Major project to implement new treatments to boost kala-azar elimination strategies

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A comprehensive four-year project including over 10,000 patients in clinical and pharmacovigilance studies for diagnosis and treatment of visceral leishmaniasis (VL, also known as kala-azar) in India and Bangladesh was launched by an international consortium formed last month to support control and elimination strategies in both countries, where the concentration of disease burden is among the world's highest.

The Drugs for Neglected Diseases initiative (DNDi), together with OneWorld Health (OWH) and the Special Programme for Research and Training in Tropical Diseases (TDR), will collaborate with the National Control Programmes of India and Bangladesh, Médecins Sans Frontières (MSF), the Bihar State Health Society, and the Indian Council for Medical Research to carry out the consortium's projects. The projects will generate the data necessary for Indian and Bangladeshi Ministries of Health to select, adopt and implement the best management strategies to support control and elimination of this deadly disease.

Kala-azar, which particularly affects women and children in remote areas, is a parasitic disease transmitted by a sandfly. It causes prolonged fever, enlarged spleen and liver, substantial weight loss, and progressive anaemia. Approximately half a million cases worldwide are recorded each year. If left untreated, the disease is fatal.

From case detection and management to implementation of new treatment modalities, including liposomal amphotericin B (AmBisome®) in monotherapy and several combination therapies - with

AmBisome®, miltefosine, and paromomycin - the project covers primary and secondary healthcare levels in the public, not-for-profit, and private sectors. Project strategies are tailored to the specific needs of each sector and expand upon the experience and expertise of the consortium members and regional stakeholders.

'Implementing new kala-azar treatments that have proven successful in clinical trials will give us new options that can improve compliance, reduce costs, and improve efficiency, while reaching patients closer to home', affirmed Dr Pradeep Das, Director of the Rajendra Memorial Research Institute of Medical Sciences, Patna, India. The treatments piloted in this programme will build upon the efforts India has undertaken to fight kala-azar, particularly in the public sector and at the primary healthcare level. Monitoring and evaluation will be key to ensuring that outcomes match real life conditions. The private sector in India will also be an important focus of the consortium's project as it represents a large proportion of kala-azar patients in the country.

Bangladesh has begun to introduce miltefosine and has been using AmBisome® with the support of MSF in one of its sub-districts. 'This project will provide the evidence necessary to choose the most appropriate new treatments for the disease', said Professor Be-Nazir Ahmed, Director of Disease Control, DGHS of the Ministry of Health and Family Welfare, Bangladesh. Clinical trials in the most endemic region of Mymensingh District, that were undertaken by DNDi, OWH, and TDR, together with the Kala-Azar Elimination Programme and other local partners, provided a first step towards facilitating registration, recommendation, and implementation of the treatments.

'This consortium, launching the largest-ever implementation study on kala-azar in Asia, is driven by regional and international actors in support of the National Control Programmes of these two highly endemic countries. Top scientists, clinicians, research institutes, and

health authorities have created the momentum and conditions necessary to contribute to elimination of kala-azar in the region', said Dr Bernard Pécoul, Executive Director of DNDi.

DNDi was awarded USD 9 million over four years by the Bill & Melinda Gates Foundation, forming part of the consortium's USD 16.1 million project to develop new VL treatments in South Asia.

About visceral leishmaniasis (VL, or kala-azar)

Transmitted by a sandfly, the protozoan parasite Leishmania causes three different forms of disease, of which visceral leishmaniasis (VL) is the most severe. Leishmaniasis affects over 12 million people, with over 350 million people at risk in 98 countries.

VL is characterized by prolonged fever, enlarged spleen and liver, substantial weight loss, progressive anaemia, and is complicated by co-infection with other infectious diseases, such as HIV, tuberculosis, or malaria. Fatal if untreated, an estimated 500,000 new cases of VL occur each year. A significant proportion of clinical cases occurs in children. Officially, 50,000 to 60,000 deaths result from VL each year.

DNDi and its partners are strongly focused on contributing to control and elimination strategies for VL. Long-term projects focus on discovery and development of an easy-to-use, efficacious, oral drug. Shorter term projects aim at development and implementation of short-course monotherapy and combination regimens, as well as geographical extensions of existing treatments. The overall approach follows the 2010 recommendations of the WHO Expert Committee on the Control of Leishmaniasis.

Provided by Drugs for Neglected Diseases Initiative

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