

# **SOMAXON PHARMACEUTICALS' SILENOR(TM) DEMONSTRATES POSITIVE RESULTS IN ITS THIRD PHASE 3 CLINICAL TRIAL IN INSOMNIA- \* SILENOR(TM) DEMONSTRATES STATISTICALLY SIGNIFICANT IMPROVEMENT VS. PLACEBO IN THE PRIMARY ENDPOINT, SUBJECTIVE T**

Somaxon Pharmaceuticals

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Somaxon Pharmaceuticals, Inc. (Nasdaq: SOMX) announced positive results from the company's Phase 3 clinical trial evaluating SILENOR(TM) (doxepin HCl) in elderly patients with primary sleep maintenance insomnia. SILENOR(TM) demonstrated a statistically significant improvement compared to placebo in the primary endpoint of this trial, subjective Total Sleep Time (sTST) as measured at week one ( $p < 0.0001$ ). Statistical significance was maintained for all timepoints measured throughout the four week treatment period.

This Phase 3 trial was a randomized, double-blind, placebo-controlled, multi-center, parallel group outpatient trial designed to assess the efficacy and safety of 6mg of SILENOR(TM) in elderly patients with primary sleep maintenance insomnia. The trial enrolled 255 elderly subjects with at least a three month history of insomnia. Safety and efficacy were evaluated over a four week period.

With respect to secondary endpoints, SILENOR(TM) achieved statistically significant results compared to placebo in subjective Wake After Sleep Onset (sWASO) ( $p < 0.0001$ ) and Sleep Quality (SQ) ( $p < 0.0001$ ) as measured at week one.

Each of these effects was maintained at the four week timepoint. SILENOR(TM) also demonstrated improvements relative to baseline in subjective Latency to Sleep Onset (LSO). This improvement was sustained throughout the four week treatment period, but statistical significance relative to placebo was not demonstrated.

This clinical trial demonstrated again that SILENOR(TM) was well tolerated. The incidence of adverse events was generally comparable to placebo. There were no reports of amnesia, memory impairment or weight gain. Phil Jochelson, M.D., Somaxon's Chief Medical Officer, said: "We are extremely pleased with the results of this important Phase 3 clinical trial.

As in all of our prior trials, SILENOR(TM) achieved statistically significant improvements compared to placebo for the primary endpoint. We have now reported results from five randomized, placebo-controlled clinical trials of SILENOR(TM), with consistent and reproducible effects shown in both the adult and the elderly insomnia populations, and in both outpatient and sleep laboratory settings."

Ken Cohen, Somaxon's President and CEO, added, "With this positive SILENOR(TM) data we are nearing completion of our Phase 3 clinical development program. We believe that the data continue to support an attractive product profile for both adults and elderly patients with insomnia, if approved by the FDA. We look forward to the results of our final Phase 3 clinical trial, which we expect in December, the continuation of ongoing strategic collaboration discussions and a New Drug Application filing targeted for the third quarter of 2007."

Somaxon has previously reported the results of two Phase 3 clinical trials evaluating SILENOR(TM) for the treatment of insomnia. The company reported the results from the first of these clinical trials, which

evaluated SILENOR(TM) in the treatment of adults with chronic insomnia, in April. SILENOR(TM) demonstrated a statistically significant improvement compared to placebo on the primary endpoint of objective Wake After Sleep Onset (WASO), as well as a range of secondary endpoints including Latency to Persistent Sleep (LPS), at both the 3mg and 6mg doses.

Somaxon reported results from its second Phase 3 clinical trial, which evaluated SILENOR(TM) in healthy adults experiencing transient insomnia in a sleep laboratory setting, last month. SILENOR(TM) demonstrated a statistically significant improvement compared to placebo on the primary endpoint of LPS, as well as a range of secondary endpoints including WASO, objective Total Sleep Time and LSO, at the 6mg dose.

The company expects results from its remaining Phase 3 clinical trial for SILENOR(TM) in December of this year. This trial is a three month polysomnography (PSG) trial in elderly patients. Assuming that this final ongoing Phase 3 clinical trial and the planned preclinical studies for SILENOR(TM) are successful and proceed as currently scheduled, Somaxon expects to file a New Drug Application (NDA) with the FDA for SILENOR(TM) in the third quarter of 2007. This timing assumes that the initial NDA submission will include all of the data from the company's completed genotoxicity and ongoing reproductive toxicology studies requested by the FDA, but that the FDA will allow the company to submit the data from the requested carcinogenicity studies at a later date. The FDA has previously indicated to Somaxon that depending on the outcome of the genotoxicity studies, it may be flexible as to the timing of the conduct of the carcinogenicity studies, including the potential that the data from those studies may be submitted as a post-NDA approval commitment. The company has submitted the results of the genotoxicity studies to the FDA and is awaiting a response; as the company previously reported, no signal indicative of genotoxicity was observed in any of those studies.