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Somaxon Pharmaceuticals Announces Positive Phase 3 Results with SILENOR™ for the Treatment of Adults with Chronic Insomnia

- **SILENOR™ demonstrated statistically significant improvements in the primary endpoint: Wake After Sleep Onset**
- **Significant improvements were also demonstrated in key secondary endpoints, including Latency to Persistent Sleep, Total Sleep Time, and Sleep Efficiency**

SAN DIEGO, CA –April 10, 2006 – Somaxon Pharmaceuticals, Inc. (NASDAQ: SOMX), today announced positive results from its initial Phase 3 clinical trial with the tested doses of 3 mg and 6 mg of SILENOR™ (doxepin HCl), achieving statistically significant results in adults with chronic insomnia. Results of the primary endpoint for this trial, 8-hour Wake After Sleep Onset (WASO), which is an objective measure of sleep maintenance using polysomnography (PSG) in a sleep laboratory setting, were significant for both doses. SILENOR™ demonstrated improvement in mean WASO of 26 minutes for 3 mg ($p < 0.0001$) and 31 minutes for 6 mg ($p < 0.0001$) versus placebo for the primary analysis. Statistical significance versus placebo was maintained at both doses for all time points.

Improvement on Total Sleep Time (TST) was statistically significant ($p < 0.0001$) for both doses at the initial treatment period, increasing from 374 minutes for placebo to 415 minutes for SILENOR™ 3 mg and 421 minutes for SILENOR™ 6 mg. After four weeks of nightly

administration, improvement in TST remained statistically significant for both doses relative to placebo. Sleep Efficiency (SE) demonstrated results that were significant and consistent with those observed for TST. In the final third of the night, SILENOR™ generally demonstrated statistically significant improvement in Sleep Efficiency versus placebo for each dose.

SILENOR™ demonstrated a statistically significant reduction in Latency to Persistent Sleep (LPS) for both doses at the initial treatment period. Compared to LPS for placebo of 45 minutes, both 3 mg and 6 mg SILENOR™ reduced LPS to 27 minutes ($p=0.011$ and $p=0.0018$, respectively). These differences were not observed at subsequent time points, largely due to an improvement in LPS in the placebo group.

Both doses of SILENOR™ were well tolerated. Side effects in the SILENOR™ groups were comparable to placebo and there were no statistically significant differences versus placebo in next day residual measures.

There was no evidence of tolerance to SILENOR™ over the treatment period and sleep architecture was preserved. Rebound insomnia, withdrawal effects, memory impairment, weight gain and anticholinergic effects were not observed.

Commenting on the clinical results, Tom Roth, Ph.D., Chief, Division Head, Sleep Disorders & Research Center, Henry Ford Hospital, stated, “In patients with chronic insomnia, doxepin 3 mg and 6 mg demonstrates significant improvements in sleep across four weeks of nightly administration. These findings occurred in the absence of rebound insomnia, amnesia and next day residual effects with a low incidence of adverse events.”

Ken Cohen, President and CEO of Somaxon stated, “We are very encouraged by these results. We are undertaking a comprehensive Phase 3 program that has the potential, if successful, to establish SILENOR™ as a first line treatment for patients with insomnia. Results from the clinical trial, coupled with the mechanism of action which is distinct from benzodiazepine and non-benzodiazepine products for insomnia, creates an opportunity for differentiation in the

market. We look forward to reporting results from the remaining Phase 3 clinical trials later in 2006 and to filing an NDA in the first quarter of 2007.”

Study Design

This trial was a Phase 3, randomized, double-blind, placebo-controlled, parallel-group, multi-center 35-day study designed to assess the efficacy and safety of 3 mg and 6 mg dose levels of SILENOR™ in adults with primary insomnia characterized by sleep maintenance difficulties in a sleep laboratory setting. This trial enrolled 229 adult male and female patients with chronic primary insomnia as defined by the Diagnostic and Statistics Manual, Fourth Edition.

About SILENOR™

SILENOR™ is a low-dose (1 mg, 3 mg, 6 mg) oral tablet formulation of doxepin hydrochloride that is patent protected for its use in insomnia. Doxepin has been prescribed for more than 40 years for the treatment of depression and anxiety at dosages typically ranging from 75 mg to 300 mg per day. Though established as an effective antidepressant, at high doses, doxepin is known to have a range of undesirable side effects including daytime sedation and drowsiness, dry mouth, dry eyes and other anticholinergic effects. However, at the low doses used in SILENOR™ in controlled clinical trials conducted by Somaxon, these side effects have not been observed.

Unlike most approved insomnia medications, SILENOR™ does not act via a set of brain receptors known as the benzodiazepine, or GABA, receptors. Drugs that act on these receptors have been associated with amnesia, hallucinations, dependency and addiction. The U.S. Drug Enforcement Agency classifies these products as Schedule IV controlled substances and carefully monitors and controls their prescribing and use. Although the mechanism of action for the sleep-promoting effects of SILENOR™ is not definitively known, it differs from the currently available sleep-promoting agents in that the effects are mediated through the histaminergic system. The active ingredient in SILENOR™, doxepin HCl, is known to be a highly potent histamine antagonist. Histamine blocking has been demonstrated to reduce wakefulness and is thought to promote the initiation and maintenance of sleep.

While SILENOR™ has been demonstrated to be a potent blocker of H₁, at the low doses that are being investigated for insomnia, it does not appear to exhibit the unwanted side effects noted at higher doses of doxepin or similar side effects evident with drugs like diphenhydramine.

About Insomnia

Nearly 70 million American adults are affected by insomnia – characterized by difficulty falling asleep, waking frequently during the night, waking too early and not being able to return to sleep, or waking up not feeling refreshed.

Results from a 2005 National Sleep Foundation Sleep in America poll reported that respondents experienced the following insomnia symptoms:

- 54% experience insomnia symptoms a few nights a week;
- 21% have difficulty falling asleep (sleep onset);
- 32% awake often during the night (sleep maintenance); and
- 21% wake up too early and can not get back to sleep (premature final awakening).

About Somaxon Pharmaceuticals

Headquartered in San Diego, CA, Somaxon Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on the in-licensing and development of proprietary product candidates for the treatment of diseases and disorders in the fields of psychiatry and neurology. Somaxon's lead product candidate, SILENOR™, is in Phase 3 clinical trials for the treatment of insomnia. Nalmefene HCl is in a Phase 2/3 clinical trial for the treatment of pathological gambling and in a pilot Phase 2 clinical trial for smoking cessation. Acamprosate Ca, a potential treatment for movement disorders, is currently in formulation development.

For more information, please visit the company's web site at www.somaxon.com.

Somaxon cautions you that statements included in this press release that are not a description of historical facts are forward-looking statements. The inclusion of forward-looking statements should not be regarded as a representation by Somaxon that any of its plans will be achieved. Actual results may differ materially from those set forth in this release due to

the risks and uncertainties inherent in Somaxon's business, including, without limitation: the potential for SILENOR™ to receive regulatory approval for one or more indications on a timely basis or at all; the results of pending clinical trials for SILENOR™ or Somaxon's other product candidates; unexpected adverse side effects or inadequate therapeutic efficacy of SILENOR™ or Somaxon's other products that could delay or prevent regulatory approval or commercialization, or that could result in recalls or product liability claims; other difficulties or delays in development, testing, manufacturing and marketing of and obtaining regulatory approval for SILENOR™ or Somaxon's other product candidates; the scope and validity of patent protection for SILENOR™ and Somaxon's other product candidates; the market potential for insomnia, and Somaxon's ability to compete; and other risks detailed in Somaxon's Annual Report on Form 10-K, filed with the Securities and Exchange Commission (SEC) on March 22, 2006 and other periodic filings with the SEC.

You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement and Somaxon undertakes no obligation to revise or update this news release to reflect events or circumstances after the date hereof.

This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

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