DNDi
Best Science for the Most Neglected

DISEASE FACTSHEET

SLEEPING SICKNESS

Delivering all-new treatments to eliminate a deadly disease

Sleeping sickness – or human African trypanosomiasis (HAT) – is caused by a parasite transmitted by the bite of the tsetse fly. It can result in severe neuropsychiatric symptoms, coma, and death if left untreated. For decades, the most widely available treatment was melarsoprol – an arsenic-derived drug so toxic it killed one in twenty patients.

FACTS

» **1.5 million**
people with moderate to high risk of being infected

» **61%**
of reported cases in the last 5 years were in the DRC

» **97%**
reduction in reported cases in the last 20 years

» THE PUSH FOR PROGRESS

In the 1990s, medical teams from our founding partner Médecins Sans Frontières (MSF) were on the front lines of devastating outbreaks of sleeping sickness in endemic African countries, treating patients in remote settings with melarsoprol as their only option. The gap between medical need and safe, practical treatments for deadly diseases sparked a clarion call for better treatments that prioritized patients' needs over profits.

We have been focused on making treatment for sleeping sickness safer and simpler since our founding in 2003. While DNDi and partners' nifurtimox-eflornithine combination therapy (NECT), delivered in 2009, met the urgent need for a less toxic treatment, its complex administration and need for refrigeration posed logistical challenges in remote and under-resourced areas. Continued innovation and a long-term strategy to develop oral, field-adapted treatments were needed. Following its identification in 2005, DNDi and partners began clinical trials of fexinidazole in 2009. Nine years later, the paradigm-changing all-oral treatment for both stages of *T.b. gambiense* sleeping sickness received a positive opinion from the European Medicines Agency (EMA), followed in 2023 by the expansion of its indication to include *T.b. rhodesiense* sleeping sickness, the less common but more acute form of the disease.

In early 2026, the long road to a safe, simple, field-adapted treatment that could be deployed in the most remote areas reached a turning point when acoziborole – an all-new, single-dose oral treatment for *T.b. gambiense* sleeping sickness developed by DNDi in partnership with Sanofi – received a positive opinion from the European Medicines Agency (EMA).

These remarkable innovations were achieved through strong collaboration with national control programmes and the DNDi-supported HAT Platform, a network of experts and institutions that helps coordinate research, evaluate new tools, and support access. For the less common, more acute *T.b. rhodesiense* form of the disease, we also coordinated the HAT-r-ACC consortium, bringing together partners with expertise in research, training, and community engagement in remote endemic settings in Uganda and Malawi.

OUR GOAL IS NOW to make the final push towards eliminating sleeping sickness by ensuring access to treatment for all who need it, including children, while strengthening disease surveillance and response in endemic countries and exploring simplified screen-and-treat strategies to support elimination goals.

ONE DOSE, ONE CURE

Registered for use in the DRC in June 2026, acoziborole represents a scientific breakthrough that helps ensure the long and devastating history of sleeping sickness can finally be brought to a close.

> When I took the medicine, I felt better quickly.

PASSY, from Kwilu in the Democratic Republic of the Congo, fell ill with sleeping sickness in 2017. In pain and unable to work, her brother took her to Masi-Manimba Hospital, where she received treatment as a participant in the acoziborole clinical trial.

Photo credit:Brent Stirton-DNDi/Getty Images

Following the identification of a promising prototype compound in the Anacor Pharmaceuticals chemical library in 2009, DNDi later joined with its industrial partner, Sanofi, to continue developing acoziborole. A pivotal clinical trial demonstrated the safety and efficacy of the single-dose cure in 2022, with high treatment success rates across both stages of the disease.

With this milestone achieved, DNDi teams and partners are now focused on facilitating registration in other endemic countries and preparing for access. This includes working with national authorities, WHO, and implementing partners to support country-level regulatory pathways, readiness planning, and introduction strategies aligned to elimination goals.

MOVING TOWARDS SIMPLIFIED MODELS OF CARE

As countries move closer to elimination, the remaining cases of sleeping sickness are increasingly concentrated in remote communities and detected through targeted screening campaigns. **Acoziborole represents an important step change in how the last cases will be treated.** As a single-dose oral treatment designed for use at the point of care, the drug enables simpler, more practical strategies for achieving and sustaining elimination gains.

In the DRC, the STROGHAT clinical trial conducted by DNDi, the Institute of Tropical Medicine (ITM) Antwerp, the national sleeping sickness control programme of the DRC, and other partners is helping to establish how acoziborole can be used to enable simplified 'screen-and-treat' approaches that do not depend on complex laboratory testing or direct observation in hospital.

Started in 2024, the trial continued to recruit participants and generate reassuring safety data in 2025. DNDi teams also continued to work with in-country partners to strengthen pharmacovigilance systems necessary to support wider use of oral therapies, build confidence among health workers and communities, and enable access to treatment closer to people's homes.

INNOVATING FOR THE MOST VULNERABLE

Current treatments for children with *T.b. gambiense* sleeping sickness who are less than six years old or under 20 kilograms still require painful lumbar punctures, hospitalization, and treatments administered through intravenous infusion.

Together with African and European experts in the ACOZI-KIDS consortium, DNDi teams and partners completed recruitment for the ACOZI-KIDS trial in March 2025, enrolling 35 children across all weight bands in the study. **If proven effective, acoziborole could transform the way young children receive – and experience – treatment for sleeping sickness.**