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Top-Line Data Show Celecoxib Met Primary Objective In Clinical Trial To Evaluate The Effects On Blood Pressure In Pediatric Patients With Juvenile Idiopathic Arthritis

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NEW YORK--(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) today announced top-line results for a Phase 4 clinical trial in which the primary objective was to measure blood pressure (hypertension) among pediatric patients with Juvenile Idiopathic Arthritis (JIA; also known as Juvenile Rheumatoid Arthritis or JRA) taking celecoxib (Celebrex) capsules or naproxen.

The results demonstrated there was virtually no difference in changes to systolic blood pressure, the primary endpoint, and diastolic blood pressure, the secondary endpoint, between the celecoxib and naproxen treatment groups. The safety profile was similar in both groups.

It is well-known that both selective and nonselective nonsteroidal anti-inflammatory drugs (NSAIDs) may lead to new-onset hypertension or worsening of underlying hypertension in adults, but little is known about the impact of NSAID therapy on blood pressure in children.

The purpose of the study was to determine the effect of six weeks of treatment with Celebrex or naproxen on blood pressure in patients aged two to 17 years with JRA. Since 2006, Celebrex has been approved by the U.S. Food and Drug Administration for the relief of the signs and symptoms of JRA in pediatric patients two years of age and older.

Juvenile Idiopathic Arthritis is a chronic and long-term disease that results in joint pain and swelling. It is the most common form of arthritis in children. According to the Centers for Disease Control and Prevention, estimates of prevalence range from 11,700 – 69,000 children under age 18 in the U.S.

About the Study

The 6-week study was a randomized, double-blind, multicenter, active-controlled trial conducted to evaluate the effects of Celecoxib (50 mg or 100 mg twice daily, determined by patient's weight) or naproxen (7.5 mg/kg twice daily, maximum dose of 500 mg twice daily) on blood pressure in pediatric patients with JIA.

A total of 201 patients were included in the study from 10 different countries. All patients were diagnosed with JIA, including patients with disease types where few joints are affected (oligoarticular JIA) and where many joints are affected (polyarticular JIA). Children with systemic onset disease – a form characterized by high fevers and rash – were included only if they still had arthritis, but no longer had systemic features like fever.

The primary endpoint analysis for the change from baseline to week 6 in systolic blood pressure (SBP) showed a 90% confidence that the true difference of the change from baseline in SBP between the celecoxib and naproxen groups was between -0.56 and 2.76, with 0 (no difference) being a possibility. Similar results were observed for the diastolic blood pressure where the 95% confidence interval was (-1.69, 1.33).

The adverse event profile was similar for the two treatment groups. The only Serious Adverse Event occurred in the naproxen group and was not treatment related. The most common adverse events reported in both treatment groups were headache, nausea and joint aches. For patients receiving celecoxib, only headache occurred in more than 5% of patients. For patients receiving naproxen, nausea and joint aches occurred in more than 5% of patients. These adverse events are consistent with what is already known about these medicines.

The study was conducted as part of a post-marketing commitment to the U.S. Food and Drug Administration for Celebrex. Results from this study will be submitted for presentation at upcoming scientific congresses and for publication in a peer-reviewed medical journal.

About CELEBREX

CELEBREX is one of most studied drugs in arthritis treatment and is approved in 134 countries. CELEBREX is approved in the U.S. for the relief of the signs and symptoms of osteoarthritis, rheumatoid arthritis in adults, juvenile rheumatoid arthritis in patients two years and older, ankylosing spondylitis, for the management of acute pain in adults and for the treatment of primary dysmenorrhea (menstrual cramps).

Cardiovascular Risk

CELEBREX may cause an increased risk of serious cardiovascular (CV) thrombotic events, myocardial infarction, and stroke, which can be fatal. All NSAIDs may have a similar risk. This risk may increase with duration of use. Patients with CV disease or risk factors for CV disease may be at greater risk.

CELEBREX is contraindicated for the treatment of perioperative pain in coronary artery bypass graft (CABG) surgery.

Gastrointestinal Risk

NSAIDs, including CELEBREX, cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal (GI) events.

NSAIDs, including CELEBREX, should be used with caution in pediatric patients with systemic onset JRA, due to the risk of disseminated intravascular coagulation.

For Celebrex prescribing information in the United States visit www.celebrex.com.

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