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NECT Added to WHO Essential Medicines List as Combination Treatment Against Sleeping Sickness

Geneva, Switzerland; 15 May 2009: NECT (Nifurtimox-Eflornithine Combination Therapy) – a new treatment option against sleeping sickness, a fatal disease which threatens 60 million people across sub-Saharan Africa – has been added to the Essential Medicines List (EML) of the World Health Organization (WHO) based on the application submitted by the non-profit Drugs for Neglected Diseases initiative (DNDi) and supported by Epicentre and Médecins Sans Frontières (MSF).

According to the WHO, NECT can now be used in patients and will provide an opportunity to improve the management of sleeping sickness cases. WHO has already made preparations for the arrival of this improved therapeutic opportunity and will work to ensure that patients have access to NECT by providing appropriate training and supplying the drugs and necessary equipment to disease-endemic countries.

NECT, a co-administration schedule of oral nifurtimox and intravenous eflornithine, is made available through donations to WHO by sanofi-aventis for eflornithine and Bayer for nifurtimox. A pivotal, 5-year long Phase III study comparing NECT with eflornithine used alone was recently completed by a partnership including Epicentre, MSF, DNDi, the Swiss Tropical Institute, and the national sleeping sickness control programmes of the Republic of the Congo and the Democratic Republic of the Congo.

"*This study was built on previous Epicentre and MSF studies that identified this particular drug combination as a promising therapy. It has provided some of the strongest evidence in sleeping sickness research to date, and has demonstrated NECT to be a better treatment option for advanced-stage sleeping sickness, as compared with the two current treatments which are either toxic or too complicated to use*," remarked Emmanuel Baron, Director of Epicentre.

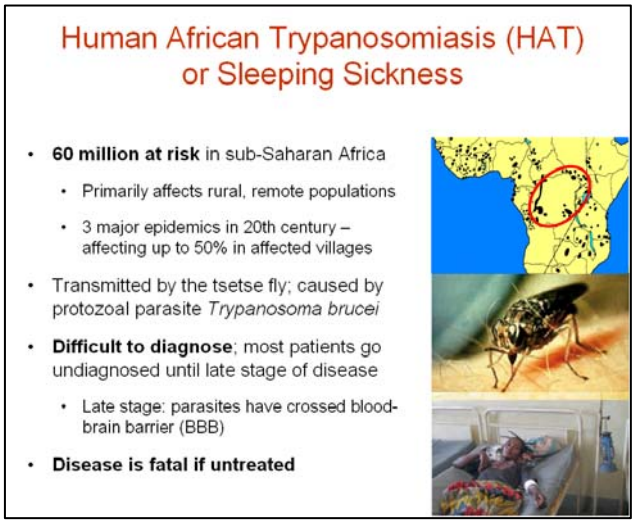
"*NECT is critical in our efforts to address the needs of neglected patients suffering from a fatal disease*," added Christophe Fournier, MSF's International Council president. "*This new treatment needs to be rolled out urgently to replace the current most commonly used therapy which kills one in every 20 patients.*"

"*We at DNDi welcome this decision and the rallying by the sleeping sickness community in support of this application as it underscores the practical improvement and impact NECT can make in the field today*," commented Bernard Pécoul, Executive Director of DNDi. "*No new drugs for stage 2 sleeping sickness are expected in the next five years, so there is an urgent need to develop new treatments based on currently available drugs, especially through combinations. However, even with the importance of this development, we have made but one step on the path to ultimately meeting patient needs.*"

###Editor Notes###

WHO information about NECT inclusion onto the Essential Medicines List
Available at: http://www.who.int/neglected_diseases/disease_management/drug_combination/en/index.html

About sleeping sickness (human African trypanosomiasis; HAT)
Commonly known as sleeping sickness, human African trypanosomiasis (HAT), is a life-threatening illness which threatens 60 million people in 36 countries, primarily in sub-Saharan Africa. HAT mainly affects working adults, which means it has an immense social and economic impact on local communities in HAT-endemic countries, many of which already have to contend with poverty and armed conflict as well as other major diseases such as malaria.



Transmitted by tsetse flies, HAT exists in two forms, *Trypanosoma brucei gambiense (T.b. gambiense*) or *Trypanosoma brucei rhodesiense (T.b. rhodesiense*) disease. *T.b. gambiense HAT* accounts for approximately 97% of reported cases and is endemic in 24 countries; this form of the disease is more chronic than its rhodesiense counterpart. The initial haemolymphatic stage disease (stage 1) often goes undiagnosed as there are few differential clinical symptoms. If left untreated, the disease progresses into the advanced meningo-encephalitic stage (stage 2) when the parasites cross over the blood-brain barrier and invade the patient's central nervous system (CNS). This stage 2 disease causes neuropsychiatric problems, convulsions, and serious sleep disturbance; eventually these symptoms lead to coma. Without appropriate treatment, the disease is invariably fatal.

HAT places a large burden on communities and individual households. In 2002, WHO estimated that approximately 1.5 million disability-adjusted life years (DALYs) were lost due to HAT. A more recent study in the DRC showed that the cost to each household following a HAT outbreak was equivalent to 5 months' income for that household.

NECT offers:

A new, improved treatment option:

- Comparable efficacy and safety with eflornithine (gold standard)
- Safer than melarsoprol (still used in 70% of patients with advanced-stage sleeping sickness)
- Easier to administer & to transport
  - Less burden on the health infrastructure
  - More convenient for the patient
- More affordable
  - Fewer quantities of drug and related materials
  - Shorter hospitalization
- Potentially protective against the emergence of resistant parasites
- HOWEVER, it involves two drugs with different routes of administration and requires trained health care workers because of the intravenous infusions

About Epicentre

Epicentre is a non-profit organisation created in 1987 by Médecins Sans Frontières, which groups health professionals specialised in public health and epidemiology. In 1996, Epicentre became a World Health Organization Collaborating Center for Research in Epidemiology and Response to Emerging Diseases. Epicentre's team carries out operational and clinical research from its offices in Paris (headquarters), Geneva, and Brussels, and a permanent research base in Mbarara, Uganda. Epicentre also offers its expertise to organisations requesting short-term field epidemiology studies in developing countries. Epicentre designs and organises training sessions for Médecins Sans Frontières and other partners in public health and epidemiology. Epidemiologists from Epicentre also give guest lectures and organise training modules in the field of applied epidemiology as part of university or diploma courses. Lastly, Epicentre has developed an expertise in the development and field installation of software applications for the management of health information. For more information, please consult: http://www.epicentre.msf.org/ .

About DND*i*

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 malaria, leishmaniasis, human African trypanosomiasis, and Chagas disease. 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 financial support to DNDi’s NECT-related activities: the Department for International Development (DFID) of the United Kingdom, Médecins Sans Frontières International, the Medicor Foundation, 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.

About MSF

Médecins Sans Frontières (MSF) is an international humanitarian aid organisation that provides emergency medical assistance to populations in danger in more than 70 countries. MSF programmes have screened more than 2 million people for sleeping sickness and treated over 40.000 patients, a majority already at an advanced stage of the disease. It is fundamentally unacceptable to MSF that access to essential medicines is increasingly difficult, particularly for the most common infectious diseases affecting poor countries. Therefore, MSF has been

campaigning internationally to find long-term, sustainable solutions to this crisis and is pushing to lower the prices of existing medicines, to bring abandoned drugs back into production, and to stimulate research and development for diseases that primarily affect the poor. For more information, please consult www.msf.org

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