to www.bayer.com.

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