

Pfizer to Present Data on New Approaches to Pain and Inflammation Treatment at ACR Meeting

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Results from Clinical Trials Show Promise for Innovative Therapies in Rheumatoid Arthritis and Osteoarthritis Pain and Fibromyalgia

[\(BUSINESS WIRE\)](#)--Pfizer will present data on three investigational compounds that represent potential new mechanisms for targeting pain and inflammation. These data will highlight tanezumab, a molecule designed to target nerve growth factor, a key pain mediator; CP-690,550, a JAK-inhibitor that suppresses immune-related inflammatory response; and esreboxetine, a highly-selective norepinephrine reuptake inhibitor which plays a role in controlling the activity of this important neurotransmitter. These data will be presented at the 2008 American College of Rheumatology Scientific Meeting in San Francisco, California.

“Pfizer has an established track record of bringing innovative therapies to patients suffering with pain and inflammation,” said Martin Mackay, Ph.D., president, Pfizer Global Research and Development. “Data to be presented at ACR confirm our clinical approaches in developing these three compounds – CP-690,550, esreboxetine and tanezumab – as potential new medicines to provide relief from these serious medical conditions.”

Rheumatoid Arthritis

Data is being presented from several clinical trials studying CP-690,550, an oral medication that inhibits the Janus Kinase enzyme (JAK). This enzyme plays a major role in controlling the activation and proliferation of white blood cells, key elements of the immune system, which play a major role in rheumatoid arthritis (RA). CP-690,550 has shown encouraging results for the treatment of rheumatoid arthritis at doses that don't appear to be associated with excessive immune suppression.

Investigators will present interim results from a late-breaking Phase 2B study evaluating the activity of CP-690,550 in combination with methotrexate, the most commonly-used RA treatment. Approximately 60 percent of patients on doses at or above 3 mg of CP-690,550 responded to treatment as compared to 37.7 percent on placebo. These data confirm and extend the promising data seen in an earlier phase 2A study to this longer, 12 week study, and to patients who are already taking methotrexate to treat their rheumatoid arthritis.

Also being presented is a pharmacokinetic drug interaction study which showed that CP-690,550 and methotrexate can be co-administered without dose adjustment. In addition, preliminary results from an open label extension study will be presented.

In these studies, the most commonly reported adverse events were nausea, headache, dizziness, disorientation, hot flushes, urinary tract infections, diarrhea and liver function tests.

Larger and longer phase 3 studies are expected to start in 2009 to help further define the benefits and risks of CP-690,550 as a potential treatment for rheumatoid arthritis.

According to the Arthritis Foundation, 1.3 million Americans live with rheumatoid arthritis, a type of arthritis that can be severe, debilitating, deforming and even shorten life.

Osteoarthritis Pain

Pfizer continues to research new ways of treating osteoarthritis pain. Two studies to be presented highlight a new compound in development and new data for Celebrex (celecoxib) in the treatment of osteoarthritis pain.

Results from a Phase 2 study exploring the safety and efficacy of tanezumab, a novel biologic designed to block nerve growth factor, show that treatment once every eight weeks may significantly decrease pain in patients suffering from moderate to severe osteoarthritis pain in the knee. In the trial, approximately 75 percent of patients in both the tanezumab 100 and 200 mg/kg treatment groups experienced a 50 percent reduction in knee pain as compared to 26 percent of patients in the placebo group. In the study, the most common adverse events associated with tanezumab include headache, upper respiratory tract infection, paresthesia (abnormal sensations), hypoesthesia (decreased sensations) and arthralgia (joint aches).

Another late-breaking study evaluated continuous use of daily Celebrex treatment over a 22-week period compared to intermittent use of the medicine in preventing spontaneous OA flares. The study showed that continuous use resulted in 42 percent fewer OA flare episodes than the intermittent use. The results from the study also demonstrated that there were no significant differences in overall adverse events between the intermittent and continuous use groups.

According to the Arthritis Foundation, osteoarthritis affects 27 million Americans. Recent data show that one in two Americans are at risk for knee osteoarthritis over their lifetime. Loss of joint function as a result of osteoarthritis is a major cause of work disability.

Fibromyalgia

Pfizer is a pioneer in the study of fibromyalgia, investing many years of research into treatment options for this complex pain condition. In June 2007, Lyrica (pregabalin) CV became the first FDA-approved treatment for the management of fibromyalgia. Data supporting that approval showed Lyrica patients experienced significant reduction in pain as early as week one in some patients.

While widespread pain is the cornerstone of fibromyalgia, the condition is also characterized by other hallmark symptoms such as fatigue and difficulty concentrating.

Data presented at ACR will highlight the results of a phase 2 proof of concept study with esreboxetine, a highly selective norepinephrine reuptake inhibitor in a fibromyalgia population.

Data from this study showed that esreboxetine may be effective in relieving key fibromyalgia symptoms, including pain, function and fatigue and was generally well tolerated. In the study, 43 percent of patients receiving esreboxetine reported their condition was much improved or very much improved as compared to 23 percent of placebo-treated patients.

The most common side effects compared to placebo were constipation, insomnia, dry mouth, headache and nausea. The proportion of patients who discontinued as a result of adverse events was 8.2 percent in the esreboxetine group and 2.3 percent in the placebo treatment group.

Fibromyalgia has been recognized by the professional community for over 30 years as a common, chronic widespread pain condition and is now thought to affect up to six million Americans. Recent evidence suggests a neurological basis to fibromyalgia, as demonstrated by brain scans and altered levels of certain neurotransmitters.

About Pfizer's Investor Briefing at ACR

On Tuesday, October 28 at 6:00 p.m. PCT, Pfizer will host a briefing for analysts and investors to review data presented at the meeting on candidates in Pfizer's pain and inflammation portfolio.

About Celebrex

CELEBREX is indicated for the relief of the signs and symptoms of osteoarthritis, rheumatoid arthritis in adults and ankylosing spondylitis, and for the management of acute pain in adults.

Cardiovascular Risk

All prescription NSAIDS, including 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.

All prescription NSAIDs, including CELEBREX, are contraindicated for the treatment of perioperative pain in coronary artery bypass graft surgery.

Gastrointestinal Risk

All prescription 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 events.

About Lyrica

LYRICA is indicated for the management of Fibromyalgia, neuropathic pain associated with Diabetic Peripheral Neuropathy, Postherpetic Neuralgia, and as adjunctive therapy for adults with Partial Onset Seizures. There have been post-marketing reports of angioedema and hypersensitivity. Treatment with Lyrica may cause dizziness, somnolence, peripheral edema or blurred vision. Other most common adverse events include dry mouth, weight gain, constipation, euphoric mood, balance disorder, increased appetite and thinking abnormally.

For more information on Pfizer's pipeline and marketed medicines, including full prescribing information, please visit www.pfizer.com.

DISCLOSURE NOTICE: The information contained in this release is as of October 25, 2008. Pfizer assumes no obligation to update any forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about the drug candidates CP-690,550, tanezumab and esreboxetine, including their potential benefits, which involve substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; decisions by regulatory authorities regarding whether and when to approve any drug applications that may be filed for any

such drug candidates as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of any such drug candidates; 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, 2007 and in its reports on Form 10-Q and Form 8-K.

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