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Sanofi gears up to introduce dengue vaccine

August 15, 2014 | Influencers | By BioSpectrum Bureau



Healthcare stakeholders are keeping high hopes with the successful results of Sanofi Pasteur's Phase III trial of dengue vaccine completed this year and a vaccine may be available soon. The drug giant has been working on a dengue vaccine for more than 20 years and is the only company successful to achieve phase III efficacy study. **Mr Guillaume Leroy, vice president-dengue vaccine head, Sanofi Pasteur** has played an instrumental role in the development of dengue vaccine. He speaks to BioSpectrum Asia about Sanofi's move to intrdouce the maiden dengue vaccine in global market

By when are you expecting to launch the dengue vaccine? Once theÃ?Â vaccine is launched, what would be Sanofi's roadmap of ensuring the availability and accessibility of the vaccine in developing countries?

For 20 years we have been working on dengue vaccine, which is one of the highest scientific challenges to successfully develop a treatment. Right now we are in a very critical milestone as we are in the last stage of the trial.

By the end of 2014 we will have full analysis of the efficacy of the vaccine after the clinical trial result from Latin America. We are expecting that the first vaccine would get the license by end of 2016 in countries that are highly endemic and prone to dengue. For that we have to define, in consideration with health authorities of the countries, where the vaccine is needed immediately and urgently. Our first concern is to address the need and then we would extend the market.

Dengue could affect population from any strata and there is no economic divide in the spread of the diseases. Hence, our plan is to reach to those countries that need it most and it is the decision of health authorities of the government to design the

distribution map of the vaccine.

How challenging it has been to gather data for clinical trials in developing countries?

Sanofi vaccine is the only vaccine that has reached phase III level with successful result and we do not have any information if any other candidate has cleared Phase II clinical trial. Dengue has not been a very well documented disease because there has been no treatment available and very less documentation has been done. Countries are looking for more data to understand the disease and they are progressing for a better investigation. But there is still a lot of work to do.

How do you plan to get the regulatory approval of the vaccine in Asia where each country has its own regulatory norms?

We are first planning to reach out to the countries that are highly endemic and also those who have been extremely supportive in carrying out the clinical trial, for instance, Philippines, Singapore, Latin America. We are planning to do in a organized way and we would also seek WHO approval for the faster and wider accessibility of the vaccine. Once we have satisfactory results from all countries from phase III clinical trial, Sanofi will also seek FDA and EU approval as their standards are acceptable by many Asian countries as well.

What are the side effects of the vaccine?
Efficacy trail of the dengue population was conducted on healthy population and there has been no side effect or any evidence of antibody resistance enhancement observed in the study.

What was Sanofi's experience in taking the clinical trial to developing countries and how supportive they were during initial phases?

I can testify that if you are the first one to approach a country that has been massively facing a disease like dengue, they demonstrate a big sign of trust and confidence. Dengue disease has been a burden and any single option for minimizing the dengue is critical for any country. Wherever Sanofi has conducted the clinical trials or has done investigation, the countries have been extremely supportive to mobilize the plan, Philippines, Mexico, Singapore or 15 other countries played a big support in developing the vaccine.

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