

MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG**Prexige® study shows significantly less impact on blood pressure than ibuprofen in osteoarthritis patients with controlled hypertension**

- *New data from 741-patient trial show those treated with Prexige experienced significantly smaller impact on blood pressure compared to ibuprofen¹*
- *Many patients with osteoarthritis also have high blood pressure; even small changes in blood pressure can impact cardiovascular risk^{2,3}*
- *Prexige approved in more than 50 countries and currently under review in US for use in osteoarthritis patients*

Basel, June 15, 2007 – Patients with osteoarthritis who also have controlled hypertension experienced a slight decrease in average daily blood pressure when treated with the selective COX-2 inhibitor Prexige® (lumiracoxib) compared to a slight increase in those taking ibuprofen, a commonly-used non-steroidal anti-inflammatory drug (NSAID)¹.

These new results, presented today at the Annual European Congress of Rheumatology (EULAR) in Barcelona, are important because around 40% of patients with osteoarthritis also have high blood pressure (or hypertension)^{4,5}.

Independent research shows that even small elevations in blood pressure can contribute to an increased risk of cardiovascular events^{2,3,6,7,8}. Osteoarthritis is the most common form of arthritis affecting 139 million people worldwide⁹.

“NSAIDs, including some COX-2s, have been associated with raised blood pressure, and this effect may be in part responsible for the increased risk of cardiovascular disease associated with this class of medications,” said Tom MacDonald, Ph.D., Professor of Clinical Pharmacology at the Hypertension Research Centre at Ninewells Hospital & Medical School in Dundee, Scotland. “These data indicate that lumiracoxib may have less impact on blood pressure than the most commonly used NSAID ibuprofen.”

Prexige, which is given to patients as a 100 mg once-daily tablet, is approved for use in certain types of patients with osteoarthritic pain of the knee and hip in more than 50 countries, including the European Union, Canada and Latin America.

In the US, this medicine is under review by the Food and Drug Administration (FDA) for relief of the signs and symptoms of osteoarthritis.

“Evidence from the large-scale TARGET study has shown that Prexige is associated with significantly smaller increases in blood pressure than commonly used NSAIDs,” said James Shannon, MD, Global Head of Development at Novartis Pharma AG. “The new research underlines how important it is for osteoarthritis patients to have a treatment option such as Prexige.”

The study presented at EULAR was a four-week, multicenter, randomized, double-blind, double-dummy, parallel group trial of 787 hypertensive osteoarthritis patients age 50 or older with ambulatory blood pressure of 140/90 mmHg or below, who were being treated with an antihypertensive medicine. A total of 741 patients completed the study, which compared Prexige 100 mg once-daily with ibuprofen 600 mg taken three times daily.

At the end of the study, patients on Prexige showed a decrease in mean ambulatory systolic blood pressure of 2.7 mmHg compared to a 2.2 mmHg increase in patients taking ibuprofen, giving an estimated difference of 5.0 mmHg between the groups ($p < 0.001$). Mean ambulatory diastolic blood pressure decreased by 1.5 mmHg in Prexige patients compared to a 0.5 mmHg increase in those on ibuprofen, an estimated difference of 2.0 mmHg ($p < 0.001$).

Systolic pressure represents the pressure within blood vessels when the heart contracts, while diastolic pressure is measured when the heart is at rest between beats. Both are monitored while the patient is active (or ambulatory), considered to be the most rigorous way of studying blood pressure. They are measured in millimeters of mercury or mmHg.

Results further showed Prexige and ibuprofen had similar efficacy as well as a comparable incidence of adverse events. These were mostly mild and did not indicate treatment-limiting toxicity. The most common adverse event in both treatment groups was upper abdominal pain, which occurred in less than 2% of patients.

Prexige has a different chemical structure from other COX-2 inhibitors. It is the only one that does not contain a sulphur molecule, which has been associated with sulphur-related skin reactions in some patients. Prexige also has a short plasma half-life of approximately four hours, yet provides 24-hour pain relief with a once-daily dose.

The clinical trial database for Prexige comprises approximately 40,000 patients, making it one of the largest bodies of evidence for any drug in its class. This includes the results of TARGET (Therapeutic Arthritis Research and Gastrointestinal Trial) involving more than 18,000 patients¹⁰. Results of this trial showed Prexige also significantly reduced the incidence of upper gastrointestinal complications by 79% in patients not taking aspirin compared to ibuprofen and naproxen¹¹.

Novartis supports the recommendation of health authorities that anti-inflammatory treatments should be used in appropriate patients at the lowest possible dose for the shortest possible duration.

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