

Fexinidazole, the first all-oral treatment for sleeping sickness, approved in Democratic Republic of Congo

- * Fexinidazole will contribute to international efforts to eliminate sleeping sickness, a fatal neglected tropical disease endemic to Africa, by 2020
- * It is the first all-oral treatment for sleeping sickness, and is effective for both stages of the disease
- * Democratic Republic of Congo bears the majority of the sleeping sickness disease burden, with around 85% of reported cases

PARIS and GENEVA – January 30, 2019 – Marketing authorization of fexinidazole for the treatment of *Trypanosoma brucei gambiense* human African trypanosomiasis (HAT), more commonly known as sleeping sickness, has been granted in the Democratic Republic of Congo (DRC). This approval paves the way for the distribution of fexinidazole in endemic countries this year, with another submission planned in Uganda.

Sleeping sickness is usually fatal without treatment. Transmitted by the bite of a tsetse fly, it causes neuropsychiatric symptoms; including aggression, psychosis, and a debilitating disruption of sleep patterns that have given this neglected disease its name. About 65 million people in sub-Saharan Africa are at risk.

“I have a personal connection to sleeping sickness. Growing up in East Africa, my mother was always worried that sleeping sickness would impact us as a family,” says Ameet Nathwani, M.D., Chief Medical Officer and Executive Vice President Sanofi Medical. *“The approval of fexinidazole in the Democratic Republic of Congo gives me great hope for our efforts to eliminate sleeping sickness by next year.”*

The current treatment option for sleeping sickness, while effective, was burdensome for patients and health workers – requiring logistical challenges of hospitalization, especially challenging for people living in remote areas.

Fexinidazole is approved in the DRC as a 10-day once-a-day treatment for *T.b. gambiense* sleeping sickness (the most common form of the disease, found in West and Central Africa). Importantly, fexinidazole is the first all-oral treatment that works both for (i) the early stage of the disease as well as the (ii) second stage of the disease in which the parasites have crossed the blood-brain barrier, causing patients to suffer from

neuropsychiatric symptoms. Fexinidazole could, therefore, eliminate the need for patients' systematic hospitalization.

On 16 November 2018, The European Medicines Agency (EMA) adopted a positive scientific opinion of fexinidazole - a result of clinical trials led by the non-profit research and development organization the Drugs for Neglected Diseases *initiative* (DNDi) and an application submitted by Sanofi.

"We look forward to the implementation of fexinidazole as a first-line treatment and welcome this rapid approval of fexinidazole in the DRC very shortly after the EMA opinion, a testament to the dedication of the DRC Government through the Ministry of Health to eliminate HAT as a public health problem by 2020," says Dr Nathalie Strub-Wourgaft, DNDi Director of Neglected Tropical Diseases. *"This shows the value of Article 58, an innovative regulatory mechanism intended for the review of new medicines destined for use outside of the European Union."*

Sanofi had submitted a regulatory dossier to the EMA under Article 58 of Regulation 726/2004 in December 2017. By allowing for the participation of endemic countries (DRC and Uganda) and of the WHO in the evaluation of the fexinidazole regulatory dossier, approval under Article 58 also facilitates and could accelerate future national product registrations and patient access.

About sleeping sickness

The majority of sleeping sickness patients live in the Democratic Republic of Congo, where 85% of *Trypanosoma brucei gambiense* sleeping sickness cases were reported in 2017, followed by the Central African Republic, Guinea and Chad. The latest data released by the WHO in July 2018 confirm a sustained decrease in the number of new cases. Only 1,447 new cases were reported to the WHO in 2017 compared to 2,164 cases in 2016 and 9,870 cases in 2009. But the history of sleeping sickness is marked by resurgence, interspersed by decades where the disease has seemed largely under control. In its roadmap on neglected tropical diseases published in 2012 and supported the same year by the London Declaration, the WHO included sleeping sickness, and targets its elimination as a public health problem by 2020.

About DNDi

A not-for-profit research and development organization, DNDi works to deliver new treatments for neglected diseases, in particular human African trypanosomiasis, leishmaniasis, Chagas disease, filarial infections, mycetoma, paediatric HIV, and hepatitis C. Since its creation in 2003, DNDi has delivered eight treatments. Fexinidazole is the first new chemical entity to be successfully developed by DNDi.

DNDi's fexinidazole programme is supported by grants from the Bill & Melinda Gates Foundation, USA; UK aid, UK; Dutch Ministry of Foreign Affairs (DGIS), The Netherlands; Federal Ministry of Education and Research (BMBF) through KfW, Germany; French Development Agency (AFD), France; German Corporation for International Cooperation (GIZ) on behalf of the Federal Republic of Germany, Germany; Ministry of European and Foreign Affairs (MEAE), France; Médecins sans Frontières; Norwegian Agency for Development Cooperation (Norad), Norwegian Ministry of Foreign Affairs, as part of Norway's in-kind contribution to EDCTP2; Republic and Canton of Geneva, International Solidarity Office, Switzerland; Spanish Agency for International Development and Cooperation (AECID), Spain; Swiss Agency for

Development and Cooperation (SDC), Switzerland; UBS Optimus Foundation, Switzerland; Brian Mercer Charitable Trust, UK; Stavros Niarchos Foundation, USA and other private foundations and individuals from the HAT campaign.

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.

Sanofi, Empowering Life

Media Relations Contact

Anna Robinson
Tel.: +33 (0)1 53 77 46 46
mr@sanofi.com

Investor Relations Contact

George Grofik
Tel.: +33 (0)1 53 77 45 45
ir@sanofi.com

DNDi Media Relations Contact

Ilan Moss
Tel.: +1 646 266 5216
imoss@dndi.org

Moyette Gibbons
Tel.: +41 79 940 9017
mgibbons@dndi.org

Sanofi Forward-Looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates regarding the marketing and other potential of the product, or regarding potential future revenues from the product. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, unexpected regulatory actions or delays, or government regulation generally, that could affect the availability or commercial potential of the product, the absence of guarantee that the product will be commercially successful, the uncertainties inherent in research and development, including future clinical data and analysis of existing clinical data relating to the product, including post marketing, unexpected safety, quality or manufacturing issues, competition in general, risks associated with intellectual property and any related future litigation and the ultimate outcome of such litigation, and volatile economic conditions, as well as those risks discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2017. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.