



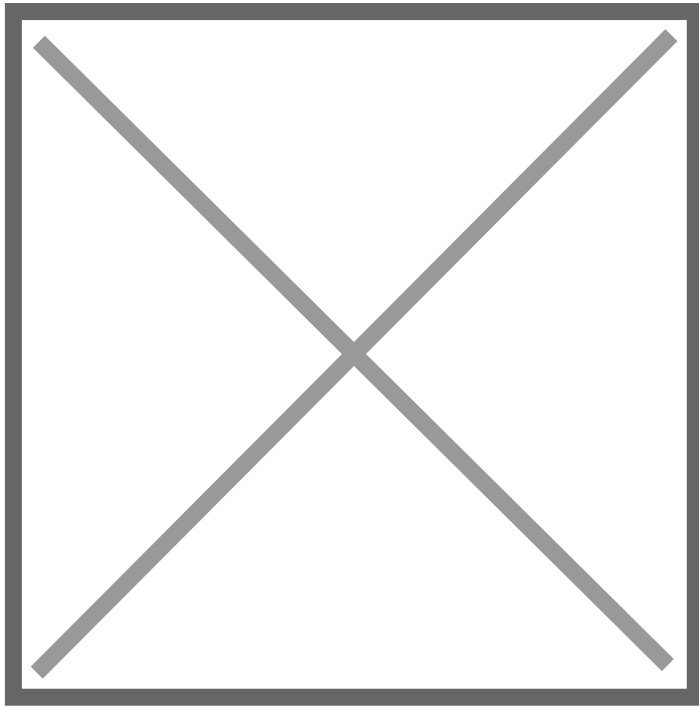
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Hope floats for vaccines against neglected diseases

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Indian companies are leading the way in developing vaccines for neglected diseases such as kala azar and chikungunya. This emerging trend will have a profound impact on improving the lives of thousands of people in the developing world

The first-of-its-kind clinical trial to test the efficacy of a novel visceral leishmaniasis vaccine is all set to start in India as a part of joint initiative by the Infectious Disease Research Institute (IDRI), a Seattle-based non-profit organization and Pune-based Gennova Biopharmaceuticals. This announcement comes close on the heels of Indian Immunologicals conducting preclinical studies for the world's first chikungunya vaccine. There are no vaccines for either of the diseases till now.

Traditionally, falling under the ambit of 'neglected tropical diseases', cases of visceral leishmaniasis and chikungunya are found largely in developing countries. Due to low or no prevalence in developed countries, the market size for vaccines or drugs for these diseases is not considered to be highly profitable. In this light, the fact that Indian companies are now taking the initiative to develop solutions for such problems is a welcome move.

According to World Health Organization (WHO), leishmaniasis, is found in 88 countries, with 1.6 million cases to occur worldwide. The most pathogenic form of this disease is visceral leishmaniasis, more commonly known as kala azar or black fever, a name derived from the darkening of face, hand, feet, and abdomen skin, which is a common occurrence in this disease. Since mandatory reporting is present in only 33 of the affected countries, only 600,000 cases of leishmaniasis are reported, of which 500,000 are that of visceral leishmaniasis. Over 90 percent of these cases occur in Bangladesh, Brazil, Ethiopia, India, Nepal, and Sudan causing 50,000 deaths every year, making it the second-largest parasitic killer in the world. If left untreated, kala azar has 90 percent chances of case fatality with death within two years.

Kala azar is caused by a parasite of the genus *Leishmania*. The pathogenesis is very much like that of the malarial parasite where the pathogen spreads through the insect vector, a sandfly. The current treatment modalities involving amphotericin still remain expensive in developing countries such as India where Bihar, with a large population below the poverty line, is the worst affected state. Of late, kala azar has been in the news for patients showing coinfection with leishmania and HIV, an emerging problem that could escalate further.

Dr Sanjay Singh, chief executive officer, Gennova Biopharmaceuticals, says, 'The kala azar vaccine is a joint effort of IDRI, which developed the vaccine, Gennova, which will produce the vaccine, and Banaras Hindu University Medical Institute that will conduct the phase I trials. The phase I trial, which has to be first conducted in the US for the highly purified, recombinant vaccine, has already started after which the Indian trials will be initiated.'

He adds that if successful 'we hope to conduct the phase II trials soon, with support from the Department of Biotechnology. Being a parasitic disease, developing a vaccine for kala azar has been very tough, but our motivation for

eradicating it is very strong. The vaccine would be produced at our recently inaugurated Vaccine Formulation and Research Center.

The phase I clinical trials are being funded by the Bill and Melinda Gates Foundation, which has made several efforts to bring diseases such as kala azar into the spotlight. Recently Bill Gates announced a five-year ₹1,900 crore (\$363 million) commitment to support product operational research for neglected tropical diseases (NTDs) on behalf of the Foundation.

Chikungunya is also a vector-borne viral disease that is transmitted through mosquitoes, and does not have any specific treatment.

According to WHO, chikungunya occurs in Africa, Asia, and the Indian subcontinent, and several outbreaks have been reported in the recent past. The most recent one occurred in 2006 in India when several states, including Andaman and Nicobar islands, were affected. Over 74,000 cases were reported in Tamil Nadu and Odisha.

KV Balasubramaniam, managing director, Indian Immunologicals (IIL), says, "Currently, no vaccine is available for chikungunya in the world. Today, it is important to find innovative solutions to India-centric problems, and putting in efforts to prevent this important disease aligns well with the mission and vision of IIL."

Along the lines of the kala azar vaccine, IIL too joined hands with a US-based research organization for the development of the chikungunya vaccine. Ramesh Mathur, general manager, research and development, IIL, explains, "Chikungunya virus vaccine that IIL is developing is a live attenuated virus vaccine. The virus strain was isolated from a patient and later converted into an attenuated vaccine strain. This vaccine strain was purified, shown not to cause chikungunya disease, and determined to be suitable as a vaccine strain." He says that it may take 12-16 months to submit an application to the regulators for clinical studies.

What makes the impact of the diseases such as chikungunya even more profound is the chronic disability caused in patients. "The quality of life post recovery from infection in the case of chikungunya can deteriorate. The negative effect lasts for a few years in severe cases. In this situation, in a country such as India, if bread winners in the low income group get infected, it disrupts their normal life and creates a huge financial burden. Value of the vaccine to the society in general is high compared to just the vaccine price," explains Mathur.

With Indian vaccine companies having the capabilities to supply more than 50 percent of the world's requirement of vaccines, it would be an irony if diseases such as these remain unaddressed. Another factor needed for the successful elimination of these diseases is a concerted government effort to make vaccines available to the target population.

Having acknowledged the problem, Bangladesh, India, and Nepal signed a memorandum of understanding in 2005 to eliminate visceral leishmaniasis by reducing the incidence of the disease to less than 1 case in 10,000 individuals by 2015. With only three years left for the deadline, vaccine initiatives need to be supported adequately by the Indian government for them to make a difference.

Industry experts and government officials agree that the need of the hour is to find a "Made in India" solution to this problem. Other neglected diseases, such as sleeping sickness and dengue, too need a strong campaign for research and development to ensure their prevention and cure. The responsibility of such initiatives to find new treatment modalities falls upon those countries that carry the burden of the disease itself, that is the only hope for effective prevention of such diseases.

Manasi Vaidya In Bangalore