

This Thursday the organization will receive the BBVA Foundation Frontiers of Knowledge Award in Development Cooperation

The Drugs for Neglected Diseases Initiative (DNDi) is testing new treatments against sleeping sickness, leishmaniasis, Chagas disease and aids

- Bernard Pécoul, Executive Director of DNDi, affirms that the drugs now under study “could drastically change the management of certain neglected diseases.”
- The BBVA Foundation Frontiers of Knowledge Award in Development Cooperation is conferred during the organization’s tenth anniversary year.

Madrid, June 18 2013.- For those in the field it goes by the name of *the 10/90 gap*: the fact that only 10 per cent of global health research is devoted to conditions that account for 90 per cent of the global disease burden. It was to challenge this imbalance that the Drugs for Neglected Diseases Initiative (DNDi) came into being in 2003. Coinciding with its tenth anniversary year, the organization has been granted the BBVA Foundation Frontiers of Knowledge Award in the Development Cooperation category. Its Executive Director, Bernard Pécoul, announced this morning at a press conference that new drugs the DNDi is working on “could drastically change the management of some of these diseases.”

The organization and its partners are studying new, easier-to-administer oral drugs against sleeping sickness, Chagas disease and leishmaniasis for use among disadvantaged populations. DNDi has already delivered improved treatments against these diseases by combining or reformulating existing

medicines, and now has new chemical compounds at different stages of the testing process.

Also under development is a new treatment for pediatric HIV. Pécoul remarked at the conference that 350,000 children each year need anti-HIV treatment and that of this number 90% are born in Africa. Although HIV is a widely studied condition, “nothing is being done specifically for children in the underdeveloped world.” Today’s treatments are neither child friendly – they taste bad and contain alcohol – nor suitable for patients in certain areas – they need refrigeration. Two years ago, DNDi started a project to combine four drugs in one; a pleasant-tasting formulation that doesn’t require the cold chain and which, according to Pécoul, “will hopefully reach the market in a few years.”

Pécoul will collect the award this Thursday at a formal ceremony in the BBVA Foundation’s Madrid headquarters.

Public-private partnerships

DNDi is a not-for-profit research and development organization working to deliver new treatments for what are commonly known as neglected diseases, a set of 17 conditions that affect hundreds of millions of people who are collectively too poor to offer a lucrative market to the pharmaceutical companies. It focuses particularly on sleeping sickness or human African trypanosomiasis, Chagas disease, leishmaniasis, filarial infections, malaria, and pediatric HIV.

DNDi was set up on the combined initiative of seven public and private institutions: Médecins Sans Frontières/Doctors Without Borders, the Indian Council for Medical Research, the Kenya Medical Research Institute, the Malaysian Ministry of Health, France’s Institut Pasteur, Brazil’s Oswaldo Cruz Foundation (Fiocruz), and the Special Program for Research and Training in Tropical Diseases of the World Health Organization.

Its strategy is to coordinate and synergize the efforts of public and private partners – including pharmaceutical companies – in the development, production and distribution of new treatments. DNDi has offices in Switzerland, Brazil, the Democratic Republic of the Congo, Kenya, India, Malaysia, the United States and Japan, and coordinates a partnership network that liaises with the public and private institutions involved in each project.

“DNDi’s innovative collaborative model,” Pécoul remarks, “has secured the increasing engagement of public and private actors, as a result of growing awareness of these urgent and neglected public health issues.”

Among the organization’s partners are a number of Spanish institutions including Médecins Sans Frontières Spain, the Barcelona Centre for International Health Research (CRESIB), Carlos III University of Madrid, and GSK Tres Cantos. DNDi has also received financial support from the Spanish development cooperation agency AECID.

Six approved treatments

Pécoul offers figures to illustrate just what is meant by *neglected* diseases: between 1975 and 1999 only 16 of the total 1,393 new drugs developed by the pharmaceutical industry were specifically indicated for tropical diseases plus malaria or tuberculosis. In the last decade “progress has been made,” but, he is quick to point out, “the fatal imbalance persists.” A bare 3.8% of the products, excluding vaccines, approved between 2000 and 2011 were targeted on neglected diseases. As were no more than 1.4% of the clinical trials conducted in the same period.

After ten years of research and development, DNDi has delivered six treatments: two antimalarials, a combination therapy for late-stage sleeping sickness, a combination therapy for visceral leishmaniasis in Africa, a set of combination therapies for visceral leishmaniasis in Asia, and a paediatric dosage form of benznidazole for Chagas disease.

Also, the organization has helped establish three clinical research platforms in Africa and the Americas: for leishmaniasis in Kenya, Ethiopia, Sudan, and Uganda; for sleeping sickness in the Democratic Republic of the Congo; and for Chagas disease in Latin America. “Strong regional networks such as these,” Pécoul affirms, “help strengthen research and treatment-implementation capacity in neglected disease-endemic countries.”

Sleeping sickness

NECT, the new sleeping sickness treatment developed by DNDi and its partners, is the first new product in 25 years indicated for the late stages of the disease. It is far safer than what was till now the standard treatment, melarsoprol, an arsenic derivative so toxic that it kills 5% of those it is supposed to cure. The new drug is already available in the twelve African countries home to 99% of declared sleeping sickness cases.

DNDi is also working with partners on two new chemical entities for this indication: oxaborole SCYX-7158 and fexinidazole. The first is an oral compound which is currently concluding Phase I clinical studies, while fexinidazole, also an oral treatment, began Phase II/III studies in the Democratic Republic of the Congo and Central African Republic in October 2012.

“A safe, effective, oral-only treatment would simplify the way the disease is managed,” Pécoul explains, “as well as supporting the WHO’s target to eliminate sleeping sickness by 2020.”

Leishmaniasis and Chagas

DNDi is also about to start Phase II studies – testing efficacy and safety – on the use of fexinidazole in visceral leishmaniasis patients in East Africa.

Ten years ago, the standard treatment for visceral leishmaniasis was a month-long course of painful daily injections, a treatment schedule that is difficult to manage in poorly equipped health centers in the remote areas where the disease is found. The combined therapy delivered by DNDi has already shortened the schedule to 17 days, but the goal remains to come up with an oral treatment.

In the case of Chagas disease, a decade ago there were no pediatric formulations. But DNDi’s dosage form for children up to the age of two is oral, inexpensive, and easy-to-use. It is also designed for home administration: an important pro-compliance factor in what is a lengthy two-month treatment.

Another oral drug, E1224, is currently being tested on adult patients in Bolivia. “If successful,” Pécoul says, “this drug could be the oral, easy-to-use, affordable and safe treatment Chagas patients are waiting for.”

These ongoing projects are joined by an early-stage pipeline of twelve entirely new chemical entities.

“Receiving this prestigious award by the BBVA Foundation is a great honor for us and our partners and recognition of our collective achievements of the past 10 years,” says Dr. Pécoul. “It is also a strong encouragement to pursue our mission and to continue to develop and deliver new and affordable treatments to neglected patients in dire need.”

For more information, contact the BBVA Foundation Communication Department
(+34 91 374 5210, +34 91 537 3769 or comunicación@bbva.es or visit
www.bbva.es