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Landmark Study Demonstrates Pfizer's Celebrex (Celecoxib)Has Similar Cardiovascular Risk As Compared To Prescription Doses Of Ibuprofen and Naproxen

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Patients Taking Pfizer's Celebrex (celecoxib) Experienced Fewer Gastrointestinal Events As Compared to Prescription Doses of Ibuprofen and Naproxen Study Findings Dispel Long Standing Perceptions of Excess Cardiovascular Risk Associated With Long Term Use Of Celebrex Results of PRECISION Study Presented at the Annual Meeting of the American Heart Association in New Orleans Provide Important Information for the Treatment of Arthritis

Results of the landmark Prospective Randomized Evaluation of CelecoxibIntegrated Safety vs. Ibuprofen Or N aproxen (PRECISION) demonstrated similar rates of cardiovascular risk in patients treated with prescription doses of celecoxib, ibuprofen and naproxen who had a clinical diagnosis of osteoarthritis (OA) or rheumatoid arthritis (RA), were at high risk for cardiovascular disease, and required daily treatment with non-steroidal anti-inflammatory drugs (NSAIDs) to control symptoms of arthritis. In addition, patients treated with celecoxib experienced significantly fewer gastrointestinal events as compared with those receiving prescription doses of ibuprofen or naproxen. The PRECISION trial helps to refute the assumption held by many physicians that naproxen treatment results in better cardiovascular outcomes as compared to other NSAIDs, including celecoxib. It is important to note that given the trial's design – prescription doses and chronic use in patients with cardiovascular risk factors – no inferences are possible regarding the safety of intermittent use of low-dose, over-the-counter NSAIDs.

The results of the PRECISION study were presented today at the annual meeting of the American Heart Association in New Orleans by Dr. Steve Nissen, chairman of cardiovascular medicine at the Cleveland Clinic and principal investigator of the PRECISION trial. In addition, the results were published today in the *New England Journal of Medicine*.

PRECISION was a prospective, long-term non-inferiority trial of 24,081 patients designed to assess the cardiovascular safety of Celebrex (celecoxib) versus prescription strength doses of ibuprofen and naproxen in patients with chronic pain from OA or RA. The trial, designed in 2005 based on discussions with the U.S. Food and Drug Administration, was funded by Pfizer but directed independently by the Cleveland Clinic and governed by an executive committee composed of cardiology, gastroenterology, and rheumatology specialists.

"We are pleased with the results of this landmark study. Questions about the cardiovascular safety of prescription NSAIDs have persisted since the withdrawal of Vioxx (rofecoxib) from the market in 2004," said Ian Read, chairman and chief executive officer of Pfizer Inc. "The study demonstrated that patients treated with prescription doses of celecoxib, ibuprofen or naproxen had similar rates of cardiovascular events and dispels the long held perception of excess cardiovascular risk associated with long term use of Celebrex."

The primary objective of PRECISION was to assess the effects of celecoxib (100-200 mg twice daily) compared to prescription strength doses of ibuprofen (600-800 mg three times a day) or naproxen (375-500mg twice a day) on the first occurrence of cardiovascular (CV) death, non-fatal myocardial infarction (MI) or non-fatal stroke in subjects with OA or RA and who have established cardiovascular disease or risk factors for cardiovascular disease. Pre-specified secondary objectives including assessments of additional cardiovascular endpoints, significant gastrointestinal events, renal events and arthritis pain improvement will be published at a later date. All subjects were provided with esomeprazole, a proton pump inhibitor, to be taken once daily as a gastro-protective agent. Patients also had the option of continuing low-dose aspirin for additional cardio-protective effects regardless of their CV risk.

Top-Line Results:

The final PRECISION trial results provide statistically strong evidence that cardiovascular risk with approved doses of celecoxib is not greater than that of prescription doses of ibuprofen and naproxen. The study showed that patients with chronic arthritic conditions and CV risk factors taking celecoxib experienced numerically fewer cardiovascular events as compared to patients receiving prescription strength doses of ibuprofen and naproxen. More specifically, a primary endpoint occurred in 2.3 percent of patients receiving celecoxib as compared to 2.5 percent for patients receiving naproxen and 2.7 percent for patients receiving ibuprofen.

In addition, regarding secondary analyses, significantly fewer GI events occurred among patients treated with celecoxib as compared with those receiving prescription doses of either ibuprofen or naproxen. More specifically, serious gastrointestinal events occurred in 1.1 percent of patients receiving celecoxib as compared to 1.5 percent for patients receiving prescription doses of naproxen and 1.6 percent for patients receiving prescription doses of ibuprofen. The gastrointestinal safety findings were observed despite providing all patients enrolled in the study with a proton pump inhibitor to reduce stomach acids. In addition, the secondary endpoint involving renal events occurred with a lower frequency in patients treated with celecoxib as compared to prescription doses of ibuprofen.

“NSAIDs are an important treatment option for millions of arthritis patients around the globe. The results of the PRECISION study underscore the cardiovascular and gastrointestinal safety of Celebrex for the long-term treatment of chronic arthritic conditions,” said Freda Lewis-Hall, M.D., chief medical officer and executive vice president of Pfizer Inc.

About Osteoarthritis and Rheumatoid Arthritis:

Arthritis is a chronic, progressive medical condition characterized by inflammation, swelling and pain in and around the joints. The two most common forms of arthritic disorders are OA and RA. According to the Centers for Disease Control and Prevention, arthritic conditions affect more than 50 million adults in the US and are a leading cause of disability. Today, more than 80 percent of OA patients have limited mobility and 25 percent of patients are unable to perform daily tasks.

NSAIDs:

Non-steroidal anti-inflammatory Drugs (NSAIDS) are among the most widely prescribed medicines in the world due to their effective anti-inflammatory and pain relieving properties which enable patients to function more normally. However, there have been concerns over the chronic, long-term use of prescription NSAIDs because of potentially serious gastrointestinal (GI) complications such as major and minor bleeding, ulcers, and perforations. GI complications resulting from prescription NSAID use are among the most common drug side effects in the United States due to the use of these medications for chronic pain management in conditions such as OA and RA.

Important Celebrex (celecoxib) Safety Information

All prescription NSAIDs, like CELEBREX, ibuprofen, naproxen, and meloxicam, increase the risk of heart attack or stroke that can lead to death. This may happen early in treatment and may increase with increasing doses of NSAIDs and with longer use of NSAIDs.

CELEBREX should never be used right before or after a heart surgery called “coronary artery bypass graft” (CABG).

Avoid taking NSAIDs after a recent heart attack, unless your healthcare provider tells you to do so. You may have an increased risk of another heart attack if you take NSAIDs after a recent heart attack.

NSAID medications, like CELEBREX, cause an increased risk of bleeding, ulcers, and tears (perforation) of the esophagus, stomach, and intestines, at any time during treatment, which can occur without warning and may cause death.

Prescription CELEBREX should be used exactly as prescribed at the lowest dose possible and for the shortest time needed.

Do not take CELEBREX if you have had an asthma attack, hives, or other allergic reactions to aspirin, any other NSAID medicine, or certain drugs called sulfonamides.

Before you take CELEBREX, inform your healthcare provider of any medical conditions you may have and of all of the medications you take, including prescription or over-the-counter medicines, vitamins, or herbal supplements as they may increase the risk for serious side effects.

Tell your doctor about all of your medical conditions, including if you:

- have liver or kidney problems
- have a history of ulcers or bleeding in the stomach or intestines
- have high blood pressure or heart failure
- have asthma
- are pregnant or plan to become pregnant—CELEBREX, and other NSAIDs should not be taken in late pregnancy (after 29 weeks)
- are breastfeeding or plan to breast feed

CELEBREX can cause serious side effects, including:

- new or worse high blood pressure
- heart failure
- liver problems including liver failure
- kidney problems including kidney failure
- low red blood cells (anemia)
- life-threatening allergic reactions
- life-threatening skin reactions

Other side effects of NSAIDs, including CELEBREX are stomach pain, constipation, diarrhea, indigestion, heartburn, nausea, vomiting, and dizziness.

Get emergency help right away if you have any of the following symptoms: shortness of breath or trouble breathing, chest pain, weakness in one part or side of your body, slurred speech, swelling of the face or throat. Discontinue CELEBREX at first sign of skin rash, or blisters with fever.

Click here for full prescribing information, including BOXED WARNING and Medication Guide.

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DISCLOSURE NOTICE: The information contained in this release is as of November 13, 2016. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information regarding CELEBREX (celecoxib) and the results of the PRECISION study, including their potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, uncertainties regarding the commercial impact of the results of the PRECISION study; the risk that clinical trial data are subject to differing interpretations, including by regulatory authorities; the uncertainties inherent in research and development; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2015 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results," as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

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