

## FDA approves kallikrein inhibitor to treat hereditary angioedema

**D**yax Corp. on December 1 announced that FDA approved the marketing of the company's ecallantide injection, or Kalbitor, for the treatment of acute attacks of hereditary angioedema in patients age 16 years or older.

Ecallantide, the company said, binds to plasma kallikrein and blocks its binding site, resulting in less production of bradykinin, a vasodilator.

According to the United States Hereditary Angioedema Association, most physicians and researchers have decided that bradykinin is the primary mediator of hereditary angioedema attacks, which can be fatal.

The FDA-approved labeling for ecallantide states that the dose to treat an acute attack is 30 mg, given as three 10-mg s.c. injections. If the attack persists, a second 30-mg dose may be given within 24 hours.

A boxed warning in the labeling states that the drug should be administered only by a health care professional who has medical support to manage anaphylaxis and hereditary angioedema.

In the clinical studies of ecallantide for the treatment of hereditary angioedema, 2.7% of the 187 patients who received the drug by s.c. injection had an anaphylactic reaction within an hour, according to the labeling's section on warnings and precautions. Symptoms included chest discomfort, pharyngeal edema, wheezing, and hypotension. Some 7.4% of the 68 patients who received the drug by i.v. injection had an anaphylactic reaction.

Dyax said the company and FDA jointly established a risk evaluation and

mitigation strategy to communicate the risk of anaphylaxis from ecallantide therapy and the importance of distinguishing a hypersensitivity reaction from the symptoms of a hereditary angioedema attack.

The medication guide for the drug tells patients that the symptoms of a serious allergic, or hypersensitivity, reaction include wheezing, shortness of breath, cough, chest tightness, dizziness, faintness, fast or weak heartbeat, nervousness, reddening of the face, itching, hives, swelling of the throat or tongue, throat tightness, hoarse voice, difficulty swallowing, runny nose, and sneezing. The guide also states that the symptoms of a serious allergic reaction to ecallantide can be similar to the symptoms of a hereditary angioedema attack.

During the two placebo-controlled studies of ecallantide 30 mg by s.c. injection, the most frequent adverse events among patients who received the drug were headache, nausea, diarrhea, fever, injection-site reaction, and inflammation of the nasopharynx.

The company did not announce when it will make its new product available.

An operator at Kalbitor Access, which is handling inquiries from patients and health care providers, said shipments of the drug will start in early 2010.

Subsidiaries of AmerisourceBergen Corporation will serve as the "exclusive specialty pharmacy" and "exclusive wholesale distributor" for Kalbitor, according to a document that Dyax filed with the government.

The drug product will be supplied in cartons containing three 10-mg/mL single-use vials. Each vial contains 10 mg of the drug and should be kept at 2–8 °C.

—Cheryl A. Thompson

DOI 10.2146/news100005

## New drugs and dosage forms

**Clonidine** extended-release suspension and tablets (Clonidine ER Suspension and Clonidine ER Tablets; Tris Pharma): The products, intended for once-daily oral administration, are indicated for the treatment of hypertension.

**Ketoprofen** oral soluble film (Nexcede, Novartis): The product is indicated for the temporary relief of minor aches and pains due to headache, toothache, backache, menstrual cramps, muscular aches, arthritis, and the common cold and for the temporary relief of fever.

**Omeprazole and sodium bicarbonate** capsules (Zegerid OTC, Santarus): A nonprescription strength, containing 20 mg of omeprazole and 1100 mg of sodium bicarbonate, for the treatment of heartburn occurring two or more days per week was added to the product line.

**Olanzapine** extended-release injectable suspension (Zyprexa Relprevv, Eli Lilly): A long-acting injectable formulation for the treatment of schizophrenia was added to the product line.

**Von Willebrand factor and coagulation factor VIII complex** powder for solution for i.v. use (Wilate, Octapharma): The plasma-derived product is indicated for the treatment of spontaneous and trauma-induced bleeding episodes in patients with severe von Willebrand disease and patients with mild or moderate disease in whom the use of desmopressin is known or suspected to be ineffective or contraindicated.

Copyright of American Journal of Health-System Pharmacy is the property of American Society of Health System Pharmacists and its content may not be copied or emailed to multiple sites or posted to a listserv without the copyright holder's express written permission. However, users may print, download, or email articles for individual use.