SANOFI

DNDi
Drugs for Neglected Diseases *initiative*

Press Release
Source: Sanofi (EURONEXT: SAN) (NYSE: SNY)

Sanofi, DND*i* seek European Medicines Agency review for sleeping sickness treatment

- Fexinidazole would be first all-oral treatment* under investigation for both first and second stages of sleeping sickness, a fatal disease, endemic in Africa
- Sanofi submission is the culmination of 10 years of collaboration with the Drugs for Neglected Diseases *initiative* (DND*i*) in research and development
- Dossier will be reviewed under the Article 58 procedure, which is intended for medicines that will be used outside of the European Union

Paris, Geneva – January 31 2018 - Sanofi has asked the European Medicines Agency (EMA) to review fexinidazole for the treatment of sleeping sickness. Fexinidazole is being developed in collaboration with the Drugs for Neglected Disease *initiative* (DND*i*). It would be the first all-oral treatment under investigation for *Trypanosoma brucei gambiense* human African trypanosomiasis (g-HAT), commonly known as sleeping sickness. It is hoped that this treatment will contribute to the elimination of the disease.

EMA has accepted the application under a special procedure called "Article 58" which allows the EMA to give a scientific opinion, in co-operation with the World Health Organization (WHO), for the evaluation of medicinal products that are intended exclusively for markets outside of the European Union. Fexinidazole was previously granted accelerated assessment by the EMA.

> *"The acceptance by the EMA of the fexinidazole regulatory dossier is a critical step in the registration process,"* said Dr. Nathalie Strub-Wourgaft, DND*i* Medical Director. "*Results of the Phase II/III clinical trials conducted with our partners in Democratic Republic of Congo and the Central African Republic, which were published in The Lancet** last November, showed the product to be effective and well tolerated."*

Following the evaluation of the dossier, the EMA will publish its scientific opinion of the benefit risk of the treatment, which will facilitate the registration of fexinidazole in HAT-endemic countries.

* vs current standard of care oral niflurtimox and IV eflornithine
** Lancet. 2018 Jan 13;391(10116):144-154. doi: 10.1016/S0140-6736(17)32758-7. Epub 2017 Nov 4

"This milestone is the result of an innovative collaboration between Sanofi and DNDi to address the burden of sleeping sickness," said Dr. Ameet Nathwani, Chief Medical Officer, Sanofi. "*Fexinidazole is being developed with the goal of addressing all stages of sleeping sickness and simplifying treatment by avoiding systematic hospitalization. It could represent a therapeutic breakthrough foremost for the patients and potentially support elimination efforts as per the WHO 2020 Roadmap."*

About sleeping sickness

Human African Trypanosomiasis (HAT) or "sleeping sickness" is a tropical disease affecting sub-Saharan African countries. Without prompt diagnosis and treatment, sleeping sickness is usually fatal as the parasites invade the central nervous system. Sixty million people who live mainly in rural parts of East, West and Central Africa are at risk of contracting sleeping sickness. In 2015, the total number of HAT reported cases was 2,804, continuing the decreasing trend observed in recent years and in line with WHO objectives to reach the goal of elimination of the disease as a public health problem by 2020 (<2,000 cases).

About fexinidazole

Fexinidazole is a 10-day oral treatment for HAT currently in clinical development. The treatment is being developed for all stages of sleeping sickness, meaning patients could potentially avoid systematic hospitalization and the need for lumbar puncture.

In the 1970s, Hoechst (now part of Sanofi) had initiated but did not pursue pre-clinical development of fexinidazole, an antiparasitic drug. In 2005, the compound was identified by DND*i* as having activity against the sleeping sickness parasite. Pre-clinical studies began in 2007. In 2009, DND*i* and Sanofi concluded a collaboration agreement for the development, manufacturing, and distribution of fexinidazole, with DND*i* responsible for pre-clinical, clinical, and pharmaceutical development, and Sanofi responsible for industrial development, registration, production and distribution of the drug. Phase I studies began in 2010, and the Phase II/III pivotal clinical study in 2012.

DND*i*'s fexinidazole program is supported by grants from the Bill & Melinda Gates Foundation, the UK Department for International Development, the Dutch Ministry of Foreign Affairs, the German Federal Ministry of Education and Research, the German Development Agency, the French Development Agency, the French Ministry of Foreign and European Affairs, the Norwegian Agency for Development Cooperation, the Spanish Agency for International Development Cooperation, the Republic and Canton of Geneva, Switzerland, the Swiss Agency for Development and Cooperation, Médecins Sans Frontières/Doctors without Borders, and other private foundations and individuals.

About DNDi

A not-for-profit research and development organization, DND*i* works to deliver new treatments for neglected diseases, in particular human African trypanosomiasis, leishmaniasis, Chagas disease, filarial infections, mycetoma, pediatric HIV, and hepatitis C. Fexinidazole is DND*i*'s first new chemical entity to successfully complete Phase II/III trials. www.dndi.org

About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

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Sanofi Forward-Looking Statements
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