Drugs recently approved or pending approval

KINRIX

The US Food and Drug Administration (FDA) has given approval to GlaxoSmithKline (Research Triangle Park, NC) to market Kinrix (diphtheria and tetanus toxoids and accellular pertussis adsorbed, and inactivated poliovirus vaccine [IPV]) for active immunization against diphtheria, tetanus, pertussis, and poliomyelitis as the fifth dose in the diphtheria, tetanus, and acellular pertussis (DTaP) vaccine series and the fourth dose in the activated IPV series in children aged 4 to 6 years whose previous DTaP vaccine doses have been with Infanrix (diphtheria and tetanus toxoids and acellular pertussis vaccine adsorbed) and/or Pediarix (diphtheria and tetanus toxoids and acellular pertussis adsorbed hepatitis B [recombinant], and IPV combined) for the first 3 doses and Infanrix for the fourth dose. Kinrix was evaluated in a US multicenter study involving 4209 children who previously received 4 doses of Infanrix, 3 doses of IPV, and 1 dose of measles, mumps, and rubella (MMR) vaccine. Patients were randomized in a 3:1 ratio to Kinrix or Infanrix and IPV coadministered concomitantly with the MMR vaccine at a separate site. Levels of antibodies to diphtheria, tetanus, pertussis, and poliovirus antigens were measured immediately prior to vaccination and at 1 month postvaccination (range, 31–48 days). The coprimary immunogenicity endpoints were antidiphtheria toxoid, antitetanus toxoid, antipertussin toxin, antifilamentous hemagglutinin, and antipertactin booster responses; and antipoliovirus (types 1, 2, and 3) geometric mean antibody titers 1 month after vaccination. Kinrix was comparable with Infanrix and IPV based on booster responses to DTaP antigens and postvaccination geometric mean antibody titers for antipoliovirus antibodies. The most common adverse effects were pain; redness, swelling, or arm circumference increase at the injection site; drowsiness; fever; and loss of appetite.

LEXISCAN

Astellas Pharma US, Inc. (Deerfield, IL) has been given FDA approval to market Lexiscan (regadenoson) injection, a pharmacologic stress agent, for radionuclide myocardial perfusion imaging in patients unable to undergo adequate exercise stress. The efficacy and safety of Lexiscan were established in 2 randomized, double-blind studies involving 2015 patients with known or suspected coronary artery disease with indications for pharmacologic stress myocardial perfusion imaging. Patients received an initial stress scan using Adenoscan (adenosine injection; 6-min infusion dose of 0.14 mg/kg/min without exercise) with a radionuclide-gated single-photon emission computed tomography (SPECT) imaging protocol. After the initial scan, patients were then randomized to Lexiscan or Adenoscan and received a second stress scan with the radionuclide-gated SPECT imaging protocol used for the initial scan (median time between scans, 7 days [range, 1–104 days]). Both studies demonstrated that Lexiscan is similar to Adenoscan in assessing the extent of reversible perfusion abnormalities. The most common adverse effects were dyspnea, headache, flushing, chest discomfort, dizziness, and nausea. The recommended dose of Lexiscan is 5 mL (0.4 mg) by rapid intravenous injection, followed immediately by saline flush and radiopharmaceutical.

PENTACEL

The FDA has given approval to Sanofi Pasteur Inc. (Swiftwater, PA) to market Pentacel (diphtheria and tetanus toxoids and acellular pertussis adsorbed, inactivated poliovirus and *Haemophilus* type b conjugate [tetanus toxoid conjugate] vaccine) for active immunization against diphtheria, tetanus, pertussis, poliomyelitis, and invasive disease due to *Haemophilus influenzae* type b in children aged 6 weeks to 4 years (prior to fifth birthday). Approval was based on several US and Canadian multicenter studies involving more than 5000 children, which evaluated the immunogenicity and safety of Pentacel and separately administered or single-entity vaccine formulations of DAPTACEL (diphtheria and tetanus toxoids and acellular pertussis vaccine adsorbed), IPOL (poliovirus vaccine inactivated), and Act-HIB (*Haemophilus* b conjugate vaccine [tetanus toxoid conjugate]) vaccines. The most common adverse effects associated with Pentacel were tenderness at the injection site, fussiness/irritability, inconsolable crying, and decreased activity/lethargy. Pentacel is approved for administration as a 4-dose series at age 2, 3, 6, and 15 to 18 months. The first dose may be given as early as age 6 weeks. Four doses of Pentacel vaccine constitute a primary immunization course against pertussis. Three doses of Pentacel vaccine constitute a primary immunization course against diphtheria, tetanus, *H. influenzae* type b invasive disease, and poliomyelitis, and the fourth dose constitutes a booster vaccination against these diseases.

Compiled from press reports and pharmaceutical company press releases. For more information, contact Farrawh Charles, Hospital Physician, *125 Strafford Avenue, Suite 220, Wayne, PA 19087-3391.*