



Drugs for Neglected Diseases *initiative*

## DNDi's Role and Projects in the VL South Asia Consortium

**Background:** Visceral leishmaniasis (VL, or kala-azar), a parasitic disease that is fatal if left untreated, is a major public health burden in South Asia. Of the 500'000 cases that reportedly occur annually worldwide, 60% affect adults and children in India, Nepal, and Bangladesh. The Bihar State in India is the worst affected with 33 endemic districts alone contributing to 50% of cases worldwide.

The current treatments for VL – monotherapy courses with antimonials, miltefosine, and amphotericin B – have serious limitations including long treatment courses, cost, feasibility, toxicity and/or drug resistance. Recently, new treatment options have been developed that considerably improve upon the current conventional monotherapy regimens.

The Indian Council of Medical Research (ICMR) with DNDi and its regional office in India completed a combination treatment study (miltefosine & paromomycin, AmBisome® & miltefosine, AmBisome® & paromomycin): the results indicated that these new options are highly efficacious with less adverse reactions and shorter duration compared to the standard amphotericin B. At the same time, Prof. Shayam Sundar published clinical trial results concluding that a single dose of AmBisome® also had high efficacy.

Taking into account these results, a WHO Technical Report published in November 2010<sup>1</sup> recommended the use of both single dose AmBisome® and combination treatments in South Asia – in place of the currently available monotherapies.

These treatments will be introduced in 'real life' settings to evaluate if they can be implemented in the endemic regions so as to ensure that clinical research advances reach and benefit populations affected by this fatal disease.

**Objectives:** The overall objective of DNDi with this four-year collaborative project between DNDi, TDR, and OWH – in addition to the overall management of the project – is:

- To treat a large number of patients suffering from VL in India, with new, efficacious, and cost effective combination treatments by implementing them in the public and private sectors
- To introduce these new treatment modalities in Bangladesh
- To strengthen local health systems by facilitating the implementation of an improved VL pharmacovigilance and surveillance system in India.

**Partners:** DNDi will carry out the project in the rural VL-endemic areas in Bihar State, India, in collaboration with the national and local Indian partners including the National Vector Borne Disease Control Programme (NVBDCP), the Indian Council of Medical Research (ICMR), the Bihar State Health Society, and the National Pharmacovigilance Programme (NPP). In Bangladesh, DNDi will partner with the Ministry of Health (DGHS), the International Centre for Diarrhoeal Disease Research (ICDDR,B), and the Shaheed Suhrawardy Medical College (ShSMC).

DNDi and its partners' ultimate goal with this project is to have a significant impact on the control of VL in India and Bangladesh and thus contribute to the national VL elimination programmes.

FOR MORE INFORMATION, PLEASE VISIT: <http://dndi.org/portfolio/new-vl-treatments-asia.html>

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<sup>1</sup> *Control of the Leishmaniasis: Report of a Meeting of the WHO Expert Committee on the Control of Leishmaniasis*, Geneva, 22-26 March 2010. WHO, Geneva, 2010.