

SOMAXON PHARMACEUTICALS' SILENOR(TM) DEMONSTRATES POSITIVE RESULTS IN A PHASE 3 TRANSIENT INSOMNIA CLINICAL TRIAL

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 adults with transient insomnia. SILENOR(TM) demonstrated statistically significant improvements compared to placebo ($p < 0.0001$) in the primary endpoint of this trial, Latency to Persistent Sleep (LPS), a measure of sleep onset. SILENOR(TM) also produced statistically significant improvements relative to placebo in multiple secondary endpoints, including measures of both sleep onset and sleep maintenance.

This Phase 3 trial was a randomized, double-blind, placebo-controlled, multi-center, parallel group study that enrolled 565 adults in a sleep laboratory setting using a phase-advance, first night assessment model of induced transient insomnia. Efficacy assessments evaluated both objective PSG (polysomnography) and subjective measures of sleep. Results demonstrated that 6mg of SILENOR(TM) was effective at inducing sleep and maintaining sleep throughout the night.

SILENOR(TM) achieved statistically significant results in multiple endpoints including:

- * Latency to Persistent Sleep (LPS): Improvement compared with placebo of 13 minutes ($p < 0.0001$)
- * Latency to Sleep Onset (LSO), a subjective measure: Improvement compared with placebo of 16 minutes ($p < 0.0001$)
- * Wake After Sleep Onset (WASO): Improvement compared with placebo of 40 minutes ($p < 0.0001$)
- * Total Sleep Time (TST): Improvement compared with placebo of 51 minutes ($p < 0.0001$)

Additionally, SILENOR(TM) achieved statistically significant results compared to placebo in Sleep Efficiency (SE) for the entire night and in each third of the night, as well as in subjective measures of sleep maintenance (sWASO, sTST) and Sleep Quality (SQ).

The study also demonstrated that SILENOR(TM) was well tolerated. The incidence of adverse events was low and comparable to placebo. There were no reports of amnesia, memory impairment, or anticholinergic effects, and there were no clinically meaningful effects on measures of next day impairment.

Phil Jochelson, M.D., Somaxon's Chief Medical Officer, said: "We are extremely pleased with the results of this important Phase 3 clinical trial. This is the first clinical trial for SILENOR(TM) that we specifically designed to evaluate sleep onset as the primary endpoint. The results from this study demonstrate significant effects on both objective and subjective measures of sleep onset. We have now reported results from four randomized, controlled clinical trials of SILENOR(TM), with consistent and reproducible effects shown in both the chronic and transient insomnia populations."

Ken Cohen, Somaxon's President and CEO, added, "With clear positive SILENOR(TM) data on both sleep onset and sleep maintenance, along with a favorable safety and tolerability profile, we believe this product candidate, if approved by the FDA, has the potential to become a significant participant in a large and rapidly expanding insomnia market. We are hopeful that SILENOR(TM) can become the first non-scheduled insomnia treatment to help patients fall asleep and maintain sleep throughout the night. This transient insomnia result is also important because our patent covering the use of SILENOR(TM) in

patients with transient insomnia extends until 2020."

The company expects results from its remaining two Phase 3 clinical trials for SILENOR(TM) by the end of this year. These include a three month PSG trial and a four week outpatient trial, both in elderly patients. Assuming that the company's ongoing Phase 3 clinical trials and 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.