



## PRESS RELEASE

### OSTEOARTHRITIS: EFFICACY OF GLUCOSAMINE SULPHATE IN THE MEDIUM-TERM MANAGEMENT OF ARTHRITIS SYMPTOMS

*March, 2006.* A new European study has revealed that the administration of Glucosamine Sulphate over a period of six months is effective in controlling symptoms of osteoarthritis of the knee when compared to a mere pain-reducing drug. The GUIDE (Glucosamine Unum In Die [once a day] Efficacy) study was presented by Prof. Gabriel Herrero-Beaumont – Director of the Jimenez Diaz Foundation Institute of Rheumatology at the University of Madrid – during a plenary session of the Sixth European Congress on Clinical and Economic Aspects of Osteoporosis and Osteoarthritis (ECCEO 6), held in Vienna, March 15-18. Specifically, the GUIDE study adopted the formulation of Glucosamine Sulphate used in Europe as a prescription drug, which is different from other glucosamine preparations that use different salts and daily dosages. The results indicate that Glucosamine Sulphate could be the drug of first choice to be introduced early on in the control of this chronic and disabling disease.

12% of the world's population is affected by osteoarthritis, the most common of the rheumatic diseases. Osteoarthritis is a chronic degenerative disease of the joints, that mainly manifests itself through pain and functional limitation, together with the progressive destruction of the joint cartilage structures. "Forms of arthritis that affect sufferers to a greater or lesser extent are frequent" – comments Prof. Montecucco, Director of the School of Specialisation in Rheumatology at the University of Pavia. "More specifically, about 30% of people over 65 suffer from problems linked to osteoarthritis of the knee. The treatment of this is complicated by the fact that in this age group other diseases (cardiovascular, pulmonary, metabolic etc.) are almost constantly present, with their attendant treatments."

When symptoms appear, patients are usually treated with simple analgesics (pain-relieving drugs) or with non-steroidal anti-inflammatory drugs, that are slightly more effective but have a much lower level of tolerance. In addition, none of these unspecific symptomatic drugs is able to prevent the progression of the joint cartilage damage and therefore of the disease which, in many cases, leads inevitably to surgery for the prosthetic replacement of the affected joint (especially knee and hip). Clearly, all of this entails enormous social costs.

Previous studies carried out with **Glucosamine Sulphate** showed that the **drug could limit structural damage to the joint if administered for at least three years**, and could actually reduce by 70% the risk of having to resort to surgery for the prosthetic replacement of the knee in the long term. These studies, presented in 2001 by Prof. Reginster of the University of Liège in the prestigious British scientific journal *The Lancet*, and in 2002 by Prof. Pavelka of the University of Prague in the equally authoritative American journal *Archives of Internal Medicine* (confirmed and extended in a series of later publications), showed that **Glucosamine Sulphate could also control the development of the symptoms of the disease** during this long period of treatment, when compared with patients who had not taken the drug. Uncertainties remained, however, over the drug's ability to alleviate pain and improve functional limitation over shorter periods of

time, especially in comparison with drugs that are simply symptomatic, despite the fact that the initial evidence appeared to confirm this.

"We therefore decided" – explains Prof. Gabriel Herrero-Beaumont, Director of the Institute of Rheumatology at the Jimenez Diaz Foundation-Capio, University of Madrid – "to investigate over a period of 6 months the drug's efficacy with regard to pain relief and functional limitation in patients affected by osteoarthritis of the knee, compared to a group that did not take any drugs and a third group that took a full daily dose of a pure analgesic, paracetamol. Paracetamol is, in fact, considered by the international scientific community the analgesic to be tried first" – continues Prof. Herrero-Beaumont – "and, if effective, is the drug of first choice for prolonged treatments, possibly in conjunction with other therapeutic measures." 318 patients have therefore received one of the three treatments and have been assessed at monthly intervals for a period of 6 months. **Glucosamine Sulphate reduced pain and improved joint function in patients to a highly significant degree in comparison with the patients who did not take the drug and received placebo.** Conversely, the pure analgesic was found to be only partly effective and to a lesser degree when compared to Glucosamine Sulphate, especially as regards the benefit/risk ratio.

"It was important to test the original formulation for Glucosamine Sulphate in this study" – adds Prof. Herrero-Beaumont – "since it was used in the previous long-term studies and is available as a prescription drug in Europe at the full dose of 1500 mg once a day." He has therefore adopted the acronym GUIDE (Glucosamine Unum in Die [once-a-day] Efficacy).

Indeed, the popularity of previous studies with this formulation has been such that preparations of glucosamine have appeared in many countries in the form of dietary supplements containing different salts (for example, glucosamine hydrochloride), often in lower doses than those used to obtain significant clinical results, or administered in several doses taken during the course of the day. These preparations lead to much lower concentrations of glucosamine in the blood, and are without any real pharmacological effect, as demonstrated by a series of research studies presented in preview, also at the ECCEO 6, by a research group directed by Prof. Lucio Rovati, professor of Clinical Pharmacology at the University of Milan, Italy and Chief Scientific Officer of the Rottapharm Group, which developed the original Glucosamine Sulphate used for the treatment of osteoarthritis. "A similar study to the European one" – explains Prof. Rovati – "but carried out in the United States by the National Institute of Health (NIH) with a different glucosamine formulation from the sulphate and administered in several separate doses during the course of the day, yielded poorer results that only approach the European results when substances are added to the glucosamine which, after metabolization in the body, produce metabolites, including glucosamine and its direct derivatives, which thus increase its levels in the blood".

"The new GUIDE study" – concludes Prof. Herrero-Beaumont – "shows that **Glucosamine Sulphate, at the recommended dose of 1500mg once a day, may be considered a drug of first choice to be administered as early as possible in the treatment of osteoarthritis,** not only because of the previous evidence concerning the long-term benefits, but also because it has been shown that **already in the first 6 months, there is an optimal control of symptoms,** that integrates perfectly with all the other therapeutic measures – pharmacological and other – that lead to the correct management of arthritis."

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