SANOFI

Media Update

US FDA approves fexinidazole as the first all-oral treatment for sleeping sickness

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The US Food and Drug Administration (FDA) has approved fexinidazole as the first all-oral treatment for both stages of the *Trypanosoma brucei gambiense* form of sleeping sickness (Human African trypanosomiasis) in patients 6 years of age and older and weighing at least 20 kg.
Fexinidazole was developed as part of an innovative partnership between the non-profit research and development organization Drugs for Neglected Diseases *initiative* (DND*i*), which conducted the pivotal clinical trials for this treatment, in partnership with the National Sleeping Sickness Programs of the Democratic Republic of Congo (DRC) and Central African Republic (CAR), and Sanofi.

Sleeping sickness is a parasitic disease transmitted by the bite of an infected tse-tse fly. It affects mostly populations living in remote rural areas of sub-Saharan Africa, where about 65 million people are at risk of infection. Left untreated, sleeping sickness is almost always fatal. Through Sanofi's collaboration the number of sleeping sickness cases reported to the WHO has been reduced by ~97% between 2001 and 2020. DND*i,* Sanofi and partners are deeply committed to ensuring access to fexinidazole in all sleeping sickness-endemic countries.

Current treatment options for the disease are effective, but burdensome for patients and health workers due to the need for infusion or injection, requiring hospitalization, especially challenging for people living in remote areas.

"Having a simple, all-oral treatment for sleeping sickness is a dream come true for frontline clinicians," said Dr Bernard Pécoul, DND*i* Executive Director*. "We are proud of this latest milestone in our long-term partnership with Sanofi, developed in close collaboration with researchers in countries hard-hit by sleeping sickness."*

Fexinidazole is indicated as a 10-day once-a-day treatment for *Trypanosoma brucei gambiense* sleeping sickness, the most common form of the disease found in West and Central Africa. Fexinidazole is the first all-oral treatment that works both for the first stage of the disease, as well as the second stage of the disease in which the parasites have crossed the blood-brain barrier, causing patients to suffer from neuropsychiatric symptoms.

"*This FDA approval is a key milestone in Sanofi's long-term commitment to fight sleeping sickness, started 20 years ago alongside the WHO through an ambitious*

partnership to combat Neglected Tropical Diseases" said Luc Kuykens, Senior Vice President, Sanofi Global Health unit. "*Following the positive scientific opinion granted by the European Medicines Agency end 2018, the FDA approval is an important step to revitalize efforts to support the sustainable elimination of the disease*".

As a result of FDA approval, a Tropical Disease Priority Review Voucher (PRV) has been awarded to DND*i*. The FDA Tropical Disease PRV Program was established in 2007 to incentivize development of new treatments for neglected tropical diseases, including sleeping sickness. Any benefits from the PRV will be shared between Sanofi and DND*i*, which will enable continued investments in innovating for and ensuring access to new health tools for sleeping sickness and other neglected diseases. Sanofi commits to continue to provide the drug free-of-charge to the World Health Organization for distribution to affected countries, as part of a long-term collaboration with WHO.

About Sleeping sickness

Sleeping sickness, or human African trypanosomiasis (HAT), is usually fatal without treatment. Transmitted by the bite of an infected tse-tse fly, following a period with nonspecific symptoms, it evolves to cause neuropsychiatric symptoms, including abnormal behaviour, 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 moderate to very high risk of infection.

About DND*i*

The Drugs for Neglected Diseases *initiative* (DND*i*) is a collaborative, patient needs-driven, not-for-profit research and development (R&D) organization that develops safe, effective, and affordable treatments for sleeping sickness, leishmaniasis, Chagas disease, filarial infections, mycetoma, paediatric HIV, hepatitis C, and covid-19. Since its inception in 2003, DND*i* has delivered eight new treatments, including nifurtimox-eflornithine combination therapy (NECT) for late-stage sleeping sickness, and fexinidazole, the first all-oral drug for sleeping sickness.

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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