OUR COMMITMENTS AGAINST NEGLECTED TROPICAL DISEASES

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Eliminating or controlling Neglected Tropical Diseases (NTDs) is achievable.

Thanks to the leadership of the World Health Organization and the combined efforts of national control programmes, academia, nongovernmental organizations and pharmaceutical companies, the day has come when the word “neglected” no longer applies to tropical diseases.

The WHO has set 2020 targets to end nine NTDs responsible for 90% of global burden: human African trypanosomiasis (sleeping sickness), Chagas, lymphatic filariasis, soil-transmitted helminths, onchocerciasis, schistosomiasis, leprosy, fascioliasis, and blinding trachoma.

Through our partnerships with the WHO, Sanofi is on track to assist them meet these goals in five diseases. Sleeping sickness and lymphatic filariasis will be eliminated and we will have a tight control of other neglected tropical diseases such as leishmaniasis, Buruli ulcer and Chagas disease.

Since the beginning of our partnership, we have worked closely with WHO to identify the real needs of people. We have ensured that our commitment not only includes, but also goes beyond, donations of medicines. As a result of the resources we have committed, and the tremendous passion and dedication of the teams, WHO can ensure that trained staff, efficient screening and diagnosis, treatment, disease surveillance and health education are available and made accessible to all patients.

We also will continue to work on Research and Development to improve treatments until we succeed in eliminating them.

As a responsible healthcare partner, we will continue to go beyond this partnership, conducting research and development to find improved, innovative treatments to treat difficult diseases such as sleeping sickness, leishmaniasis and Chagas disease. We will also work on improving access to affordable healthcare while we strive to protect the health, enhance the life of people and provide hope to those in need, wherever they may be.
One billion people\(^{(1)}\) are at risk of or are affected by tropical diseases that the international community considers to be “neglected diseases.” These diseases often affect communities living in remote rural areas, in urban slums and/or in conflict zones with poor living and hygiene conditions.

The continued support of endemic countries and the increased awareness within the international community are fundamental factors for the elimination and control of these diseases. Success relies on a multi-stakeholder approach which integrates elements such as environmental improvements, boosting capacity-building efforts, adequate policies, better diagnostics, availability of quality, safe and effective medicines, and, in some cases, further research and development (R&D).

**SLEEPING SICKNESS**

FEWER THAN

10,000

NEW CASES IN 2010\(^{(2)}\)

**LEISHMANIASIS**

1.6 MILLION

NEW CASES EACH YEAR\(^{(3)}\)

**CHAGAS DISEASE**

10 MILLION

PATIENTS WORLDWIDE\(^{(4)}\)

**LYMPHATIC FILARIASIS**

A THREAT TO MORE THAN

1.3 BILLION

PEOPLE IN 81 COUNTRIES\(^{(5)}\)

**BURULI ULCER**

5,000

NEW CASES REPORTED IN 2009\(^{(3)}\)
SANOFI AND THE WHO: A 15 YEAR PARTNERSHIP

In the fight against sleeping sickness, leishmaniasis, Chagas disease and Buruli ulcer.

2001-2005: Initial partnership signed to combat sleeping sickness (Human African trypanosomiasis (HAT)).

2006-2010: The partnership is expanded to include other neglected tropical diseases: leishmaniasis, Buruli ulcer and Chagas disease.

2011-2016: The partnership is renewed for an additional five years with the goal of eliminating sleeping sickness and improving the management of leishmaniasis, Buruli ulcer and Chagas disease.

The total contribution of this current partnership which extends to 2015, amounts to $75 million and includes donation of medicines and the necessary resources to ensure the WHO can train staff, conduct efficient screening and diagnosis, treatment, disease surveillance and health education.

This contribution made it possible to provide treatment for more than 170,000 patients with sleeping sickness, which is generally fatal if left untreated, and to improve the surveillance of leishmaniasis, Chagas disease and Buruli ulcer.

Sanofi also announced the extension of its existing donation of eflorenithine, melarsoprol and pentamidine for sleeping sickness to 2020, together with logistic support necessary to ensure that the drugs reach patients in need at no cost.

“Over the last ten years, the success of the partnership between the WHO and Sanofi for the treatment of sleeping sickness, which has made it possible to treat over 170,000 patients, is a marvelous illustration of what can be accomplished when the complementary skills of two key healthcare actors are combined. We welcome the renewal of this partnership for the next five years.”

DR. JEAN JANNIN, COORDINATOR, INTENSIFIED DISEASE MANAGEMENT, DEPARTMENT OF NEGLECTED TROPICAL DISEASES, WHO, 27 MAY 2011
FEWER THAN 10,000 NEW CASES IN 2010 (2)

Human African Trypanosomiasis (HAT or sleeping sickness) is one of the most complex endemic tropical diseases. It is a parasitic disease spread by the bite of the ‘Glossina’ insect, or tsetse fly. Initial symptoms, when the treatment has the greatest chance of success, are often mild or nonspecific and include headaches, fever, weakness, sweating, pain in the joints, and stiffness. However, patients often seek help only when the disease is already advanced, when more complex treatment is needed and when chances of success are decreased. Untreated HAT is generally fatal with death following prolonged agony.

Since 2001, more than 170,000(6) patients have received treatment for the disease, which is fatal if left untreated. Thanks to active screening and disease management, the annual number of patients being treated fell below the symbolic number of 10,000 in 2009 for the first time in 25 years. Moreover, this decrease has continued, with 7,139 new cases(2) reported in 2010.

Five medicines are available to treat sleeping sickness. Sanofi manufactures three of them and provides them to the WHO within the scope of the partnership:

- Pentamidine
- Eflornithine
- Melarsoprol

INFORMATION AND EDUCATION

Thanks to our partnership, the WHO organized training for personnel from national sleeping sickness programs in several countries. Training focused on the administration and optimum utilization of HAT treatments.

Target 2020: Elimination of the sleeping sickness

RESEARCH AND DEVELOPMENT

The first line treatment for stage 2 ‘gambiense’ sleeping sickness, is eflornithine used in combination with Bayer’s drug nifurtimox. Current treatments for stage 2 sleeping sickness require several infusions and are not always well tolerated. In 2009, Sanofi entered into a partnership agreement with DNDi (Drugs for Neglected Diseases initiative) for the development of a new oral medication. If drug development is successful, the new treatment will considerably simplify patients’ lives. Sanofi will be responsible for the manufacture, registration and distribution of the new compound, should the development programme be successful.

SINCE 2001, MORE THAN 170,000(6) PATIENTS HAVE RECEIVED TREATMENT FOR THE DISEASE

MOBILE MEDICAL TEAMS DEDICATED TO COMBATING SLEEPING SICKNESS

In addition, mobile medical teams from National Programs to Combat HAT organize screening for sleeping sickness in remote villages, that are difficult to reach. Patients who are diagnosed with stage 1 sleeping sickness can be treated in the village by the local healthcare professional. Those who are diagnosed with stage 2 of the disease are taken for treatment to the nearest hospital, which may be several hours away by car or boat.
Leishmaniasis is a disease caused by protozoan parasites transmitted through the bites of infected sand flies. Leishmaniasis is a poverty-related disease. It affects the poorest of the poor and is associated with malnutrition, displacement, poor housing, illiteracy, gender discrimination, weakness of the immune system and lack of resources.

Sanofi’s commitment to the combat against leishmaniasis takes several forms:
• Partnership with the WHO since 2006 to improve epidemiological surveillance and treatment centers for this disease, especially in the Middle-East region
• Providing 4 million doses of meglumine antimoniate annually for developing countries at a single, preferential price
• Forming research partnerships to find new treatments that are better adapted to patients’ needs, including a partnership with DNDi to screen molecules
• The publication of a book by Dr Pierre Buffet on leishmaniasis therapy, covering both cutaneous and visceral forms, which is available in 5 languages (English, French, Spanish, Portuguese, Arabic) and in 2012 in Farsi for healthcare professionals

Chagas disease, which is also called American Trypanosomiasis, is a parasitic disease transmitted by the fecal matter of a bug (the triatome). Chronic infection, which usually begins in childhood, can in 30% of cases cause irreversible damage to the heart, esophagus, colon or peripheral nervous system. The disease affects 10 million people, especially in Latin America, but due to mass migration, patients are found today outside of traditional endemic areas.

Through its partnership with the WHO, Sanofi contributes to developing epidemiological surveillance of Chagas disease in Europe. New treatments are necessary and Sanofi has formed new partnerships with researchers such as DNDi, to pursue research into Chagas disease treatments.
Buruli ulcer is a cutaneous infection caused by a mycobacterium, which may lead to extensive destruction of the skin and soft tissues, usually in legs or arms, if antibiotic treatment is not started quickly. Although a vast majority of the 5,000 patients\(^{(3)}\) reported to have the disease each year live in West Africa, a small number of cases occur annually in Australia.

Through our partnership with the WHO, we are working to facilitate earlier treatment of the disease, and to develop an antibiotic regimen that only requires oral administration (current approved regimen is a combination of oral and intra-muscular administration).

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**BURULI ULCER: MOVING TOWARDS EARLIER, SIMPLIFIED TREATMENT**

5,000 NEW CASES REPORTED IN 2009\(^{(3)}\)

**LYMPHATIC FILARIASIS: NEW PARTNERSHIP WITH THE BILL & MELINDA GATES FOUNDATION AND EISA**

Lymphatic Filariasis, commonly known as elephantiasis, is a threat to more than 1.3 billion people in 81 countries worldwide. Over 120 million people are currently infected, with about 40 million disfigured and incapacitated by the disease. Lymphatic filariasis can result in an altered lymphatic system and the abnormal enlargement of body parts, causing pain and severe disability.

Sanofi announced a new partnership with the Bill & Melinda Gates Foundation and Eisai to donate 120 million DEC (diethylcarbamazine) tablets to the World Health Organisation (WHO) for their Global Programme to Eliminate Lymphatic Filariasis.

The consortium, the first of its kind, sees the partners jointly financing the donation which will allow the WHO to provide treatment for 30 million people. The donation will ensure a stable supply of DEC to the WHO’s Global Programme to Eliminate Lymphatic Filariasis for 2012 and 2013. Subsequently, Eisai will begin a Lymphatic Filariasis Elimination Partnership with WHO and will continue to provide DEC at “zero-price” until 2020.
SANOFI JOINS WIPO RE: SEARCH TO PROVIDE ACCESS TO SCIENTIFIC DATA TO THE NTDS RESEARCHERS

In November 2011, Sanofi joined a new initiative to fight neglected tropical diseases (including tuberculosis and malaria) in the developing world, the WIPO Re: Search consortium. As members of the consortium, the World Intellectual Property Organisation (WIPO) is managing the database, and BIO Ventures for Global Health are the managing agents. The consortium, which currently includes seven other pharmaceutical companies (Alnylam, AstraZeneca, Eisai, GlaxoSmithKline, Merck, Novartis, Pfizer), as well as Public research institutions, enables public and private sector organisations to share information to facilitate the development of new drugs, vaccines and diagnostics.

The consortium - WIPO Re: Search - will allow member organisations to share valuable intellectual property and expertise with the global health research community. This will enable the development of faster and more effective treatments to help fight the neglected tropical diseases such as tuberculosis and malaria, which affect the most disadvantaged communities in the world disproportionately.

“By providing a centralised database of the intellectual property assets available, including about compounds, regulatory data and other information, WIPO Re: Search will significantly increase the amount of focused research and development that can take place across these fields. The intellectual property held by companies such as Sanofi obviously includes patents, but also technical know-how – the art behind the science. This includes drug discovery tools, expertise in areas such as toxicology or medicinal chemistry, not to mention countless other knowledge bases. I am confident this consortium will deliver results for patients in developing world with neglected tropical diseases. We look forward to working with the WIPO Re:Search consortium to deliver treatments for conditions such as tuberculosis and malaria to patients.”

Dr Robert Sebbag, Vice President of Access to Medicines, Sanofi

Partnership with DNDi (Drugs for Neglected Diseases initiative)

- To provide targeted access to proprietary compound libraries to develop new medicines for, visceral leishmaniasis, Chagas Disease and sleeping sickness.
- Continue development of first potential oral monotherapy (fexinidazole) for the treatment of stage 2 gambiense sleeping sickness.

SOURCES


(3) Source OMS : Agir pour réduire l’impact mondial des maladies tropicales négligées, premier rapport de l’OMS sur les maladies tropicales négligées, 2010

