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FOR IMMEDIATE RELEASE

FDA Approves SOMA® (carisoprodol) 250 mg

New Recommended Dose for Relief of Discomfort Associated with Acute, Musculoskeletal Conditions such as Back Pain

Somerset, New Jersey, September 17, 2007 – MedPointe Pharmaceuticals today announced that the Food and Drug Administration (FDA) has approved SOMA® (carisoprodol) 250 mg as a new recommended dose of SOMA for the relief of discomfort associated with acute, painful musculoskeletal conditions, such as backache. SOMA 250 mg offers comparable efficacy to the widely prescribed skeletal muscle relaxant SOMA 350 mg with a more favorable tolerability profile, including less drowsiness. SOMA 250 mg will be available by prescription nationwide immediately.

Back pain is the fifth leading reason for patient visits to physicians and ranks among the top ten most costly physical disorders. This ailment is responsible for direct health care expenditures of more than $20 billion annually and as much as $50 billion per year when indirect costs are included.

“The clinical benefits of SOMA 250 mg are in line with current treatment strategies for back pain which focus on helping patients to return to normal physical activity as quickly as possible,” said Lee Ralph, M.D., Assistant Clinical Professor, Department of Family and Preventative Medicine, University of California, San Diego, LaJolla; physician partner, San Diego Sports Medicine and Family Health Center; and a lead author and investigator for the SOMA 250 mg clinical trials. “I look forward to offering my patients SOMA 250 mg as data indicates that it can help relieve discomfort from acute backache. Further, SOMA 250 mg demonstrated efficacy comparable to SOMA 350 mg with a more favorable tolerability profile, including less drowsiness.”

“The availability of SOMA 250 mg marks a significant milestone in the treatment of acute backache, a common and terribly painful condition which also has a tremendous economic impact on our nation’s health care system,” said Paul R. Edick, President & Chief Executive Officer of MedPointe Pharmaceuticals. “While SOMA has a long history in the treatment of discomfort associated with acute, painful musculoskeletal conditions with nearly 50 years on the market, we are pleased to provide a new recommended dose that provides a proven clinical benefit to help relieve the burden of these conditions.”

Clinical Trials Demonstrate SOMA 250 mg Efficacy and Favorable Tolerability Profile

FDA approval of SOMA 250 mg was based on the results from two randomized, double-blind, placebo-controlled, multi-site parallel group studies (MP502 and MP505) which included more than 1,300 patients aged 18 to 65 who suffered from acute painful muscle spasm of the lower back. Results from both studies showed that SOMA 250 mg provided significant and rapid relief of back pain compared to placebo ($P = 0.0001$) with efficacy comparable to SOMA 350 mg.

Results from the studies also showed that SOMA 250 mg provided efficacy comparable to SOMA 350 mg with a more favorable tolerability profile, resulting in fewer discontinuations due to treatment-related adverse events. In the studies, the discontinuation rate due to adverse events for SOMA 250 mg was comparable to placebo and lower than that for SOMA 350 mg (2% versus 2.7% versus 5.4% respectively). The most common side effects associated with SOMA 250 mg in clinical trials included drowsiness (13%), dizziness (8%) and headache (5%). The most common side effects for SOMA 350 mg included drowsiness (17%), dizziness (7%) and headache (3%).

This new recommended dose of SOMA is 250 mg three times a day and at bedtime.

Important Information

SOMA (carisoprodol) is indicated for the relief of discomfort associated with acute, painful musculoskeletal conditions in adults. SOMA should be used for short periods (up to two or three weeks) because adequate evidence of effectiveness for more prolonged use has not been established and because acute, painful musculoskeletal conditions are generally of short duration.

Since the effects of SOMA and CNS depressants (including alcohol) or psychotropic drugs may be additive, appropriate caution should be exercised with patients who take more than one of these agents simultaneously. In postmarketing experience with SOMA, cases of dependence, withdrawal, and abuse have been reported with prolonged use. SOMA should be used with caution in addiction-prone patients. There have been postmarketing reports of seizures in SOMA treated patients with most cases having occurred in the setting of multiple drug overdoses.

Most common side effects include drowsiness, dizziness and headache.

Complete prescribing information about SOMA® 250 mg can be obtained by visiting www.soma250.com.

About MedPointe Pharmaceuticals

MedPointe Pharmaceuticals is the U.S. subsidiary of Meda AB. MedPointe specializes in respiratory, allergy, central nervous system, and cough-cold products. The company maintains a manufacturing facility in Decatur, Illinois. For more information on MedPointe, visit www.medpointepharma.com. For more information on Meda, visit www.meda.se.

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