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**SARS vaccine enters Phase I trials**

Sinovac Biotech Ltd. (Beijing, China) have announced that the first four student volunteers to have been tested with an experimental severe acute respiratory syndrome (SARS) vaccine on 22 May, 2004, have received the second vaccination on 19 June, and no adverse side effects have thus far been reported.

The vaccine, developed with Sinovac in conjunction with the Chinese government, underwent preclinical studies in November 2003, after which time an application was made to the Chinese State Food and Drug Administration (FDA). Trials of the vaccine, which were approved in January 2004, commenced in May in 36 healthy volunteers between the ages of 21–40 years.

The volunteers are to be observed for a total of 210 days in order to complete the trial. The first four healthy volunteers to be inoculated with either the vaccine or placebo on day 0 and again on day 28, with strict observation in between shots. The volunteers are to be observed for a total of 210 days in order to complete the trial.

The first four healthy volunteers to be inoculated with the vaccine are to be examined to determine whether the vaccine is safe for humans, as the USA have already successfully tested a SARS vaccine on animals. A further 14 volunteers are to receive their first inoculation with the vaccine in the near future. However, the World Health Organization (WHO) have commented that they predict that a safe and efficacious human vaccine against the disease is still at least a year or 2 away.

In May 2004 Sinovac also received funding from the National Institutes of Health (NIH) in order to carry out comparisons of analyses of immunoresponse to SARS coronavirus, inactive vaccine candidate, viral protein fractions and recombinant viral proteins in biosassays. The Chinese company is the first in the world to have received approval to carry out human clinical trials of a SARS vaccine.

The SARS virus first emerged in China, in the southern province of Guangdong, late in 2002, when it infected over 8000 individuals worldwide. It then subsided in July 2003, and since this time, China has been victim to two further outbreaks of the disease. The last remaining patient in the most recent outbreak was released from a Beijing hospital recently.

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The vaccine will be aimed mainly at individuals who have already successfully given up smoking but are in danger of relapse, for example on social occasions. If a vaccinated individual smokes, the nicotine binds to antibodies in the bloodstream to form a large complex incapable of crossing the blood-brain barrier, thus blocking the pleasurable stimulus usually associated with smoking.

The company now plan to initiate a rolling Phase II/III study at the end of 2004 with up to 400 patients. The vaccine is to be evaluated in combination with nicotine replacement therapy with a view to monitoring relapse rates. This will then be followed by a Phase III expansion in approximately 2000 subjects. However, full-scale trials are likely to prove too expensive for Xenova to fund solely, and it may seek a partner. Oxlade commented on the suggestion "we will of course be exploring various options."

TA-NIC joins the long list of current treatment options for nicotine addiction, including transdermal patches and inhalers, however, current treatment generally focuses on nicotine replacement therapy to aid in relieving the withdrawal symptoms associated with smoking cessation. Bupropion (Zyban®, GlaxoSmithKline), a nicotine-free anti-depressant, is now also being used in some countries. TA-NIC however uses a protein conjugate consisting of a nicotine derivative coupled to recombinant cholera toxin B. The protein conjugate is then adsorbed onto an aluminium hydroxide gel adjuvant in a sodium phosphate buffer which contains mannitol. The route of administration of the vaccine is intramuscular, and it is thought that merely a short course of injections will be sufficient to elicit an antibody response to nicotine.

Preliminary results of clinical trials of Xenova's (Slough, UK) TA-NIC smokers vaccine have reported 43% of smokers either quit or got less pleasure from cigarettes. The trial, which was originally designed to calculate the optimum dose of the vaccine, has led to an increase in Xenova's shares of 2.5% to Stg10.25p.

Speaking of the results, David Oxlade, CEO of Xenova commented "The interesting point, without overstating the case, is that all the participants were told they were not being asked to change their smoking habits, so we were quite positively encouraged to see a significant number were either voluntarily quitting or they reported the pleasure from smoking was substantially reduced."

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