Pharm: Repro drugs

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FDA Approves Drug to Curb Risk for Preterm Birth

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February 4, 2011 (***UPDATED February 10, 2011***) — The US Food and Drug Administration today approved hydroxyprogesterone caproate injection (*Makena*) to reduce the risk for preterm delivery before 37 weeks of pregnancy in women with singleton pregnancy and a history of at least 1 spontaneous preterm birth.

The drug, a synthetic form of the hormone progesterone, is not intended for use in women with a multiple pregnancy or other risk factors for preterm birth.

"Preterm birth is a significant public health issue in the United States," Sandra Kweder, MD, deputy director of the Office of New Drugs in the FDA's Center for Drug Evaluation and Research, said in a statement. "This is the first drug approved by the FDA that is indicated to specifically reduce this risk."

Alan R. Fleischman, MD, medical director of the March of Dimes, said: "The approval of this new treatment is a breakthrough in our fight against preterm birth. Although the United States has made great progress in caring for premature babies, there is no greater advance than allowing a baby to mature in a mother's womb."

Accelerated Approval

The FDA approved Makena under the agency's accelerated approval regulations that allow promising drugs to be approved based on a surrogate endpoint benefit (in this case, reducing the risk for preterm delivery) that is reasonably likely to predict a clinical benefit. Under these regulations, the manufacturer will be required to conduct additional studies to demonstrate that the drug does, in fact, have a clinical benefit, the agency notes.

The FDA reviewed data on the safety and effectiveness of Makena in a multicenter randomized double-blind study sponsored by the National Institutes of Health. The study involved 463 women who were pregnant with a single fetus and had a history of a prior spontaneous preterm birth.

According to the FDA, of the women treated with Makena, 37% delivered early (before 37 weeks) compared with 55% of women in the control group.

Makena is administered once a week by intramuscular injection. Treatment should begin at 16 weeks — and no later than at 21 weeks — of pregnancy and continue until 37 completed weeks or delivery.

The most common adverse effects reported with Makena in trials to date include pain, swelling, or itching at the injection site; hives; nausea; and diarrhea. Serious adverse reactions were rare; there was a single report each of pulmonary embolism and an infection at the injection site.

Makena will be manufactured by Baxter Pharmaceuticals for KV Pharmaceutical/Ther-Rx Corporation. Ther-Rx Corporation will market the drug.

According to Ther-Rx Corporation, Makena will be available for prescribing in early March. Makena is a specialty injectable and will not be available in retail pharmacies. Instead, Makena will be available through a network of specialty pharmacies and distributors that specialize in distributing specialty injectables and will be express mailed directly from the pharmacy/distributor to the healthcare provider or to the patient, depending on the preferred location for administration of weekly injections.

Warnings and Precautions

Makena should be discontinued if thrombosis or thromboembolism occurs during treatment. If allergic reactions occur,

the clinician should consider discontinuing Makena.

Because Makena may decrease glucose tolerance, prediabetic and diabetic women receiving Makena should be monitored. Women with conditions that could be adversely affected by fluid retention, including preeclampsia, epilepsy, or cardiac or renal dysfunction, should be monitored while taking Makena, as this drug may cause fluid retention. Monitoring is also indicated for women with a history of clinical depression, and Makena should be discontinued if there is evidence of recurrent depression.

More information on Makena is available on the FDA Web site.

Laurie Barclay, MD, contributed to this news article.