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Hope floats for neglected tropical diseases

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Hope floats for vaccines to treat tropical diseases

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

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

According to the World Health Organisation (WHO), Leishmaniasis is found in 88 countries, with 1.6 million cases estimated 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 six lakh cases of leishmaniasis are reported, of which five lakh 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, which makes it the second-largest parasitic killer in the world. If left untreated, kala azar has 90 percent chances of case fatality with death with two years.

Kala azar is caused due to 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 co-infection with Leishmania and HIV, an emerging problem that could escalate further.

Dr Sanjay Singh, chief executive officer, Gennova Biopharmaceuticals, outlines the plan for kala azar vaccine. "The kala azar vaccine is a joint effort between the 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 have to be first conducted in the US for the highly purified, recombinant vaccine, have already started after which the Indian trials will be initiated," he informs.

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 the recently inaugurated Vaccine Formulation and Research Center inaugurated recently at Gennova," he says.

The phase I clinical trials are being funded by the Bill & Melinda Gates Foundation, which has made several efforts to bring diseases such as kala azar into the spotlight. Recently, Mr Bill Gates announced a five-year $363-million commitment to support product and operational research for neglected tropical diseases (NTD) on behalf of the Foundation. He has also spearheaded a collaboration with 13 pharma giants and different governments to accelerate the progress in eliminating or controlling 10 NTDs by the end of the decade.

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 recent past. The most was the one that occurred in 2006 in India. Several states, including Andaman and Nicobar Islands, were affected. Over 74,000 cases were reported in Tamil Nadu and Orissa alone.

Mr K V Balasubramaniam, managing director, Indian Immunologicals (IIL), says, "Currently, no vaccine is available for chikungunya anywhere 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. Dr Ramesh Mathur, general manager, R&D, IIL, explains, "CHIKV 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 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. Dr Ramesh Mathur elaborates how this justifies the need for the vaccine. "The quality of life post recovery from infection in the case of chkiungunya can deteriorate. The negative effect lasts for few years in severe cases. In this situation, in a country like India, where bread winners in the low income group get infected, it disrupts their normal life and creates huge financial burden. Value of the vaccine to the society in general is high compared to just the vaccine price. "

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 would remain unaddressed. Another factor needed for the successful elimination of these diseases is a concerted government effort that would make the vaccine, when produced, 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 one case in 10,000 individuals by 2015. With only three years left for the deadline, vaccine initiatives such as the ones mentioned 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 R&D to ensure their prevention and cure. The responsibility of such initiatives to find new treatment modalities fall upon those countries that carry the burden of the disease itself, and initiatives such as these provide hope for effective prevention of such diseases.