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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

New data confirm that Prexige® (lumiracoxib) is effective in relieving symptoms of osteoarthritis

Basel, Switzerland, 20 June 2003 – Data from key clinical Phase III studies presented for the first time at EULAR, the European League Against Rheumatism annual congress in Lisbon, demonstrate that Prexige® (lumiracoxib), a novel COX-2 selective inhibitor, provides effective relief of the symptoms of osteoarthritis (OA).

Commenting on the trial data presented at EULAR, Dr Joerg Reinhardt, Head of Development, Novartis Pharma AG, said: "This body of data confirms that Prexige is an efficacious COX-2 selective inhibitor which could offer substantial benefit to patients with osteoarthritis."

The data presented include results from a 13-week pivotal study in OA that evaluated Prexige at 200mg and 400mg given once daily (od) compared with placebo and a 200mg single daily dose of celecoxib. Using Visual Analogue Scale (VAS) and the Western Ontario McMaster Universities osteoarthritis index (WOMAC) disease scores, the investigators, Fleischmann *et al.*, demonstrated that Prexige was significantly ($p<0.001$) more effective in reducing OA pain intensity and improving functional status compared with placebo at end of study treatment. Furthermore, Prexige was as effective as celecoxib in terms of all primary efficacy assessments after 13 weeks (study duration) of treatment.

A further study by Schell *et al.* was presented which showed, for the first time, the long-term efficacy in patients with OA receiving Prexige at 200mg or 400mg od compared with celecoxib 200mg od for up to one year. Both doses of Prexige provided sustained long-term pain relief and maintained improvements in functional status in patients with OA of the knee. Prexige was as effective as celecoxib in terms of pain relief and improved functional status.

In a model conducted over 4 weeks of treatment, Benevolenskaya *et al.* showed that Prexige 100mg od was effective in reducing pain in patients with OA of the hip or knee, with the estimated treatment difference (VAS) of 8.41mm ($p=0.003$). Prexige 100mg od significantly improved disease status, as assessed by the patient's and physician's global assessment of disease activity, with treatment differences of 8.81mm ($p=0.001$) and 7.98mm ($p=0.002$) respectively.

Additional benefits of Prexige were demonstrated through a one week study by Wittenberg *et al.*, who found that OA patients experienced effective relief of pain as little as three hours after taking Prexige ($p=0.03$). The investigators found an overall adverse event profile similar to placebo and celecoxib. Prexige was significantly superior to placebo for overall pain relief throughout the study at both morning and evening assessments, with 13.9% of patients on lumiracoxib reporting complete pain relief at the study end, compared with 5.3% on placebo.

COX-2 selective inhibitors selectively block the inflammation-producing COX-2 specific enzyme that is produced in arthritic joints, and unlike traditional NSAIDs, do not affect the

COX-1 enzyme, which is important for protecting against gastrointestinal problems. Prexige is being evaluated for the treatment of arthritis and acute pain.

OA is the most common form of arthritis and is a significant burden for patients around the world. It is characterized by the breakdown of cartilage in joints, causing affected bones to rub against each other and leading to inflammation, pain and loss of movement. It is estimated that more than 25 million Europeans and 20.7 million Americans are affected by OA. Globally, it accounts for half of all chronic conditions in those age 65 and older.

The foregoing press release contains forward-looking statements that can be identified by express or implied statements regarding future clinical trial results regarding the safety or efficacy of Prexige, the potential for regulatory approvals to market Prexige, or potential future revenues from Prexige. Such forward looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that other ongoing clinical trials, including the ongoing TARGET trial, will have the same results as the clinical trials described above. Nor can there be any guarantee that the clinical trials described above will result in the commercialisation of Prexige in any market. Neither can there be any guarantee regarding the potential future sales of Prexige, if it is approved. In particular, the fact that Prexige was shown to have similar safety and efficacy profiles as celecoxib does not mean that, if approved, Prexige sales would reach the same sales levels as celecoxib. Any such results can be affected by, amongst other things, uncertainties relating to product development, including the results of other clinical trials, including the ongoing TARGET trial and other trials, regulatory actions or delays or government regulation generally, the ability to obtain or maintain patent or other proprietary intellectual property protection and competition in general, as well as factors discussed in Novartis AG's Form 20-F filed with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialise, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected.

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[1] Fleischmann *et al.*, A prospective randomized 13-week study evaluating the efficacy of lumiracoxib in patients with osteoarthritis of the knee (Study 109), EULAR 2003 Abstract Number FRI0233.

[2] Schell *et al.*, Long-term efficacy and tolerability of lumiracoxib in patients with osteoarthritis of the knee (Study 112E), EULAR 2003 Abstract Number FRI0224.

[3] Benevolenskaya *et al.*, Lumiracoxib is effective in relieving symptoms of osteoarthritis of the hip or knee after 4 weeks of treatment: results from a randomized placebo-controlled trial (Study 2316), EULAR 2003 Abstract Number FRI0246.

[4] Wittenberg *et al.*, Prospective, randomized study on the first-dose analgesic effect of lumiracoxib in osteoarthritis of the knee (Study 2301), EULAR 2003 Abstract Number FRI0229.