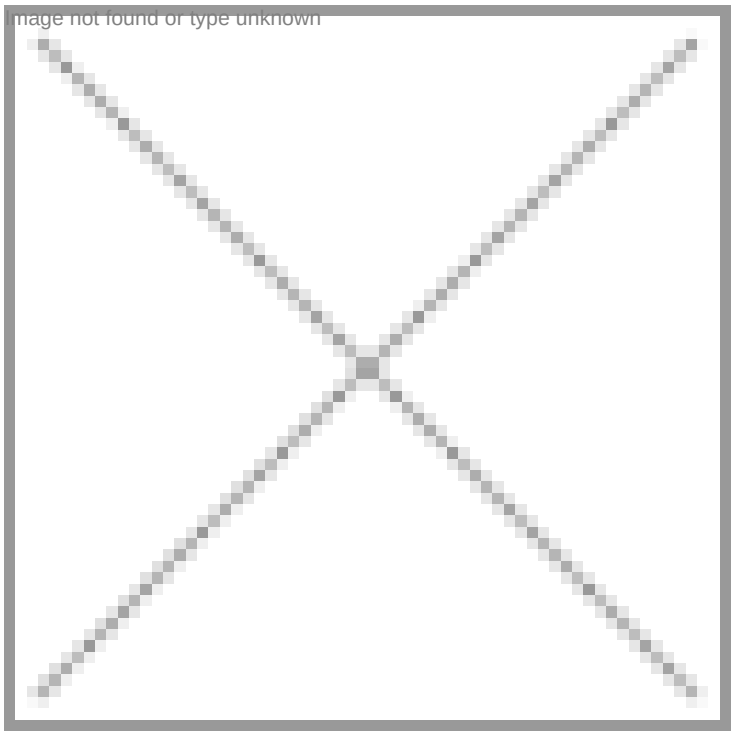
BioSpectrum the business of Bio & Health Sciences

Sanofi dengue vaccine trial enters phase II

09 December 2011 | News

Image not found or type unknown



The approval for phase II clinical trials of tetravalent dengue vaccine to Sanofi Pasteur India has raised India's hopes to have a vaccine to fight the disease

Shutterstock106417 1vaccin In October 2011, the Genetic Engineering Appraisal Committee (GEAC) gave a go-ahead to Mumbai-based Sanofi Pasteur India to import a dengue vaccine from Sanofi Pasteur, France. The company will study immunogenicity and safety of the vaccine on Indian population under Protocol No CYD 47. The GEAC's decision was based on the recommendation of the Drug Controller General of India (DCGI) and other experts who favored the proposal to conduct phase II clinical trials for this vaccine.

When Sanofi Pasteur approached the DCGI for permission, the regulatory body had referred the case to its Investigations New Drug Committee. After a go-ahead by the committee, the company approached the GEAC early in 2011.

Worldwide, an estimated 50 million dengue infections occur annually, with approximately 500,000 cases of severe dengue and 20,000 deaths. Currently, there is no vaccine available for dengue fever caused by viruses carried by the Aedes mosquito. The disease is caused by any one of the four closely related, yet antigenically distinct, dengue viruses (DENV-1, DENV-2, DENV-3 and DENV-4) of the family. This candidate vaccine from Sanofi targets all four virus serotypes circulating in the US, Asia and Latin America. Clinical studies (phase III) among adults and children are now on in Mexico, Columbia, Honduras, Puerto Rico, Peru, Phillipines, Vietnam, Singapore, Australia and Thailand.

The vaccine has reportedly shown over 90 percent safety and efficacy profile during the phase II trials that were done in various other countries. Currently, an efficacy trial of the three-shot vaccine is going on in Thailand on 4,000 children and it will be a critical milestone in its development. Data is expected to be available by the end of 2012.

In India, Sanofi is expected to do trials initially on the two-to-45 years age group and after the review of results, on those between nine months and 65 years. If everything goes well, the vaccine could possibly be available in the market by 2015 or 2016.

According to Dr P L Joshi, faculty, National Institute for Health and Family Welfare, New Delhi, who is on the Indian Council of Medical Research panel of experts in the field of leprosy and vector borne diseases, â€œThe mortality rate for dengue can be reduced considerably if self mangement practices are followed. Being a vector borne disease, the success of dengue control also depends highly on the environment policy."

There are other ongoing efforts to develop a vaccine indigenously in India. The National Institute of Allergy & Infectious Disease, Laboratory of Infectious Diseases has licensed a deletion/chimeric technology to Biological E and Panacea Biotec to move a dengue vaccine forward for product registration. There is a tendency among the live viruses in the tetravalent vaccine to interfere with each other and that has led to the emphasis on the need to develop non-infectious dengue vaccines as safer alternatives.

Dr Rajesh Jain, MD, Panacea Biotec, says, â€œThis is an important development and let us hope that it will be significant in terms of safety and cost-effectiveness. The need for an indigenous vaccine in India is due to the lack of accessibility and affordability that plays an important role here."

â€œIt has huge economic and social consequences," agrees Dr M K Bhan, secretary, DBT, and adds, â€œMillions ofdollars have been spent on the dengue vaccine intitiatives and everybody is looking forward to an early breakthrough. We should have an indigenous vaccine as soon as possible."

Appreciating the efforts of the International Center for Genetic Engineering and Biotechnology (ICGEB), New Delhi, Dr Bhan says, â€œThey are developing a non-infectious dengue vaccine based on the well-established hepatitis B vaccine technology with the help of National Institutes of Health. The program led by Dr Navin Khanna is promising and we expect the trials to be done soon."

Currently, the Recombinant Gene Products Group at the ICGEB is developing sub-unit vaccines, based on the DENV envelope protein domain III, which mediates virus entry into cells and elicits virus-neutralizing antibodies. Their research activities are focused towards the development of experimental dengue tetravalent sub-unit vaccine in yeast. In consultation with the Indo-US Vaccine Action Program, the ICGEB has created DENV-2 EDIII HBsAg virus-like particles and is currently evaluating them physically and functionally.

According to Dr Virander Chauhan, director, ICGEB, â€œThis is indeed a great step forward as having more options totackle dengue are always welcome. Meanwhile, the ICGEB is also moving ahead with its vaccine program and the results, so far, have been very encouraging."

About half of the estimated 2.5 billion people across the globe who are at risk of infection reside in India. This makes a dengue vaccine an absolute requirement for the country. Therefore, positive results from Sanofi vaccine trials will be a great development. Additionally, an indigenously developed vaccine will prove to be more affordable and will have a broader reach.

Rahul Koul in New Delhi