



“An all-oral treatment has been my dream for decades. Less than ten years ago we were still treating this disease with an arsenic derivative that killed 5% of all patients and now we have a treatment that is safe, effective, and simple. ”

**Dr Victor Kande**, from the National Sleeping Sickness Control Programme of the Democratic Republic of Congo, screening villagers for sleeping sickness in Lwano village, DRC.



# SLEEPING SICKNESS

## BRINGING NEW HOPE TO PATIENTS THANKS TO REVOLUTIONARY TREATMENT

Sleeping sickness is usually fatal without treatment. Transmitted by the bite of a tsetse fly, it causes neuropsychiatric symptoms, including aggression, psychosis, the debilitating disruption of sleep patterns that have given this neglected disease its name and, finally, coma. While it is now on the cusp of elimination, history shows that it can surge again if control measures are withdrawn, as happened in the 1960s and '70s.



**8.5 MILLION** people live in areas at moderate to very high risk



**67.5%** of the world's sleeping sickness cases in 2018 were reported in the Democratic Republic of Congo



**24 COUNTRIES** in West & Central Africa are endemic for the *T.b. gambiense* strain

AND

**13 COUNTRIES** in East & Southern Africa are endemic for the *T.b. rhodesiense* strain.

## MAKING MEDICAL HISTORY: A TREATMENT BREAKTHROUGH FOR SLEEPING SICKNESS

In 2018, DNDi and partners delivered fexinidazole, the first all-oral treatment for the *T.b. gambiense* strain of sleeping sickness that affects West and Central Africa (see p. 5).

Fexinidazole will help to increase access to treatment for rural patients and support the global goal of disease elimination. With elimination getting closer every year – fewer than 1,000 cases of the *T.b. gambiense* strain were diagnosed in 2018 – a simplified oral treatment is needed to reach the last cases and then to sustain elimination.

**DNDi aims to deliver new oral treatments to cure sleeping sickness that are safe, affordable, effective and easy to use, and support the sustainable elimination of the disease.** DNDi is now evaluating the safety of fexinidazole to treat the *T.b. rhodesiense* strain of the disease found in East Africa. DNDi is also developing a single-dose oral cure, acoziborole, for *T.b. gambiense*.

### A doctor's dream – DNDi delivers an all-oral treatment for sleeping sickness

In November 2018, the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use issued a 'positive opinion' on the use of fexinidazole as the first oral treatment effective for both stages of sleeping sickness, paving the way for national registration of the drug in affected countries.

Fexinidazole, a 10-day, once-a-day treatment for the *T.b. gambiense* strain of the disease, constitutes a huge leap forward in the treatment of sleeping sickness. It eliminates the need for systematic hospitalization for late-stage patients, reduces the number of lumbar punctures needed for diagnosis and follow-up, and brings treatment closer to the rural and remote areas where patients live. Following the EMA decision, the Democratic Republic of Congo (DRC) was the first country to register fexinidazole just 39 days later. Registration in Uganda and approval for use in other endemic countries is expected in 2019 followed by the update of the World Health Organization treatment guidelines.

Fexinidazole is the result of a ten-year partnership between DNDi, Sanofi, National Sleeping Sickness Control Programmes, and clinical partners. Beginning in 2019, Sanofi will donate the medicine to the World Health Organization for distribution to national sleeping sickness control programmes in affected countries.

### Continuing research to support and sustain disease elimination

DNDi continues to run a study (Phase IIIb) in the DRC and Guinea to assess fexinidazole in special populations, including pregnant and lactating women, and people with poor nutritional status or chronic disease.

While fexinidazole was approved to treat the *T.b. gambiense* strain of sleeping sickness, which occurs in West and Central Africa, DNDi is also studying its efficacy in the other, less common form of the disease. Called *T.b. rhodesiense*, this strain occurs primarily in East Africa. To this end, in 2018 DNDi began preparations for a study in Malawi and Uganda to begin in mid-2019.

In 2018, DNDi also continued to develop its second sleeping sickness drug, acoziborole, an oral drug that could be administered as a single dose to treat both stages of sleeping sickness in adults, which could give a radical boost to sleeping sickness elimination plans. The drug is currently in a Phase II/III study in the DRC and Guinea, with results expected by the end of 2020.

