

Fexinidazole, the first all-oral treatment for sleeping sickness, approved in DRC

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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, Director of Neglected Tropical Diseases at DNDi. "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.

Provided by Drugs for Neglected Diseases Initiative

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