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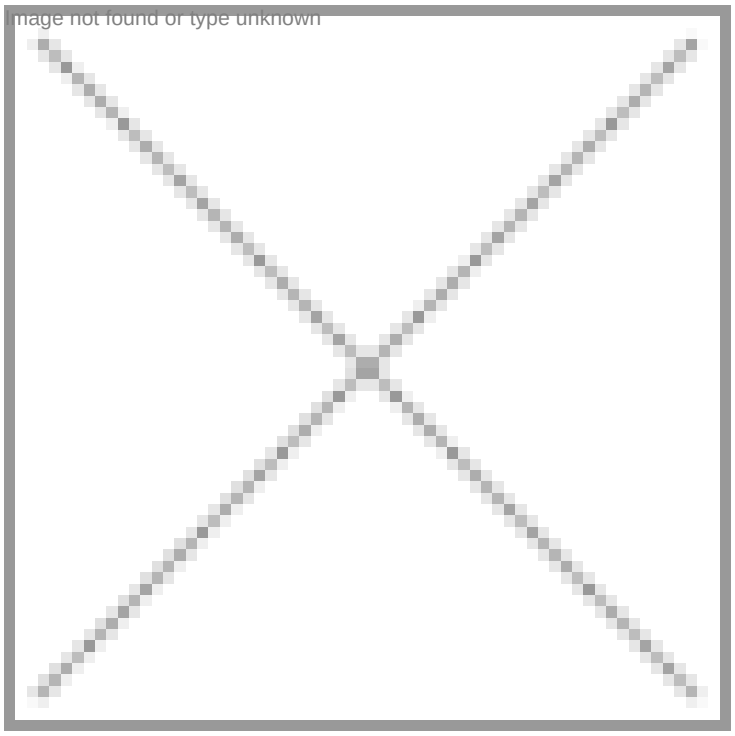

'We've begun Panflu phase II trials'

-Weidong Yin, President & CEO, Sinovac

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China's leading emerging biotech company, Sinovac Biotech (also known in China as Beijing Kexing Bioproducts) specializes in the research, development, commercialization, and sales of human vaccines for infectious illnesses such as Hepatitis A and Hepatitis B, influenza and SARS.

Working closely with Chinese public health officials, Sinovac focuses on manufacturing and marketing human-use vaccines and related products, and currently markets its vaccine for Hepatitis A. Sinovac is the first and currently, the only company in the world to have been granted permission to begin clinical trials for a vaccine to prevent SARS. In an e-mail interview with BioSpectrum, Mr Weidong Yin, President and CEO, Sinovac, elaborates on the success the company has had with its various products.

How well are Sinovac products (Healive, Bilive and Anflu) doing? Which one is the best seller?

There are three products on the market, Healive: the first Inactivated Hepatitis A vaccine in China, Bilive: Hepatitis A &B combined vaccine and Anflu: the Split Influenza vaccine.

Healive was launched in 2002. In the past, most inactivated Hepatitis A vaccines in China were imported from other

countries. Through the National Ninth Five-year Scientific and Technological Project on medicines, we successfully developed the first proprietary inactivated Hepatitis A vaccine in China and commercialized the vaccine. The clinical research data shows the seroconversive rate of the subjects inoculated with the vaccines for full vaccination schedule is 100 percent and the safety, immunogenicity, the clinical result and the quality of the vaccine is comparable to the imported inactivated Hepatitis A vaccines. Currently, Healive is being sold in 27 provinces in China and is the most widely used inactivated Hepatitis A vaccine in the country. In 2006, 2.6 million doses were sold in China, which generated the sales revenue of RMB 100 million.

Bilive was launched into market in 2005, which is used to enhance the immunogenicity. As the supplement of Hepatitis A vaccine and Hepatitis B vaccine, the demand is not very large.

Anflu was launched in the autumn of 2006 and the key purpose is to introduce the new product to our customers.

Who are your main customers for each of these products?

In China, the disease control system includes provincial CDC, municipal CDC, county CDC and inoculation clinic. Sinovac's vaccines are distributed through different CDC systems in China. Based on the principle of disease control, companies provide the high-quality vaccines to the disease control system. Sinovac sells all its vaccine products only to provincial, municipal, and county CDCs. The provincial CDCs and municipal CDCs are responsible for purchasing the vaccines and then distributing it to subordinate CDC and inoculation clinic, which regulate the execution of vaccination program.

Currently, what kind of method is Sinovac using for vaccine production? Cell culture or eggs?

Sinovac has used and established several technology platforms during the production process, which involves all aspects in vaccine production. We use different platforms according to the types of vaccines. For example, we use egg-culture to produce influenza vaccines and cell-based technology to produce Hep A antigens.

What are your views on DNA vaccine? Will it be workable? When?

DNA vaccine is a new development in vaccine technology. The technology can be used as foundation for the development of future vaccines and speed up the R&D process of vaccines. Compared with traditional vaccines, DNA molecule is more stable, making it easy for transportation and storage, but some issues need further research. Those are whether DNA vaccine, as an exogenous DNA, could intergrade or interrupt the normal function of DNA in host, whether these exogenous DNA could induce immunifaction. With the development of technology and research, DNA vaccine will bring huge benefit for human beings.

What other products are in the pipeline?

Our product pipeline includes pandemic influenza vaccine Panflu, Japanese Encephalitis vaccine and SARS vaccine. Panflu is being co-developed by Sinovac and China CDC, and its phase II trials commenced in May 2007. For the Japanese Encephalitis Vaccine, we are getting ready with the application for phase I clinical trial. For SARS vaccine, phase I clinical trial has been completed. However, the entire three phases of clinical trials cannot be completed without outbreaks. Currently, as there are no more cases, the project is suspended. We intend to resume the process required to obtain regulatory approvals if the virus re-emerges.

Can you please elaborate on the avian flu vaccine that Sinovac is working on? At what stage of development it is now?

The China State Food and Drug Administration (SFDA) recently granted Sinovac approval to commence the phase II clinical trial of Panflu, a human use vaccine against the H5N1 strain of pandemic influenza virus.

Two types of the H5N1 vaccine were approved by the SFDA to commence clinical trials. The first type is the H5N1 whole viron inactivated vaccine for which the phase I clinical trial was completed in 2006. The phase Ib and II clinical trials for the H5N1 whole viron inactivated vaccine will be conducted to further test the tolerance, safety, and immunogenicity and to determine the dosage and inoculation schedule. During the phase Ib and II trials, the age-groups of the participants will be enlarged by adding youths and the elderly.

The second type of vaccine is the H5N1 split viron vaccine, for which the phase I and II clinical trials will be conducted continuously. The trials will focus on the vaccine's tolerance, safety, and immunogenicity. It is anticipated that the phase II clinical trials will commence simultaneously for the two types of vaccines in order to determine the vaccination dosage and inoculation schedule for drafting the registration standards and specifications for the vaccine.

Sinovac commenced development of Panflu in February 2004 as part of the global united battle to fight against pandemic influenza.

In June 2006, the results of phase I clinical trial were unblinded and showed good immunogenicity and safety. On September 7, 2006, the results were published in The Lancet, a global renowned medical periodical, that provided worldwide recognition for the phase I clinical trial results of the pandemic influenza vaccine (H5N1) developed by Chinese scientists.

Sinovac has received invitation from WHO to participate into the campaign to solve the issue with access to pandemic flu vaccine by developing countries. We are willing and capable to help our country and many other countries for this public health issue.

Has Sinovac turned the corner financially?

In 2006, Sinovac incurred a loss, but net loss decreased by 86.4 percent to $696,000 in 2006 from $5,111,000 in 2005.

Nandita Singh