Astellas and DNDi to Collaborate on New Drug Discovery Research for the Treatment of Neglected Tropical Diseases

[Tokyo, Japan and Geneva, Switzerland, June 12, 2012] - Astellas Pharma Inc. (Tokyo:4503, ”Astellas“) and the Drugs for Neglected Diseases initiative (DNDi) announced an agreement today to collaborate on drug discovery research for leishmaniasis, Chagas disease, and sleeping sickness – three neglected tropical diseases (NTDs) which together affect nearly 10 million people worldwide. The agreement is a first critical step in Astellas’ new strategy to enter into the field of NTDs, with DNDi as its first partner.

Under the agreement, Astellas will provide DNDi with a selection of original compounds. These will be screened at the Swiss Tropical and Public Health Institute in Switzerland. The pharmaceutical profiles of the compounds were studied in pre-clinical and/or clinical stages at Astellas. DNDi will conduct reprofiling of the compounds to test their anti/protozoan activities and assess their potential as new anti/protozoan candidates for the three targeted diseases.

‘We welcome Astellas as a new partner both in the field of NTDs and as part of a product development partnership. In the field of neglected diseases, and particularly for the most neglected – leishmaniasis, Chagas disease, and sleeping sickness – this new partnership reinforces the critical mass of engaged actors necessary to address urgent patient needs’ said Dr Bernard Pécout, Executive Director of DNDi.

‘Astellas believes that this joint research method leads to the early entry into the development stage of new potential agents if promising compounds are identified as candidates. Astellas will seek the way to contribute drug discovery research for NTDs based on Astellas’ advanced science ’, says Dr Shin-ichi Tsukamoto, Senior Vice President of Astellas Drug Discovery Research.

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About Neglected Tropical Diseases (NTDs)
NTDs are a group of tropical infections that disproportionately affect the world’s poor and marginalized populations. According to the World Health Organization (WHO), more than a billion people, or one-sixth of the global population, suffer from one or more of 17 NTDs. The partnership between DNDi and Astellas is focused on finding new treatments to address the following NTDs:

- **Leishmaniasis** occurs in 98 countries, placing 350 million people at risk worldwide. The parasite that leads to infection is called *Leishmania* and is transmitted by a sandfly. Leishmaniasis is a poverty-associated
disease with several different forms. Visceral leishmaniasis, which is fatal without treatment, and cutaneous leishmaniasis are the most common. Existing treatments are difficult to administer, toxic, and/or costly. Drug resistance also is an increasing problem.

- **Chagas disease** (American trypanosomiasis) is endemic in 21 countries across Latin America and kills more people in the region than any other parasite-borne disease, including malaria. In total, 100 million people are at risk worldwide and patient numbers are growing in non-endemic countries such as the United States and Australia, as well as some European countries. The disease is transmitted by an insect known as the ‘kissing bug’ and, without treatment, is potentially fatal. Existing treatments are known to have serious safety limitations and their efficacy diminishes the longer the patient has been infected.

- **Sleeping sickness** (human African trypanosomiasis, or HAT) threatens millions of people in sub-Saharan Africa. The disease is transmitted by the bite of the tsse fly. Without treatment in the initial phase, which causes general symptoms, the disease progresses to a second stage where mental debilitation and death frequently occur within six months to three years. Existing treatments are toxic, difficult to administer, and/or have severe side effects. The disease is fatal if left untreated.

**About Astellas Pharma**

Astellas Pharma Inc., located in Tokyo, Japan, is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. Astellas has approximately 17,000 employees worldwide. The organization is committed to becoming a global category leader in Urology, Immunology (including Transplantation) and Infectious Diseases, Oncology, Neuroscience and Diabetes Mellitus (DM) Complications and Kidney Diseases. For more information on Astellas Pharma Inc., please visit the company website at www.astellas.com/en.

Astellas is committed to improving “Access to Health*” in developing countries through its partnership initiatives. As part of the contribution to Access to Health, Astellas is committed to undertake an initiative of drug discovery for patients infected with and suffer NTDs in the world by utilizing its know-how and assets of drug discovery research. There have been not too many new drug candidates for the treatment of NTDs to date because few bio ventures and/or pharmaceutical companies entered into such drug discovery steps. Astellas expects that its in-house drug discovery and research know-how of infectious diseases and/or assets, such as its own unique compound library, can be effectively utilized for the drug discovery research of NTDs.

**About DNDi**

The Drugs for Neglected Diseases initiative (DNDi) is a not-for-profit research and development organization working to deliver new treatments for neglected diseases, in particular sleeping sickness (human African trypanosomiasis), Chagas disease, leishmaniasis, malaria, specific helminth infections, and paediatric HIV. DNDi was established in 2003 by Médecins Sans Frontières/Doctors Without Borders (MSF), the Oswaldo Cruz Foundation (FIOCRUZ) of Brazil, the Indian Council of Medical Research (ICMR), the Kenya Medical Research Institute (KEMRI), the Ministry of Health of Malaysia, and the Pasteur Institute of France. The Special Programme for Tropical Disease Research (WHO/TDR) serves as permanent observer.

Since its inception in 2003, DNDi has delivered six new treatments for neglected patients: two fixed-dose antimalarials (ASAQ and ASMQ), nifurtimox-eflornithine combination therapy (NECT) for late-stage sleeping sickness, sodium stibogluconate and paromomycin (SSG&PM) combination therapy for visceral leishmaniasis in Africa, a set of combination therapies for visceral leishmaniasis in Asia, and a paediatric dosage form of benznidazole for Chagas disease.

* Unmet medical needs remain in many therapeutic areas. Furthermore, there are many people who are unable to access adequate medical care due to poverty or weak health systems. Astellas recognized these remaining issues as ‘Access to Health’ and proactively addresses them as part of its responsible corporate citizenship.
Access to Health

DNDi has helped establish three clinical research platforms: the Leishmaniasis East Africa Platform (LEAP) in Kenya, Ethiopia, Sudan, and Uganda; the HAT Platform based in the Democratic Republic of Congo (DRC) for sleeping sickness; and the Chagas Clinical Research Platform in Latin America. Strong regional networks such as these help strengthen research and treatment-implementation capacity in neglected disease-endemic countries.

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