News in Brief

New smallpox vaccine approved by US FDA

ACAM2000™, a second-generation, single-dose smallpox vaccine by Acambis (UK and MA, USA), has been approved by the US FDA for vaccination of high-risk subjects and for use in an emergency, such as a bioterrorist attack.

Smallpox is a contagious infection caused by variola virus. An infected individual presents with fever and body aches followed by raised, pus-filled blisters on the skin. Death is often associated with complications, such as bacterial infections, and the mortality rate is approximately 30% as estimated by the US CDC. Treatment is only supportive and vaccination is the only means of prevention. Although smallpox has been eradicated worldwide since the 1980s and vaccines are no longer produced, recent threats of bioterrorism have renewed interest and necessity of stockpiling smallpox vaccines, especially by the US Government.

“Smallpox could be a particularly dangerous biological threat to us that would kill or debilitate a high percentage of the population,” said Craig Vanderwagen, assistant secretary for preparedness and response, US Department of Health and Human Services.

ACAM2000 contains cell-cultured live vaccinia, a related virus to variola that results in protective immunity to smallpox without causing the disease. The cell culture technology allows fast and consistent large-scale vaccine production. Acambis has supplied 192.5 million doses to the CDC Strategic National Stockpile so far.

“The licensure of ACAM2000 is a significant milestone not only for Acambis but also for the US Government in its plans to ensure a state of readiness against the threat of smallpox. This has been a highly successful collaboration between Acambis and the CDC, and we look forward to finalizing the warm-base manufacturing contract to secure this vaccine production capability for the US Government for the long term,” said Ian Garland, Acambis’ chief executive officer.

“This new licensure means ‘we are more prepared to protect the population should the virus ever be used as a weapon,’” added Jesse Goodman, director of FDA’s Center for Biologics Evaluation and Research.

Source: The US FDA: www.fda.gov; Acambis PLC, UK: www.acambis.com

Toward a hepatitis C vaccine

Results from a study using human antibodies to HCV to prevent hepatitis C were presented by Alexander Tarr of the University of Nottingham at the UK Society for General Microbiology’s 161st meeting in Edinburgh last September. The findings may be an important step toward a vaccine against HCV.

HCV infection is the most common cause of liver transplantation. The virus infects 180 million people worldwide and up to 500,000 people in the UK alone. As the majority of cases are undiagnosed, long-term HCV infection often leads to liver cirrhosis and cancer. Treatment is costly and not always successful, and there is no vaccine available.

The antibodies have been shown to prevent infection with many diverse strains of HCV in laboratory models. “Historically, successful vaccines against viruses have required the production of antibodies and this is likely to be the case for HCV. Identifying regions of the virus that are able to induce broadly reactive neutralizing antibodies is a significant milestone in the development of a HCV vaccine, which will have distinct healthcare benefits for hepatitis sufferers, and could also help us design vaccines for other chronic viral diseases, such as HIV,” said Tarr. “We are also currently exploring the possibility of improving liver transplantation success rates by passively infusing people with these antibodies.”

Source: University of Nottingham, UK: www.nottingham.ac.uk

Promising HIV vaccine funded for further clinical development

Funding has been given to develop a novel HIV vaccine that was created at the Wistar Institute (PA, USA). The 5-year, US$13.3-million grant will support further clinical development of the vaccine toward clinical trials in humans.

The new vaccine is based on a simian adenoviral vector that carries HIV antigens. This novel approach eliminates the main drawback of other HIV vaccines based on human
First order of cattle Escherichia coli vaccine dispatched

Bioniche Life Sciences Inc. (Canada) has released the first shipment of its Escherichia coli O157:H7 vaccine for cattle. The vaccine received permits from the Canadian Food Inspection Agency (CFIA) in December 2006 to release its vaccine to Canadian veterinarians, through whom cattle owners should request the vaccine if they wish their cattle to be vaccinated. The vaccine aims to reduce E. coli O157:H7 shedding in cattle. Bacterial shedding from cattle to the environment results in approximately 100,000 cases of human illness every year in North America. The vaccine is still under review by the CFIA and the US Department of Agriculture. Additional data have been sent to the CFIA, which confirmed the effectiveness of the vaccine in reducing E. coli O157:H7 shedding in vaccinated animals. For the time being, Bioniche is manufacturing the vaccine at its Belleville (ON, Canada) facility, which will be scaled up when full domestic and international license approvals are achieved.

Source: Bioniche Life Sciences Inc., ON, Canada: www.bioniche.com

Novavax revealed preclinical data of virus-like particle HIV vaccine

Findings from a preclinical study using a virus-like particle (VLP) HIV vaccine were presented by Weimin Liu of the University of Alabama School of Medicine (AL, USA) at the AIDS Vaccine Conference, Seattle (WA, USA) in August. The VLP-based HIV-1 vaccine was developed by Novavax Inc. (MD, USA) in collaboration with researchers from the University of Alabama, Emory University and Duke University with funding from the NIH. VLP consists of viral structural proteins and sometimes a lipid bilayer envelope, hence resembling the real virus, only without any viral nucleic acid. Therefore, VLPs are not infectious but can trigger effective antibody, as well as cell-mediated, immune responses to the virus. Human papillomavirus and hepatitis B vaccines are the first VLP-based vaccines approved by the US FDA, and the VLP technology is being applied to many other viral vaccines under research.

“VLPs represent an exciting new vaccine delivery platform for HIV, the full potential of which has not yet been realized,” said Beatrice Hahn of the University of Alabama.

“The data presented demonstrate that immunization with VLPs containing a consensus envelope protein is a promising approach to achieving the desired broadly neutralizing antibody response against the HIV-1 virus. These data also substantiate the promise of our recombinant VLP technology to design vaccines to ultimately generate an immune response that can prevent complex diseases, such as HIV/AIDS,” commented Rahul Singhvi, Novavax’s President and Chief Executive Officer.

DNA priming followed by HIV VLP boost resulted in HIV-1-neutralizing antibodies to several virus strains including some that are difficult to neutralize, such as HIV-1 subtypes B and C, which are associated with more than 50% of AIDS worldwide. In addition, vaccination with VLPs without adjuvants could trigger comparable levels of antibodies to those induced by adjuvanted protein subunit vaccine.
“This vaccine approach differs from most others now in clinical trials in that VLPs are designed to produce neutralizing antibodies. Such antibodies have the potential to block the HIV infection process at its earliest stage,” said Richard Comans of Emory University School of Medicine, also the senior investigator of the research team.

In this study, the HIV-1 VLP also carries a modified envelope protein that can induce cross-reactive immune responses against several HIV strains. As genetic variation remains an obstacle in HIV vaccine development, artificially designed sequences that represent most common and essential regions of different HIV envelope proteins may provide a solution.

Novavax-supported preclinical studies of the consensus envelope HIV-1 VLP candidate vaccine will be completed in the next 12–18 months and human clinical trials may begin in 2009. In addition, vaccines against influenza and other viral diseases are being developed by Novavax using its proprietary VLP technology.

Source: Novavax Inc., MD, USA: www.novavax.com

Monoclonal antibody may reduce hospitalizations due to respiratory syncytial virus

Results of a randomized, double-blind Phase III clinical trial have revealed that motavizumab, a monoclonal antibody developed by MedImmune Inc. (MD, USA), could reduce hospitalizations due to respiratory syncytial virus (RSV) by 83% compared with placebo. In addition, a 71% reduction in RSV-related lower respiratory infections (LRIs) in outpatients was also observed.

RSV is the leading cause of LRIs in infants in the USA, with more than 100,000 cases of hospitalization occurring every year. RSV infections may also occur in the elderly, immunocompromised and those with underlying respiratory or cardiac disease.

Motavizumab is a humanized monoclonal antibody that was designed to prevent LRIs due to RSV in pediatric patients. Phase I and II clinical trial results have showed that motavizumab has a similar safety and pharmacokinetic profile to Synagis® (palivizumab) in infants. Also developed by MedImmune, Synagis is a monoclonal antibody approved by the FDA for prevention LRIs due to RSV in high-risk pediatric patients. The product is administered by intramuscular injection and is currently available in 62 countries.

This Phase III study included 1410 full-term infants of less than 6 months of age in two Native American populations that are known to have high risk of RSV infections. Motavizumab was well tolerated in these infants and reduced the risk of hospitalization due to RSV compared with placebo.

“We are pleased with the results of this study, which support the positive results seen in our Phase III pivotal trial comparing motavizumab and Synagis that were previously reported at the Pediatric Academic Societies meeting in May 2007,” said Genevieve Losonsky, Vice-President of clinical development and infectious disease at MedImmune.

Source: MedImmune Inc., MD, USA: www.medimmune.com

About the News in Brief
The News in Brief highlights some of the most important events and launches in the vaccine field. The editorial team welcomes suggestions for timely, relevant items. If you have newsworthy information, please contact:

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