



## FACTS



# 3 M

people with moderate to high risk of being infected



# 70%

of reported cases in the last decade were in the DRC



# 20%

of infections are in children

# SLEEPING SICKNESS

## Delivering breakthrough treatments and expediting access for sustained elimination

**S**leeping sickness – or human African trypanosomiasis (HAT) – is a parasitic disease spread by the bite of the tsetse fly. Over time, it causes severe neuropsychiatric symptoms and is almost always fatal if left untreated. Until 2008, the only treatment available for advanced sleeping sickness was melarsoprol, an arsenic derivative so toxic it killed 1 in 20 patients.

### The push for progress

We have been focused on developing better treatments for sleeping sickness since our founding in 2003. By 2009, working closely with partners including Epicentre and Médecins Sans Frontières (MSF), we finalized the development of nifurtimox and eflornithine (NECT), a simpler, safer treatment for the second stage of the most common form of the disease. In 2018, DNDi, Sanofi, and partners delivered fexinidazole, a paradigm-changing simple oral treatment for both stages of the disease that can be taken at home. And we have helped build the HAT Platform, a network of 120 experts from over 20 research institutions in affected countries, closely linked with policymakers, working to increase diagnosis, care, treatment, and research so that new treatments can be rapidly and effectively evaluated, registered, and rolled out.

**Our goal is now** to complete development of, and then ensure access to, acoziborole, a single-dose oral treatment that holds tremendous promise for efforts to sustainably eliminate the disease. We will also continue work to scale up access to fexinidazole while studying its use for *T.b. rhodesiense* sleeping sickness, a less common but more acute form of the disease.



**Sophy Akecho** is a former sleeping sickness patient who lives in Angorom village in eastern Uganda. Sophy had *T.b. rhodesiense* sleeping sickness, the most common form of the disease in Uganda, which often causes death within weeks or months if left untreated. Better treatments are urgently needed: the only treatment currently available for second-stage *T.b. rhodesiense* sleeping sickness is still melarsoprol. Administered by injection, the toxic and painful arsenic-based drug kills up to 5% of patients who receive it.

“ I had to receive my treatment with injections. I cried because it hurt so much.

## Ensuring access to the first all-oral treatment

Following earlier positive scientific opinion granted by the European Medicines Agency and regulatory approvals in the DRC and Uganda, fexinidazole was approved by the US FDA in July 2021 for both stages of *T.b. gambiense* sleeping sickness. Now authorized for use in 10 of 13 countries with cases of *T.b. gambiense* sleeping sickness reported in the last five years, a majority of eligible patients are receiving the improved treatment.

In 2021, our teams continued work with partners to further ensure access, training nearly 500 health workers on diagnosis, treatment, and pharmacovigilance. We also worked with national control programmes and the HAT-r-ACC Consortium to provide clinical data to assess the use of fexinidazole for both stages of *T.b. rhodesiense* sleeping sickness, the less common form of the disease prevalent in East Africa, and to raise community awareness about diagnosis and treatment. DNDi's pivotal Phase II/III study of fexinidazole for *T.b. rhodesiense* sleeping sickness completed recruitment in 2021, with patient follow-up continuing through late 2022.

## Acoziborole

While the delivery of fexinidazole has greatly improved therapeutic options for sleeping sickness, we are pushing further with Sanofi and partners to develop an additional oral drug, especially one that could be given as a one-day, single-dose treatment, that could simplify administration and strengthen efforts towards sustained elimination of the disease. In 2021, we completed data analysis for our pivotal Phase II/III clinical trial evaluating acoziborole for adult patients with *T.b. gambiense* sleeping sickness. We also enrolled the first patients in a follow-on trial to evaluate the safety and tolerability of acoziborole in *T.b. gambiense* seropositive, non-parasitologically confirmed participants.

Together with partners in the ACOZI-KIDS consortium, our teams continued preparations to assess acoziborole for children aged between 1 and 14 years old in the DRC and Guinea, with the first participants expected to be enrolled by mid-2022. If successful, acoziborole could serve as a child-friendly, single-dose oral treatment.