

## **Sanofi-aventis and DNDi enter into a Collaboration Agreement on a New Drug for Sleeping Sickness, Fexinidazole**

**Paris, France, and Geneva, Switzerland, May 18, 2009** – Sanofi-aventis (EURONEXT: SAN and NYSE: SNY) and the non-profit Drugs for Neglected Diseases initiative (DNDi) announced today that they have signed an agreement for the development, manufacturing and distribution of fexinidazole, a promising new drug for the treatment of human African trypanosomiasis, also known as sleeping sickness, a fatal disease that threatens 60 million people in Sub-Saharan Africa.

Fexinidazole will enter clinical development in the first half of 2009 and is the only new drug candidate in clinical development for sleeping sickness. Under the terms of the agreement, DNDi will be responsible for preclinical, clinical and pharmaceutical development. Sanofi-aventis will be responsible for the industrial development, registration, and production of the drug at its manufacturing sites. Considering their respective commitments to fight sleeping sickness, sanofi-aventis and DNDi have decided to combine their expertise to making fexinidazole available on a non-profit basis to all patients who need it.

*“DNDi was created in 2003 to develop a new generation of better adapted, better tolerated and more efficacious drugs for the treatment of neglected diseases”* declared Dr Bernard Pécoul, Executive Director of DNDi. *“Fexinidazole is the first compound to be advanced by DNDi all the way from discovery into clinical development, and is currently the only compound in clinical development for the treatment of sleeping sickness. Thus, this project holds great promise for the patients and the practitioners in the field.”*

*“The success of our first collaboration with DNDi on the development of a fixed-dose combination of artesunate/amodiaquine (ASAQ) for the treatment of malaria demonstrated how innovative models for drug development can be implemented to address neglected diseases”,* emphasized Dr Robert Sebbag, Vice President, Access to Medicines, sanofi-aventis. *“This naturally led us to expand our partnership to include this project which, upon completion, will change treatment methods for sleeping sickness, a disease that we have been addressing for more than eight years through our partnership with the WHO.”*

Transmitted by the bite of tsetse flies, sleeping sickness is one of the tropical diseases affecting the poorest populations. Sleeping sickness is a real public health problem in Sub-Saharan Africa, and there is, currently, no simple treatment for this disease. Available therapeutic options are either poorly tolerated or difficult to administer, particularly for late-stage disease. In this context, the development of a new treatment that is as efficacious as current treatments, better tolerated, and which could be given orally, would be a breakthrough.

Through more than two years of investigation on the different compounds of the nitroimidazoles family, DNDi has confirmed that one of these compounds, fexinidazole, might be a promising drug candidate against sleeping sickness. Fexinidazole is an antiprotozoal compound that could be used orally and could allow for a much simpler treatment schedule than currently existing treatments. DNDi successfully conducted preclinical development of fexinidazole in 2007 and 2008.

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### **About sleeping sickness (Human African trypanosomiasis, HAT)**

Human African trypanosomiasis (HAT), also known as sleeping sickness, is a fatal disease that threatens 60 million people in 36 sub-Saharan African countries. The disease affects mainly adults with enormous economic and social burden on communities of the endemic countries. The disease also affects those in conflict, poverty-stricken, remote, rural areas, who are also confronted with malaria. Carried by tsetse fly, HAT is caused by two subspecies of the kinetoplastid protozoan parasite, *Trypanosoma brucei*: *T. b. gambiense* (West African), *T. b. rhodesiense* (East African). *T.b. gambiense* HAT affects ~97% of the reported cases in 24 endemic countries; this form of the disease is more chronic than the *rhodesiense*. The first stage of the disease – the haemolymphatic phase – generally goes undiagnosed, due to its unspecific symptoms. The late, meningo-encephalitic stage of the disease (referred to as stage 2 HAT) is characterised by serious neurological and behavioral symptoms including severe sleep disturbances that progress to coma. Without treatment, stage 2 HAT is invariably fatal.

In 2002, WHO estimates approximately 1.5 million the sum of years of potential life lost due to premature mortality and the years of productive life lost due to disability (DALY). A different study has also demonstrated that the burden of the disease on each affected household could reach the equivalent of 5 months of income.

### **About the WHO/sanofi-aventis partnership for fighting against neglected diseases**

In October 2006, sanofi-aventis renewed its agreement with WHO for a new, five-year collaboration to fight some of the world's most neglected diseases. Overall, this ten-year collaboration with the WHO includes a commitment to the elimination of sleeping sickness, making drugs available (pentamidine, melarsoprol and eflornithine) and providing direct financial support for WHO activities to increase screening, early detection and treatment for the best chance of success.

[\(http://www.who.int/neglected\\_diseases/\)](http://www.who.int/neglected_diseases/)

### **About DNDi**

*The Drugs for Neglected Diseases initiative* (DNDi) is an independent, not-for-profit product development partnership, working to research and develop new and improved treatments for neglected diseases such as leishmaniasis, human African trypanosomiasis or sleeping sickness, Chagas disease, and malaria.

DNDi was founded in 2003 by the humanitarian organization Médecins Sans Frontières (MSF) along with five research institutions in Brazil, France, India, Kenya, and Malaysia. With the objective to address unmet patient needs for these diseases, DNDi has developed the largest ever R&D portfolio for the kinetoplastid diseases and has already made available two new antimalarial treatments: "ASAQ" in 2007 with sanofi-aventis, and "ASMQ" in 2008 with Brazil's Farmanguinhos. In December 2008, DNDi, Epicentre, and MSF released promising Phase III clinical study results of NECT (nifurtimox-eflornithine combination therapy), which show NECT is a safe, effective treatment for the advanced stage of HAT.

The following donors have provided support of DNDi's fexinidazole-related activities: the Department for International Development (DFID) of the United Kingdom, Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ) on behalf of the Government of the

Federal Republic of Germany, Médecins Sans Frontières / Doctors without Borders, the Ministry of Foreign and European Affairs (MAEE) of France, and the Spanish Agency of International Cooperation for Development (AECID). For further information, please consult [www.dndi.org](http://www.dndi.org).

### About sanofi-aventis

Sanofi-aventis, a leading global pharmaceutical company, discovers, develops and distributes therapeutic solutions to improve the lives of everyone. Sanofi-aventis is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

### Forward Looking Statements

*This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include product development, product potential projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future events, operations, products and services, and statements regarding future performance. Forward-looking statements are generally identified by the words “expects,” “anticipates,” “believes,” “intends,” “estimates,” “plans” and similar expressions. Although sanofi-aventis’ 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-aventis, 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 FDA or the EMEA, 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 products candidates, the absence of guarantee that the products candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives as well as those discussed or identified in the public filings with the SEC and the AMF made by sanofi-aventis, including those listed under “Risk Factors” and “Cautionary Statement Regarding Forward-Looking Statements” in sanofi-aventis’ annual report on Form 20-F for the year ended December 31, 2008. Other than as required by applicable law, sanofi-aventis does not undertake any obligation to update or revise any forward-looking information or statements.*

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