Clinical study confirms previous results of glucosamine sulfate on joint health

Philadelphia, November 2, 2000 - Results of a clinical trial on the effects of Dona™, the original Glucosamine Sulfate product from Rotta Pharmaceuticals Inc., will be presented by lead researcher Karel Pavelka, M.D. at the 64th American College of Rheumatology and the 35th Association of Rheumatology Health Professionals Annual Scientific Meetings on November 1, 2000 at the Philadelphia Convention Center. In the three-year, independent clinical trial recently completed, the effects of this glucosamine sulfate formula were studied, with results upholding previous findings on Dona's™ positive effect on supporting joint health. The study, (Glucosamine sulfate decreases progression of knee osteoarthritis in a long-term, randomized, placebo-controlled, independent, confirmatory trial. Arthritis Rheum 2000; 43 (Suppl.): 1908.) , was conducted in the Prague Institute of Rheumatology, and it verifies the results of a previous study, presented by Jean-Yves Reginster at last year ACR meeting,(Glucosamine sulfate significantly reduces progression of knee osteoarthritis over 3 years: a large, randomized, placebo-controlled, double-blind, prospective trial. Arthritis Rheum 1999; 42 (Suppl.): 1975). Both studies were carried out according to international guidelines for conducting clinical trials on osteoarthritis drugs.

The objective of the randomized, double blind, placebo controlled study was to test the effects of Glucosamine Sulfate on the long-term progression of knee osteoarthritis joint structural changes and symptoms.

In the study 202 patients with osteoarthritis were randomly assigned to treatment with 1500 mg of oral glucosamine sulfate once a day or a placebo, for three years. A radiograph of each weight-bearing, antero-posterior knee was taken upon enrollment into the study and at the completion of the study three years later. The Western Ontario and McMaster Universities (WOMAC) osteoarthritis index, the Lequesne Algofunctional index, and measurements of joint space narrowing (JSN) on the knee radiograph were used to assess Dona's™ effectiveness in supporting joint health. The WOMAC index is a 24-item questionnaire completed by the patient and focusing on joint pain, stiffness and loss of function related to osteoarthritis of the knee and hip. The Lequesne index consists of a 10-item questionnaire administered by trained staff, that allows patients to rate pain or discomfort, stiffness, difficulty performing daily activities and their maximum walking capacity.

Results from the study confirmed the previous findings by Reginster and coworkers, demonstrating that Glucosamine Sulfate slowed disease progression as measured by JSN. Placebo-treated patients had an average three-year JSN of -0.2mm, in contrast to no JSN in the Glucosamine Sulfate group. Data collected in this study also supported the belief that Glucosamine Sulfate has a significant clinical improvement on joint pain and function as compared to a placebo.

Dona™, the Glucosamine Sulfate product used in this study is sold by Rotta Pharmaceuticals, and is the original form of Glucosamine Sulfate that has been the subject of over 150 preclinical and clinical studies, demonstrating therefore its superiority compared to other glucosamine supplements on the market. Sold as a prescription drug in Europe, Dona™ must withstand European regulations similar to those of the US Food and Drug Administration.

Rotta Pharmaceuticals, Inc. is a subsidiary of Rottapharm, a Milano, Italy-based pharmaceutical group with a strong market presence in Europe, Far East and Latin America. Rotta Research Laboratorium, inventor of Dona™, has the most patents and original pharmaceutical products on the market in Italy.