Celebrex Approved for Juvenile Rheumatoid Arthritis

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By Mark Bloom [3]

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ROCKVILLE, Md., Dec. 15 -- Acting with uncommon speed, the FDA today approved Celebrex (celecoxib) for the pain of juvenile rheumatoid arthritis -- less than a month after an advisory committee recommended overwhelmingly that it do so.

The panel had voted 15 to one that the benefits of the Cox-2 inhibitor outweighed its risks in rheumatoid arthritis patients ages two and older. In the approval, the agency noted that Celebrex has not been studied in patients under the age of two years, in patients who weigh less than 22 pounds, or in patients showing signs of having systemic-onset JRA -- a more serious type of the disease associated with high fever and rash. The FDA said Celebrex should be used only with caution in patients with systemic-onset JRA due to the risk for serious adverse reactions, including abnormal clotting tests, which can be associated with disseminated intravascular coagulation.

"Safety and efficacy were not studied beyond six months, and experience with adults suggests the possibility of longer term cardiovascular problems," said the FDA. The agency said Pfizer, the maker of Celebrex, agreed to conduct two phase IV post-marketing studies -- a short-term controlled trial to evaluate high blood pressure, and a several-year registry study to further evaluate long-term safety issues, including renal toxicity, high blood pressure, and cardiovascular events.

"JRA is often a devastating disease," said Steven Galson, M.D., director of the FDA's Center for Drug Evaluation and Research. "While there are other medicines approved for the treatment of this disorder, for some children they may have limited effectiveness or cause intolerable side effects. Celebrex will be a needed additional treatment option for children."

A company study indicted that Celebrex is about as effective as naproxen in treating children, and both drugs had similar side effects.

Celebrex is the only Cox-2 inhibitor currently on the market. Merck's blockbuster Cox-2 drug, Vioxx (rofecoxib), was voluntarily taken off the market in September 2004 when clinical trials linked the drug to increased risk of cardiovascular events.

Bextra (valdecoxib), a Cox-2 drug marketed by Pfizer, was withdrawn in the first quarter of 2005 when it, too, was linked to increased risk of cardiovascular events.

The FDA cited a 24-week study of Celebrex involving 242 patients between the ages of two and 17 years that demonstrated its effectiveness in treating JRA. The most commonly reported side effects were cough, cold, upper respiratory tract infection, abdominal pain, headache, fever, nausea, diarrhea, and vomiting.

Celebrex, was originally approved in 1998 for the relief of signs and symptoms of rheumatoid arthritis and osteoarthritis in adults.

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