First Smallpox Vaccine Since 1931 Approved by FDA

BY JEFF EVANS
Senior Writer

The Food and Drug Administration has approved a new smallpox vaccine, ACAM2000, for active immunization against smallpox in individuals determined to be at high risk for smallpox infection. The vaccine also could be used to immunize populations during a bioterrorist attack.

The single-dose vaccine is approved under licensing that requires providers of the vaccine and patients to be educated about the risks of the virus.

Many doses of the vaccine will be stored in the Centers for Disease Control and Prevention's Strategic National Stockpile of medical supplies. The vaccine manufacturer, Acambis Inc., of Cambridge, England, and Cambridge, Mass., so far has supplied 192.5 million doses of ACAM2000 to the stockpile, according to the company.

The single-dose vaccine is approved under licensing that requires providers of the vaccine and patients to be educated about the risks of the virus through a Risk Minimization Action Plan. Patient education is supposed to be conducted through an FDA-approved medication guide, which describes the proper care of the vaccination site and the serious side effects that can occur.

Dryvax, the only other smallpox vaccine that is licensed by the FDA, was approved in 1931 and is now in limited supply because it is no longer manufactured. Dryvax was used to create ACAM2000, which is made using a live poxvirus called vaccinia. Vaccinia is related to, but different from, the virus that causes smallpox, and works by causing a mild infection that stimulates an immune response that will protect against smallpox, according to the FDA.

In one clinical study of ACAM2000, investigators found that the percentage of successful immunization reactions was similar for both ACAM2000 (96%) and Dryvax (99%) in patients who had never been vaccinated for smallpox prior to the trial.

Another study showed that ACAM2000 worked as successfully as Dryvax as a booster for those who previously had been vaccinated for smallpox (84% vs. 98%, respectively).

Cases of suspected myocarditis and/or pericarditis developed in 0.6% to 1% of all vaccinia-naive patients who received either ACAM2000 or Dryvax. Overall, 10 patients developed suspected myocarditis/pericarditis, which occurred at a mean of 11 days after vaccination with either vaccine. Only two of these patients required hospitalization. Eight of the cases were not detected until abnormalities were found on ECG. All patients had recovered by 9 months except for one, who had a persistent borderline abnormal left ventricular ejection fraction, according to the product label.

No cardiovascular inflammation or swelling occurred in previously vaccinated patients.

Patients who are vaccinated with ACAM2000 have to take precautions to prevent the virus from spreading from the inoculation site to other parts of the body and to other individuals, according to the vaccine's label. ■

CDC Information On Immunization

The Centers for Disease Control and Prevention expects to release its 2007-2008 Adult Immunization Schedule in English toward the end of October 2007, and in Spanish 2 months later. To download the schedule or to obtain information on other vaccine-related topics, contact the CDC by visiting www.cdc.gov/vaccines/recs/schedules/adult-schedule.htm.

In addition, the CDC's Advisory Committee on Immunization Practices (ACIP) has revised its Web site. The site is user-friendly for health professionals and the general public and includes ACIP vaccine recommendations by age groups, specific vaccines, and specific diseases. The site also has information about the Vaccines for Children program. For more information, visit the new site at www.cdc.gov/vaccines/recs/acip. ■