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Sanofi, DNDi ask for EMA review to treat sleeping sickness

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Sanofi has asked the European Medicines Agency (EMA) to review an experimental medicine fexinidazole.

Fexinidazole is being developed in collaboration with the Drugs for Neglected Disease initiative (DNDi) for the treatment of sleeping sickness, which is endemic in Africa.

Fexinidazole is a 10-day oral treatment under investigation for Trypanosoma brucei gambiense human African trypanosomiasis (g-HAT), a fatal disease more commonly known as sleeping sickness.

The Paris, France-based drugmaker said it is hoped that the treatment will contribute to the elimination of the disease.

The European Medicines Agency has accepted the application under a special procedure called “Article 58”, which allows it to give a scientific opinion, in co-operation with the World Health Organisation (WHO), for medicinal products intended exclusively for markets outside of the European Union.

Fexinidazole was previously granted accelerated assessment by the EMA.

Following the evaluation of the dossier, the EMA will publish its scientific opinion of the benefit risk of the treatment and facilitate the registration of fexinidazole in HAT-endemic countries.