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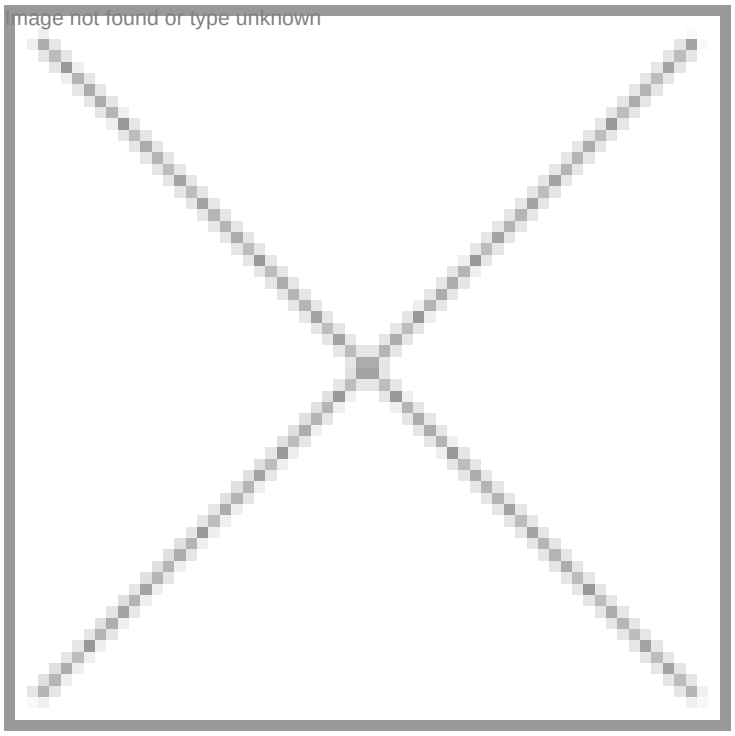


Animal trials start for India’s swine flu vaccine

Slowly and steadily India’s swine flu vaccine developing companies are making good progress even as the influenza virus infects hundreds of people every day across the country.

“Serum Institute will be ready to seek permission from the regulator (DCGI) in November to seek permission for clinical trials of its swine flu vaccine on human volunteers,” said Dr Satish D Ravetkar, senior director of Serum Institute who is handling the vaccine project. If that happens, the human trials could start in early December.

Hyderabad-based Bharat Biotech International has developed the swine flu vaccine using the cell lines method. “We are now doing the characterization and quality control studies on the vaccine,” said Dr Krishna Ella, chairman of Bharat Biotech. While most companies in the world have used the traditional chicken egg method, Bharat has used cell lines methodology like Novartis and Baxter.

Bharat Biotech is likely to approach the regulator for approvals to start animal trials in September to generate data for human trials after three to four months.

What is worrying the vaccine makers, however, is the absence of any firm commitment from the government to buy theswine flu vaccines. So far, the government has announced its intention to order 10 millions doses of the swine flu vaccine when it is ready. “But we have not got any firm order from the government on purchase quantities or price,” said sources handling the government negotiations in both Serum Institute and Bharat Biotech.

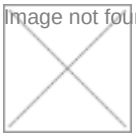
Panacea Biotec’s joint MD Rajesh Jain had talked about the absence of support from the government to these vaccine making initiatives with no indication of quantity requirements. This is in contrast to national governments in most developed countries making advance orders to influenza H1N1 vaccine companies in the US, Europe, China and Australia to stock up

as much vaccine as possible when it is ready, pointed out an industry expert.

Dr Ella indicated that if everything goes well, the swine flu vaccine will be ready for the flu season starting in the winter of 2010. Bharat Biotech is even planning to use its animal vaccine manufacturing facility, run by its associate company, Biovet, to make the swine flu vaccine, if the nation requires it.

However, even with all these preparation, the company will be aiming to manufacture just 50 to 70 million doses of the vaccine, said Dr Ella. At Serum too, an elaborate exercise is on to determine the manufacturing capacities which could be readied for large scale production. “As the influenza strain is new, the vaccine yield will be very low during the initial stages. Further, we still don’t know what will be the standard dosage to combat the H1N1 virus,” Dr Ravetkar said.

The process itself is complex and time-consuming. Dr Ravetkar indicated that the immunogenicity trials will take four-to-five weeks. The toxicity studies could be taken only after reviewing these results. The toxicity studies will take another six to seven weeks. Bangalore-based Advinus Therapeutics is understood to be conducting some of the immunogenicity trials for Serum Institute. A Pune-based laboratory, Toxicology Research Foundation is reportedly doing the toxicity studies.



CSL starts pediatric trials in US

CSL Biotherapies has meanwhile started clinical trials of its influenza vaccine in the US too. The US government-fundedtrials will happen in 24 sites in the country. It is anticipated that findings from these trials will be used to determine the most appropriate dosing schedule of the Influenza A/H1N1 2009 vaccine for use in the general population.

CSL said this clinical trial program was part of a larger, global effort by CSL Biotherapies, in partnership with government and regulatory bodies, to bring an Influenza A/H1N1 2009 vaccine to market in the US, Australia and in select regions of the southern hemisphere.

“The H1N1 pandemic has had a significant toll on the health and well-being of people worldwide, which makes the development of an effective vaccine against the virus an urgent public health need,” said Dr Kawsar Talaat, principal investigator of the CSL vaccine adult trials and assistant scientist in the Johns Hopkins Bloomberg School’s Department of International Health. “Through these trials, we hope to identify the most effective dose and dosing regimen to protect the public against this highly infectious new strain of influenza virus.”

“Children are often at greater risk from influenza infection and its complications than adults, so it is extremely important to understand the efficacy of an H1N1 vaccine in this very vulnerable population,” said Dr Pedro Piedra, principal investigator for the vaccine pediatric trials and professor in the department of molecular virology and microbiology, and pediatrics at Baylor College of Medicine.

Narayanan Suresh