NEWS FROM THE FDA

Nonsurgical Dupuytren's Tx Gets Nod

A biologic drug that breaks down collagen and is injected directly into the cords involved in Dupuytren's contracture of the hand has been approved by the Food and Drug Administration, providing the first nonsurgical treatment for this condition, the agency announced.

The product, collagenase clostridium histolyticum, was approved specifically for adults with Dupuytren's contracture with a palpable cord, and will be marketed as Xiaflex by Auxilium Pharmaceuticals Inc. It is injected directly into the palpable Dupuytren's cord, followed by a finger extension procedure 24 hours later to help disrupt the cord in cases of persistent contracture. Xiaflex will be launched in late March, according to the company.

The company plans to market the product to physicians experienced in hand injection procedures, and will provide the product only to those who attest they have completed a training program. The FDA is also requiring a risk evaluation and mitigation strategy for the product, which includes a communication plan that will provide information for clinicians, according to Auxilium.

The most concerning potential risk is tendon rupture, which was not common. In about 1,000 cases treated, there were three tendon ruptures within a week of treatment, the company said.

The most common adverse reactions were fluid buildup, swelling, bleeding, and pain in the injected area. No serious allergic reactions have been reported.

Statin Okayed for Primary Prevention

In addition to its other approved indications, rosuvastatin (Crestor, AstraZeneca) can now be used for primary prevention in reducing the risk of MI, stroke, and arterial revascularization procedures.

The new indication is for people "without clinically evident coronary heart disease, but with an increased risk of cardiovascular disease" based on multiple risk factors.

In 2003, the FDA originally approved rosuvastatin to reduce elevated levels of total cholesterol, LDL cholesterol, apolipoprotein B, and triglycerides, and to increase HDL cholesterol in patients with primary hyperlipidemia and mixed dyslipidemia.

Approval of the new indication was based on the results of the JUPITER (Justification for the Use of Statins in Primary Prevention: An Intervention Trial Evaluating Rosuvastatin) study, which compared the rate of cardiovascular events in 17,802 men and women aged 50 years and older.

Over a mean of 1.9 years, the primary composite end point of time to first occurrence of a major cardiovascular event was reduced by 44% in the treated group, compared with those on placebo, a highly significant difference that represented an absolute risk reduction of 1.2 % (N. Engl. J. Med. 2008;359: 2195-207).

The study was stopped early because of the positive results.

Warning Added for Didanosine

Cases of noncirrhotic portal hypertension have been reported in adults and children with HIV who are taking the antiretroviral drug didanosine, including some fatal cases, according to the FDA.

Over an 18-year period, the FDA's Adverse Event Reporting System received 42 reports of noncirrhotic portal hypertension in patients aged 10-66 years taking didanosine (Videx, Bristol-Myers Squibb) or the delayed-release formulation (Videx EC). These cases included four patients who died from bleeding or liver failure.

The FDA has revised the warnings and precautions section of the drug's label "because of the potential severity of portal hypertension, including death from hemorrhaging esophageal varices," according to the statement.

"The clinical benefits of didanosine for certain patients with HIV continue to outweigh its potential risks," but the decision to prescribe the drug "must be made on an individual basis between the treating physician and the patient," the FDA said.

The drug's label already included a boxed warning about the risk of lactic acidosis and hepatomegaly with steatosis. In addition, the combination of didanosine with other antiretroviral agents, and hydroxyurea or ribavirin, has been associated with hepatotoxicity, according to the FDA.

—From staff reports