

# Visceral Leishmaniasis in the Developing World



Gilead Sciences is committed to supporting global efforts to control and eliminate visceral leishmaniasis (VL), a parasitic infectious disease that predominantly affects people in developing world countries. AmBisome® is a World Health Organization (WHO)-preferred treatment for VL in most endemic regions,<sup>1</sup> and Gilead undertakes a number of activities to expand global access to this therapy for patients in need.

## Snapshot

- Visceral leishmaniasis (VL) is the world's **second-deadliest** parasitic disease, after malaria.<sup>1</sup>
- Since 1992, Gilead has provided **AmBisome®**, a preferred treatment for VL, at no-profit prices.
- Gilead is donating **445,000 vials** of AmBisome to the World Health Organization over 5 years.<sup>2</sup>



## VL: A Deadly Disease in the Developing World

VL is the world's second-deadliest parasitic disease after malaria, with 400,000 cases and 40,000 deaths occurring annually.<sup>1,3</sup> It is caused by several species of the Leishmania parasite, which are transmitted to humans through the bite of infected female sandflies. Without treatment, VL is nearly always fatal.<sup>3</sup>

Most VL cases worldwide affect children and young adults. In some endemic areas, more than half of new infections are among children younger than 10.<sup>1</sup> More than 90 percent of cases occur in Bangladesh, Brazil, Ethiopia, India, Sudan and South Sudan, with three-quarters of those in India alone. The symptoms of VL include prolonged fever, weight loss, an enlarged spleen (causing abdominal distension) and anemia.<sup>4</sup>

Inadequate surveillance, diagnosis and treatment are ongoing obstacles to VL control. Reported incidence figures grossly underestimate actual disease burden, with house-to-house surveys in India suggesting that incidence is 4 to 8 times higher than official estimates.<sup>3</sup>



## Expanding Access to VL Treatment

There is no vaccine for VL, but treatments can cure infected individuals.<sup>1</sup> AmBisome, a liposomal formulation of amphotericin B that is administered by intravenous injection, is a World Health Organization (WHO)-preferred treatment for VL in most endemic regions.<sup>1</sup> In clinical trials, a single dose of AmBisome has been associated with cure rates of 90 percent or higher

and, in a recent study in India, this regimen was shown to be significantly more cost-effective than conventional amphotericin B-containing treatment regimens.<sup>5</sup>

Gilead has worked since 1992 to increase access to VL treatment by providing AmBisome to public sector agencies, including WHO, at no-profit prices. In December 2011, Gilead signed a new agreement with WHO to donate 445,000 vials of AmBisome over five years to treat VL in countries including Bangladesh, Ethiopia, South Sudan and Sudan. The donation will provide treatment for more than 50,000 patients.<sup>2</sup>



## VL Initiatives Gaining Momentum

Worldwide, efforts to increase VL surveillance, vector control, diagnosis and treatment are making important progress. In 2012, WHO launched an action plan for reducing the impact of Neglected Tropical Diseases (NTDs), including VL. The roadmap includes a goal to detect and treat all VL cases in Africa, the Americas, Europe and the Eastern Mediterranean region by 2020 and to eliminate the disease – defined as a reduction in incidence to less than 1 case per 10,000 people per year – in Southeast Asia and the Indian subcontinent.<sup>6</sup>

In response to WHO's roadmap, a coalition of organizations and pharmaceutical companies, including Gilead, endorsed the London Declaration on NTDs, a pledge to work together to meet WHO's targets. The coalition, Uniting to Combat NTDs, includes 12 other pharmaceutical companies, the World Bank, the Bill & Melinda Gates Foundation and the U.S., UK and United Arab Emirates governments.<sup>2</sup>

## Sources

<sup>1</sup> WHO. Control of the leishmaniases. Report of a meeting of the WHO expert committee on the control of the leishmaniases, Geneva, 22-26 March 2010. WHO Technical Report Series 949. Available at: [http://apps.who.int/iris/bitstream/10665/44412/1/WHO\\_TRS\\_949\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/44412/1/WHO_TRS_949_eng.pdf)

<sup>2</sup> WHO. Sustaining the drive to overcome the global impact of neglected tropical diseases. Second WHO report on neglected diseases, 2013. Available at: [http://www.who.int/neglected\\_diseases/2012report/en/](http://www.who.int/neglected_diseases/2012report/en/)

<sup>3</sup> Alvar J et al., Leishmaniasis Worldwide and Global Estimates of Its Incidence. PLoS ONE, 2012.

<sup>4</sup> Official web site of Médecins Sans Frontières. Overview of MSF's work with

Kala Azar. Available at: <http://www.doctorswithoutborders.org/news/issue.cfm?id=2394&cat=issue-page&ref=tag-index>

<sup>5</sup> Sundar S et al., Single-Dose Liposomal Amphotericin B in the Treatment of Visceral Leishmaniasis in India: A Multicenter Study, Clinical Infectious Diseases. 2003; Sundar S et al., Treatment of Indian Visceral Leishmaniasis with Single or Daily Infusions of Low Dose Liposomal Amphotericin B: Randomised Trial, BMJ. 2001; Sundar S et al., Single-Dose Liposomal Amphotericin B for Visceral Leishmaniasis in India, NEJM. 2010.

<sup>6</sup> WHO. Accelerating Work To Overcome The Global Impact Of Neglected Tropical Diseases: A Roadmap For Implementation, 2012. Available at: [http://www.who.int/neglected\\_diseases/NTD\\_RoadMap\\_2012\\_Fullversion.pdf](http://www.who.int/neglected_diseases/NTD_RoadMap_2012_Fullversion.pdf)