

DNDi Launches Phase I In-Human Clinical Trial for Promising Oral Drug for Sleeping Sickness

[Geneva, Switzerland – 12 March 2012] – **The Drugs for Neglected Diseases *initiative* (DNDi) has commenced a Phase I clinical trial in healthy adults in Paris, France, to determine the safety and tolerability of a promising oral drug candidate Oxaborole SCYX-7158, to treat human African trypanosomiasis (HAT, or sleeping sickness) for stage 1 and stage 2 of the disease.**

This randomized, double-blind, placebo-controlled study will assess the safety, tolerability, pharmacokinetics and pharmacodynamics of SCYX-7158 in healthy volunteers. The study is a combined trial including three sequential parts: first, administration of single oral ascending doses; second, concomitant food intake with single oral dose administration, in order to assess the bioavailability of SCYX-7158 (food effect); and third, administration of multiple oral ascending dose. The study is taking place in a Phase I unit in Paris, at SGS Aster, and will recruit up to 120 volunteers.

Approval for the study was obtained from a French Ethics Committee (Comité de Protection des Personnes) and the French Regulatory Authority AFSSAPS (Agence Française de Sécurité Sanitaire des Produits de Santé).

'This is an important milestone in our efforts to build and maintain a strong pipeline for new oral treatments against sleeping sickness. DNDi and its partners are committed to harnessing all of the efforts and expertise necessary to support the WHO goal of eliminating this disease by the year 2020. New oral treatments that can be administered at the field level would be a vital part of this', comments Dr Bernard Pécou, Executive Director, DNDi.

Oxaborole SCYX-7158 is DNDi's first clinical candidate issued from the DNDi Lead Optimization Consortium to enter Phase I trials. The development of the compound was the result of a unique collaboration between DNDi and Anacor Pharmaceuticals (USA), SCYNEXIS (USA), within a consortium including also Pace University (USA) and the Swiss Tropical and Public Health Institute (Switzerland). Together they worked on the Oxaboroles series and amongst the molecules studied, SCYX-7158 was selected for its very promising pre-clinical results.

If Oxaborole SCYX-7158 progresses successfully through Phase I clinical trials, DNDi plans to advance the treatment into a multi-center Phase II trial in sub-Saharan African countries where the disease occurs.

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About sleeping sickness

Sleeping sickness, which threatens millions in 36 countries in sub-Saharan Africa, is fatal if left untreated. The disease is caused by parasites transmitted by the bite of a tsetse fly and is often asymptomatic for years (stage 1) until the infection reaches stage 2, where it crosses into the central nervous system and brain. Currently available treatments are limited to drugs developed decades ago that are either highly toxic, difficult to administer in resource-limited settings, or are only effective in one stage of the disease. In addition, prior to being treated, the stage of the disease must be determined using a diagnostic spinal tap to extract cerebrospinal fluid from the patient.



About the partnership

A collaboration led by the Drugs for Neglected Disease *initiative* (DNDi) combined Anacor Pharmaceuticals' novel boron chemistry with the chemistry and parasitology expertise at SCYNEXIS. A scientific consortium led by DNDi and including SCYNEXIS, Pace University, Swiss Tropical and Public Health Institute, and Anacor worked on the optimization of a series of benzoxaboroles, which led to the discovery of SCYX-7158. Advinus Therapeutics conducted toxicology testing on the compound. The project has mostly been supported by the Bill & Melinda Gates Foundation and the Ministry of Foreign and European Affairs (MAEE), France. Additional funding is provided by the Department for International Development (DFID), UK, Dutch Ministry of Foreign Affairs (DGIS), The Netherlands, Spanish Agency of International Cooperation for Development (AECID), Spain, Federal Ministry of Education and Research (BMBF), Germany, Swiss Agency for Development and Cooperation (SDC), Switzerland, and Doctors Without Borders/Médecins Sans Frontières (MSF).

For more information on the partnership:

http://www.dndi.org/images/stories/pdf_press_releases/Sleeping%20Sickness%20Background%20Document_June%202011.pdf

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, malaria, and paediatric HIV. DNDi was established in 2003 by Médecins Sans Frontières/Doctors Without Borders (MSF), the Oswaldo Cruz Foundation (FIOCRUZ) of Brazil, the Indian Council of Medical Research (ICMR), the Kenya Medical Research Institute (KEMRI), the Ministry of Health of Malaysia, and the Pasteur Institute of France. The Special Programme for Tropical Disease Research (WHO/TDR) serves as permanent observer.

Since its inception in 2003, DNDi has delivered six 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, a set of combination therapies for visceral leishmaniasis in Asia, and a paediatric dosage form of benznidazole for Chagas disease.

DNDi has helped establish three clinical research platforms: Leishmaniasis East Africa Platform (LEAP) in Kenya, Ethiopia, Sudan, and Uganda; the HAT Platform based in the Democratic Republic of Congo (DRC) for sleeping sickness; and the Chagas Clinical Research Platform in Latin America. Strong regional networks such as these help strengthen research and treatment-implementation capacity in neglected disease-endemic countries.

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