Bird flu vaccine passes Phase I trial

An experimental H5N1 bird flu vaccine has been proved to be safe and immunogenic, as revealed by new research published in the journal the Lancet last month.

The inactivated vaccine made by Sanofi Aventis was tested with various formulations. Scientists found a two-dose regimen of 30 mg with aluminium hydroxide adjuvant produced the best outcome.

"The vaccine that we tested appeared to be safe and well-tolerated and we did see a good immune response", said Melanie Saville, head of the trial team. It also met the European regulatory requirements for human influenza vaccine.

Another aim of this trial was to reduce the vaccine dosage. The current production capacity for human influenza vaccines can make 300 million doses per year. Improving this capacity is difficult and expensive, hence dosing strategies are important to meet the demand. In an earlier trial, two doses of 90 mg of another vaccine produced by Sanofi showed a satisfactory result. The dosage is important as more people can benefit if less vaccine is needed per dose. In this trial, doses lower than 30 mg have revealed encouraging results, although further research is needed.

"We will be moving into Phase II very shortly", added Saville.

Other pharmaceutical companies have also started clinical trials. GlaxoSmithKline is working with two vaccines against the H5N1 virus and Chiron Corp with one.

The risk of the H5N1 bird flu virus spreading from Asia to Europe, the Middle East and Africa presents a prominent threat if it mutates into a highly infectious strain that can be transmitted among humans. Drug companies are racing to develop a H5N1 vaccine to prepare for the possible pandemic of a mutated bird flu virus.

Another hope against cervical cancer

A Phase I/II clinical trial of Lovaxin C was launched last month involving 20 cervical cancer patients in Serbia, Israel and Mexico and is scheduled to last for 6 months.

This is the first human trial of a Listeria-based cancer vaccine. The safety and therapeutic effect of Lovaxin C will be addressed in this trial. The vaccine utilizes the bacterium Listeria monocytogenes, which can trigger human cytotoxic T killer cells. The microorganism has been modified such that it activates the body's immune system to fight against cancer cells. "Lovaxin C might prevent the transformation into cancer and provide protection against recurrence, replacing the need for surgical intervention," said John Rothman, vice-president of the company Advaxis Inc.

The vaccine has been developed by Yvonne Paterson, professor of microbiology at the University of Pennsylvania (PA, USA), who is also chairperson of scientific advisory board of the company. Lovaxin C is designed to target cervical cancer, while other Listeria-based vaccines are being developed to fight breast, ovarian and lung cancers.

Paterson and her team have recently published several research papers on Listeria cancer vaccines in scientific journals, such as Cancer Research and Cancer Immunology and Immunotherapy.

Another company, Merck and Co., has gone ahead after its human papillomavirus-based cervical cancer vaccine Gardasil passed the first human trial last month and is awaiting the USFDA approval in June this year.

AIDS vaccine trials never enough

GeoVax Inc's new HIV/AIDS vaccine, developed in collaboration with Emory University (GA, USA), the NIH and the CDC, began clinical trials in the USA at the end of last month.

The complex vaccine comprises two priming injections of a DNA vaccine followed by two boosters of a modified MVA poxvirus. Three important proteins of HIV are included in the vaccine, which can hopefully make the body's immune system recognize the harmful virus should it appear. The vaccine was proved safe after a preclinical trial in 2003.

Team leader, Harriet Robinson of Emory University and head of the GeoVax scientific advisory board, has published research on this vaccine since 1999 in the journal Nature Medicine, and later in Science.

The first phase of this trial involves 12 volunteers with low doses of two vaccine components. If it is safe, the vaccine will be tested in 36 people with higher doses. When safety and immunogenicity of the first phase are confirmed, 72 people will be included in the second phase of the trial to initially establish the dosing regime.

To date, over 60 Phase I/II trials of more than 30 candidate HIV vaccines have been carried out worldwide in Asia, Africa, Latin America, the Caribbean, and the USA.

Largest clinical trial of HIV vaccine hammered

AIDS Healthcare Foundation (AHF) called on the US Congress on May 22 to halt the US$120 million HIV vaccine clinical trial in Thailand.

The trial involves 16,000 HIV-negative volunteers from two provinces, Rayong and Chon Buri, and is scheduled to end in 2009. The candidate vaccines used are AIDSvAX made by VaxGen and ALVAC by Sanofi Pasteur. All
Phase I/II trials showed that the vaccines were safe and produced a certain level of immune responses. A Phase III trial started in 2003 where ALVAC was used as a booster for AIDSVAX. The trials are funded by the NIH.

In the January 2004 issue of the journal Science, 22 experts in the field stated that the trial should be stopped because the vaccines failed to induce adequate immune responses in the first two phase trials. The issue was followed up with the AHF call on the US Congress last month.

The president of AHF, Michael Weinstein said "At a time when Americans in need of treatment remain on waiting lists to receive HIV/AIDS medicines ..., and millions in the developing world still lack access to lifesaving AIDS drugs, it is a waste of limited resources for the NIH to spend US$120 million on an AIDS vaccine trial based on questionable science".

The Washington Post also investigated the issue and reported that the trial is "the largest, most expensive, most resource-intensive AIDS vaccine trial ever". It emphasized that the two vaccines ‘individually have been disappointing in previous trials'. 
