First recombinant flu vaccine approved

FDA on January 16 approved the licensing of Flublok, the nation’s first trivalent seasonal influenza vaccine that contains recombinant viral proteins instead of antigens derived from live virus.

Limited amounts of Flublok will be available during the current flu season, according to Meriden, Connecticut-based Protein Sciences Corporation.

Flublok is indicated for use in adults 18–49 years of age and is administered as a single, 0.5-mL dose, according to the product’s labeling.

Each dose of the vaccine contains 45 μg of purified recombinant hemagglutinin corresponding to the hemagglutinin antigens from each of the influenza virus strains selected for the flu season’s trivalent vaccines.

The proteins in Flublok are derived from a recombinant baculovirus vector and expressed in a continuous insect cell line.

The vaccine will be supplied in cartons of 10 single-dose vials for intramuscular injection. The vials should be refrigerated and protected from light. If freezing occurs, the vaccine should be discarded.

According to FDA, Flublok must be used within 16 weeks after its production. The agency urged health care providers to carefully check the expiration date before administering the vaccine.

In clinical trials, the most commonly reported adverse events associated with Flublok were injection-site reactions.

Flublok is the second FDA-approved cell-based vaccine for protection against seasonal influenza. Flucelvax, by Novartis Vaccines, was licensed in November. Flucelvax is derived from live virus grown in a canine cell line and is not a recombinant vaccine.

Efficacy data for Flublok came from a placebo-controlled clinical trial involving 4648 patients that was conducted during the 2007–08 flu season.

Flublok’s overall efficacy during the study was 44% against all strains of circulating viruses.

According to the labeling, the efficacy of Flublok against the three strains used in the vaccine could not be determined because 96% of the viruses isolated during the study did not match the vaccine strains.

The Centers for Disease Control and Prevention reported that during the 2007–08 flu season, 66% of influenza type A H1N1 viruses characterized by the agency matched the vaccine strain, as did 23% of influenza type A H3N2 viruses and 2% of influenza type B viruses.

—Kate Traynor

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New drugs and dosage forms

Alogliptin tablets (Nesina, Takeda Pharmaceuticals): The dipeptidyl peptidase-4 inhibitor is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. The product has a medication guide.

Alogliptin and metformin hydrochloride tablets (Kazano, Takeda Pharmaceuticals): The combination product is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. The product has a medication guide.

Alogliptin and pioglitazone tablets (Osen, Takeda Pharmaceuticals): The combination product is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. The product has a medication guide.

Aspirin capsules (no brand name, PLx Pharma): The nonprescription product, containing an aspirin-phosphatidylcholine complex, is indicated for the temporary relief of minor aches and pains associated with a cold, headache, backache, toothache, and premenstrual or menstrual cramps; temporary relief of minor pain of backache, toothache, and pains associated with a cold, headache, and exercise to improve glycemic control in adults with type 2 diabetes mellitus. The product has a medication guide.

Budesonide extended-release tablets (Uceris, Santarus): The glucocorticosteroid is indicated for the induction of remission in patients with active mild-to-moderate ulcerative colitis.

Levonorgestrel-releasing intrauterine system (Skyla, Bayer HealthCare Pharmaceuticals): The progestin-containing intrauterine system is indicated for the prevention of pregnancy for up to three years.

Mipomersen sodium injection (Kynamro, Genzyme Corporation): The antisense oligonucleotide is indicated as an adjunct to lipid-lowering drugs and diet in patients with homozygous familial hypercholesterolemia. The product has a risk evaluation and mitigation strategy and medication guide.

Pooled human plasma solution (Octaplas, Octapharma USA): The blood product is indicated for the replacement of multiple coagulation factors in patients with acquired deficiencies due to liver disease or who are undergoing cardiac surgery or liver transplantation and for plasma exchange in patients with thrombotic thrombocytopenic purpura.

Sodium sulfate, potassium sulfate, and magnesium sulfate oral solution and PEG-3350, sodium chloride, sodium bicarbonate, and potassium chloride for oral solution (Suclear, Braintree Laboratories): The two-container combination of osmotic laxatives is indicated for cleansing the colon and expressed in a continuous insect cell line.

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