Press Release

Acoziborole Winthrop, developed by DNDi and Sanofi, receives CHMP positive opinion as three-tablet, single-dose treatment for most common form of sleeping sickness

- Recommendation based on phase 2/3 study demonstrating up to 96 percent success rates at 18 months across both early and advanced stages of *T.b. gambiense*, the most common form of sleeping sickness
- The therapy, given as a single dose of three tablets, could offer a simpler alternative to longer, more complex regimens and help support the World Health Organization's (WHO) goal of eliminating the disease by 2030
- Sanofi will donate the medicine to WHO through its philanthropic arm Foundation S

Kinshasa / Paris / Geneva / Amsterdam – February 27, 2026. The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has granted a positive opinion to Acoziborole Winthrop (acoziborole) as a single-dose oral treatment for both early and advanced-stage gambiense sleeping sickness in adults as well as in adolescents 12 years and older weighing at least 40 kilograms.

The CHMP positive opinion is a critical step. It is granted through accelerated assessment under a specific procedure intended for countries outside of the European Union and used for high-priority medicines for diseases with unmet needs. This will facilitate approval of the medicine in the Democratic Republic of Congo (DRC) and pave the way for an update of WHO's sleeping sickness treatment guidelines, a move that would eventually expand access to other countries in Central and West Africa, where the disease is endemic.

Once approved in endemic countries, the medicine, co-developed by the Drugs for Neglected Diseases initiative (DNDi) and Sanofi, could provide a significant advance over current therapies. Existing treatments require either a 10-day course of oral medicine or a combination of injections and oral therapy for advanced cases.

Transmitted by the bite of an infected tsetse fly, human African trypanosomiasis, commonly known as sleeping sickness, is almost always fatal without treatment. In the early stage of the disease, people experience headaches or fever. In the late stage, the parasite crosses the blood-brain barrier and invades the central nervous system, causing behavioral, cognitive and neurological symptoms, including seizures, sleep disturbances, aggression, confusion, lethargy, convulsions, and, ultimately, death.

> "*In just 20 years, we have gone from complicated treatments including arsenic derivatives with serious side effects, to today, when a single-dose, one-day therapy could safely cure patients,"* said Luis Pizarro, MD, Executive Director at DNDi. "*This progress is testament to the transformative power of collaborative science and will bring us closer to finally eliminating sleeping sickness, a disease that has killed millions on the African continent in the past century."*

DNDi conducted a pivotal phase 2/3 study in the DRC and Guinea in partnership with National Sleeping Sickness Control Programs, while Sanofi carried out the regulatory approval process. The CHMP positive opinion is based on clinical and non-clinical data provided by the partners, with efficacy and safety supported by the phase 2/3 study, published in *The Lancet Infectious Diseases* medical journal, which demonstrated success rates at 18 months of up to 96 percent across both stages of the disease with a good safety profile.

> "*The development of acoziborole and today's positive scientific opinion is a victory for Africa-led science, made possible thanks to African doctors and researchers who conducted cutting-edge pharmaceutical research in some of the most remote and difficult-to-reach areas on the continent,"* said Erick Miaka, MD, Director of the DRC's national sleeping sickness control program.

In 1998, nearly 40,000 cases of *gambiense* sleeping sickness were reported, with an estimated 300,000 undiagnosed. At the time, the only available treatment for those with the late stage of the disease was an injectable arsenic derivative with serious side effects. More than two decades of investment in new therapeutic tools resulted in increasingly improved treatments, including nifurtimox-eflornithine combination therapy in 2009 and the first oral treatment fexinidazole in 2018. In 2024, fewer than 600 cases of the disease were reported.

> *"For decades, Sanofi has maintained an unwavering commitment to the fight against sleeping sickness, standing alongside DNDi, the World Health Organization, and other partners in one of the most enduring and successful public-private health collaborations," said Audrey Duval, Executive Vice President, Corporate Affairs at Sanofi. "Together, we have helped drive cases to historic lows—achieving a remarkable 98% reduction since 2001—by putting patients first and investing in innovation where it is needed most. Acoziborole builds on this legacy and represents a decisive step forward in eliminating gambiense sleeping sickness by 2030."*

Sanofi will donate Acoziborole Winthrop to the WHO through its philanthropic organization, Foundation S – The Sanofi Collective. The medicine will be available free of charge to patients.

Another study underway in the DRC and Guinea is investigating Acoziborole Winthrop for the treatment of children ages one to 14.

About the DNDi programme for the development of acoziborole

The DNDi programme for the development of acoziborole was supported by grants from the Federal Ministry of Research, Technology and Space (BMFTR) through KfW, Germany; the BBVA Foundation (through the 'Frontiers of Knowledge Award in Development Cooperation'); Dutch Ministry of Foreign Affairs (DGIS), the Netherlands; European and Developing Countries Clinical Trials Partnership Association (EDCTP2 programme) supported by the European Union; Global Health EDCTP3 and its members; Gates Foundation; Médecins Sans Frontières International; Norwegian Agency for Development Cooperation (Norad), Norwegian Ministry of Foreign Affairs, as part of Norway's in-kind contribution to EDCTP2; Swiss Agency for Development and Cooperation (SDC); Swiss State Secretariat for Education, Research and Innovation (SERI); Stavros Niarchos Foundation; Spanish Agency for International Development Cooperation (AECID); UK International Development; and other private foundations and individuals.

About DNDi's sleeping sickness programme

Acoziborole Winthrop is the first oral single-dose new chemical entity to be issued from DNDi's lead optimization programme for sleeping sickness. It started with an initial hit identified in the chemical library of Anacor Pharmaceuticals, which was acquired by Pfizer in 2016. The initial structure was then optimized with Scynexis and Pace University and was then selected as a

candidate for development and Phase I safety studies conducted successfully in France, the UK, and Malaysia.

Acoziborole Winthrop is the latest innovation brought by more than two decades of innovation efforts by DNDi, Sanofi, and partners. In 2009, they developed a combination of existing drugs known as NECT, which was extremely effective and with a good safety profile. A donation programme was set up by Sanofi and Bayer to provide NECT free of charge to endemic countries through the World Health Organization (WHO), radically improving treatment options for patients.

DNDi, Sanofi, and partners developed fexinidazole, which in 2018 became the first all-oral treatment available for gambiense sleeping sickness. This ten-day treatment is now available in all sleeping sickness-endemic countries.

Acoziborole Winthrop can be administered as a single oral dose, potentially without the need of hospitalization or supervision of the treatment at home. This means it could become a major tool to facilitate efforts to finally eliminate sleeping sickness.

About DNDi

The Drugs for Neglected Diseases initiative (DNDi) is a not-for-profit medical research organization that discovers, develops, and delivers safe, effective, and affordable treatments for neglected populations. DNDi is developing medicines for sleeping sickness, leishmaniasis, Chagas disease, river blindness, mycetoma, dengue, paediatric HIV, cryptococcal meningitis, and hepatitis C. Its research priorities include children's health; gender equity and gender-responsive R&D; and diseases impacted by climate change. Since its creation in 2003, DNDi has collaborated with public and private partners worldwide to deliver new treatments for six deadly diseases, saving millions of lives. Acoziborole is the 14th treatment delivered by DNDi. dndi.org

About Sanofi

Sanofi is an R&D driven, AI-powered biopharma company committed to improving people's lives and delivering compelling growth. We apply our deep understanding of the immune system to invent medicines and vaccines that treat and protect millions of people around the world, with an innovative pipeline that could benefit millions more. Our team is guided by one purpose: we chase the miracles of science to improve people's lives; this inspires us to drive progress and deliver positive impact for our people and the communities we serve, by addressing the most urgent healthcare, environmental, and societal challenges of our time.
Sanofi is listed on EURONEXT: SAN and NASDAQ: SNY

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Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the U.S Food and Drug Administration or the European Medicines Agency, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates; the fact that product candidates if approved may not be commercially successful; unexpected regulatory actions or delays, or government regulation generally; authorities' decisions regarding whether and when to approve a product candidate; political pressure in the United States to mandate lower drug prices including "most favored nation" pricing for State Medicaid programs; the future approval and commercial success of therapeutic alternatives; Sanofi's ability to benefit from external growth opportunities, to complete related transactions and/or obtain regulatory clearances, including future clinical data and analysis of existing clinical data relating to the product, including post marketing, unexpected safety, quality or manufacturing issues, competition in general; risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation; trends in exchange rates and prevailing interest rates, volatile economic and market conditions, cost containment initiatives and subsequent changes thereto, and the impact that global crises may have on us, our customers, suppliers, vendors, and other business partners, and the financial condition of any one of them, as well as on our employees and on the global economy as a whole. The risks and uncertainties also include the uncertainties discussed or identified in the public filings with the SEC and the French Markest Authority (AMF) made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2025 or contained in our periodic reports on Form 6-K. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements. In light of these risks, uncertainties and assumptions, you should not place undue reliance on any forward-looking statements contained herein.