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DNDi
Drugs for Neglected Diseases *initiative*

Press Release
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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* (DND*i*) 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, DND*i* 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 DND*i*

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, paediatric HIV, and hepatitis C. Since its creation in 2003, DND*i* has delivered eight treatments. Fexinidazole is the first new chemical entity to be successfully developed by DND*i*.

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.

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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

DND*i* Media Relations Contact
Ilan Moss
Tel.: +1 646 266 5216
imoss@dndi.org

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

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