New Landmark Study Promises Good News for Osteoarthritis Sufferers

Submitted by: Athena Medical PR
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·TARGET is the largest study in osteoarthritis to date (18,325 patients), demonstrating reduction in side effects, and demonstrating 'real-life' benefits for patients taking Prexige® (lumiracoxib), a highly selective COX-2 inhibitor
·Stomach ulcer complications reduced by 79% in lumiracoxib patients compared with established NSAIDs, the current gold standard treatment for osteoarthritis
·NSAID complications are the most common cause of drug related hospital admissions
·Lumiracoxib did not increase overall cardiovascular (CV) risk versus the NSAIDs
·The degree of benefits seen in the TARGET trial have not been shown by any other COX-2 inhibitor

Frimley, Surrey, Friday, August 20, 2004 – Announced today in The Lancet, the landmark TARGET (Therapeutic Arthritis Research & Gastrointestinal Event Trial of lumiracoxib) study shows a 79% reduction in the incidence of upper gastrointestinal (GI) ulcer complications without increasing cardiovascular (CV) risk, when compared to the traditional non-steroidal anti-inflammatory drugs (NSAIDs) naproxen and ibuprofen. The GI benefit seen in this study is greater than seen in similar studies for other COX-2's.

Osteoarthritis (OA) affects an estimated 8.5 million people in the UK and is a leading cause of disability, costing the UK approximately £5.5 million per year. Current treatments for osteoarthritis include NSAIDs and the most recent advance of COX-2 inhibitors. Earlier studies have proven lumiracoxib is as effective as NSAIDs in OA and acute pain. Previous large clinical studies have not answered all the questions of the medical community highlighting the need for a trial like TARGET, investigating real-life benefits for people with OA.

TARGET is the largest study ever to have been completed in OA, with 18,325 patients (1,209 of whom were from the UK), taking part in more than 800 study centres throughout the world. 13% of these patients were at high risk of cardiovascular disease. The study was designed firstly to examine the effect of lumiracoxib on stomach complications like ulcers. These complications from NSAID usage are the most common cause of drug-induced hospital admission in the UK. TARGET also had a secondary focus, looking at the effect of the treatment on the heart and circulation. This is particularly important because many patients with osteoarthritis also have heart problems such as high blood pressure or may even have had a heart attack.

Commenting on the results of the TARGET study, David Scott, Professor of Rheumatology at King's College Hospital, London said:
'The degree of benefits seen in the TARGET trial have not been shown by any other COX-2 inhibitor. TARGET is a landmark study in its design that laid out strict objectives to research prior to commencing the trial. TARGET also has the largest patient involvement of any trial of this kind and demonstrated a four-fold reduction for lumiracoxib patients in the occurrence of upper GI or stomach problems such as ulcers which are common side effects for patients taking these drugs.'

The trial design drew on the experience of other similar studies of selective COX-2 inhibitors. Patients taking part received either 400 mg of lumiracoxib once daily (2-4 times the maximum dose for OA) or

ibuprofen 800 mg three times daily or naproxen 500 mg twice daily over twelve months.

Lumiracoxib showed a reduction of 79% versus the two comparator medicines for the incidence of definite or probable upper GI ulcer complications. Lumiracoxib significantly reduced the incidence of upper GI ulcer complications in those patients not taking aspirin by 83% versus ibuprofen, and by 76% versus naproxen.

For the whole study population (including patients taking low dose aspirin), lumiracoxib significantly reduced the incidence of upper GI ulcer complications by 66% versus both NSAIDs.

Overall, serious GI and CV risk was reduced by more than a third in the lumiracoxib group compared to the NSAID group. Therefore TARGET further confirms that the superior GI benefit of lumiracoxib is achieved without increasing CV risk versus NSAIDs. Importantly, patients receiving lumiracoxib experienced significantly smaller changes in blood pressure than all those taking the NSAIDs.

Neil Betteridge, Director of Public Affairs, Arthritis Care commented, “Arthritis Care welcomes the development of any new treatment where there is evidence that it is safe and efficacious. People with arthritis need and deserve access to the best treatments available so that they can live with independence and dignity.”

Lumiracoxib will be marketed as Prexige® by Novartis Pharmaceuticals and is due to launch in the UK in 2005.
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