New CELEBREX® (celecoxib) Study Using Novel Endpoint, Published By The Lancet, Contributes to Knowledge Of NSAID-Associated Gastrointestinal Adverse Events

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Head-to-Head CONDOR Study Investigating CELEBREX (celecoxib) Capsules Compared to Diclofenac Plus Omeprazole in More Than 4,400 Arthritis Patients

"CONDOR results expand the knowledge of NSAID-associated GI adverse events relevant to the management of arthritis pain,"

(BUSINESS WIRE)--Pfizer Inc. (NYSE:PFE) announced that new data, published today by The Lancet, show that arthritis patients at increased gastrointestinal (GI) risk taking CELEBREX demonstrated a significantly lower incidence of the novel composite endpoint of clinically significant upper and lower GI events compared with patients taking diclofenac plus omeprazole. This difference was driven by clinically significant decreases in hemoglobin and/or hematocrit of defined or presumed GI origin.1 CONDOR (Celecoxib vs. Omeprazole aNd Diclofenac for at-risk Osteoarthritis and Rheumatoid arthritis patients) is the first large-scale study to use this composite GI endpoint.

Due to their anti-inflammatory and analgesic properties, NSAIDs are among the most widely prescribed arthritis medicines worldwide. However, NSAID-associated GI adverse events, such as ulcer, perforation and hemorrhage, remain a major clinical problem, significantly impacting hospital admissions, mortality and health care expenditure.2

"Physicians are aware of the potential for damage to the upper GI tract with NSAID use, however a growing body of evidence suggests that NSAID-induced GI toxicity also extends to the lower GI tract," said Dr. Francis Chan, lead investigator and professor of medicine and therapeutics, chief of gastroenterology and hepatology at the Chinese University of Hong Kong.

The CONDOR trial addressed the need for a more comprehensive evaluation of NSAID-associated GI adverse events by assessing both the upper and lower GI tract. CONDOR is the first large- scale (conducted in 32 countries, excluding the United States, with more than 4,400 patients), double-blind, randomized study using this composite endpoint to assess two common treatment strategies for arthritis patients at increased GI risk - CELEBREX alone, or treatment with diclofenac plus omeprazole.3

Designed by gastroenterology experts, the study endpoint is a composite of upper and lower GI events including clinically significant decreases in hemoglobin (the protein that transports oxygen in red blood cells) and/or hematocrit (the proportion of blood volume occupied by red blood cells).4

Commenting on the endpoint, Dr. Chan said, "Hemoglobin was included in the primary endpoint of CONDOR because a clinically significant drop in hemoglobin can indicate blood loss from the upper or lower GI tract and have important clinical implications, such as requiring early discontinuation of treatment and the need for further clinical investigation."

An independent data safety and monitoring committee oversaw overall safety throughout the CONDOR trial. The most common treatment-emergent adverse events in the CELEBREX treatment group were dyspepsia, upper abdominal pain, diarrhea, hypertension and headache. Cardiovascular (CV) adverse events were also included in the safety review and reported by Chan et al. Since CONDOR was not designed or powered to evaluate CV safety, the authors advised that these data should be interpreted with caution.

"CONDOR results expand the knowledge of NSAID-associated GI adverse events relevant to the management of arthritis pain," said Dr. Briggs Morrison, senior vice president, clinical development, primary care business unit, Pfizer. "Improving patient health is Pfizer's top priority and we intend to continue to sponsor important outcomes studies like CONDOR, which can give health care providers valuable information when making treatment decisions."

Topline results from the CONDOR study were first presented at Digestive Disease Week® 2010 (DDW®) in New Orleans on May 2, 2010. Additional data from CONDOR are being presented this week at the 2010 Annual European Congress of Rheumatology (EULAR) in Rome.

About CELEBREX

CELEBREX is one of most studied drugs in arthritis treatment and is currently approved in 120 countries. CELEBREX is currently 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, for the treatment of primary dysmenorrhea (menstrual cramps), and to reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis, as adjunct to usual care.

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.

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1Chan, F., Lanas, A., Scheiman, J., Berger, M.F., Nguyen, H., Goldstein, J.L. Celecoxib versus omeprazole and diclofenac in patients with osteoarthritis and rheumatoid arthritis (CONDOR): a randomised trial. The Lancet. 2010. Advance online publication. DOI:10.1016/S0140-6736(10)60839-2

2Chan, F., Cryer. B., Goldstein, J., et al. A novel composite endpoint to evaluate the gastrointestinal (GI) effects of nonsteroidal antiinflammatory drugs through the entire GI tract. The J of Rheum. 2009; 36:12 1-8.

3Chan, F., Lanas, A., Scheiman, J., Berger, M.F., Nguyen, H., Goldstein, J.L. Celecoxib versus omeprazole and diclofenac in patients with osteoarthritis and rheumatoid arthritis (CONDOR): a randomised trial. The Lancet. 2010. Advance online publication. DOI:10.1016/S0140-6736(10)60839-2

4Chan, F., Cryer. B., Goldstein, J., et al. A novel composite endpoint to evaluate the gastrointestinal (GI) effects of nonsteroidal antiinflammatory drugs through the entire GI tract. The J of Rheum. 2009; 36:12 1-8.

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