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## Somaxon Pharmaceuticals Provides Update on Preclinical and Clinical Programs for SILENOR<sup>™</sup>

- Genotoxicity studies completed
- Data from remaining Phase 3 trials to be announced by end of 2006

**SAN DIEGO, CA – September 11, 2006** – Somaxon Pharmaceuticals, Inc. (NASDAQ: SOMX) today announced that it has completed the genotoxicity studies requested by the U.S. Food and Drug Administration (FDA) for SILENOR<sup>™</sup> (doxepin HCl), the company's lead product candidate for the treatment of insomnia. In accordance with FDA guidance, these studies consisted of an *in vitro* bacterial reverse mutation test, an *in vitro* mammalian chromosomal aberration test and an *in vivo* rodent micronucleus test to assess for chromosomal damage.

The company, in its assessment of the results, did not observe a signal indicative of genotoxicity in any of the assays. The company plans to shortly submit the data to the FDA and, based on its assessment, request that the agency permit the company to submit the data from the requested carcinogenicity studies of SILENOR<sup>™</sup> as a post- New Drug Application (NDA) approval commitment. 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 post-approval.

The company is also conducting the reproductive toxicology studies of SILENOR<sup>™</sup> requested by the FDA and plans to complete those studies in the first half of 2007. If the FDA agrees with the company's assessment of the genotoxicity results, and assuming that the

company's ongoing Phase 3 clinical trials and planned reproductive toxicology studies for SILENOR™ are successful and proceed as currently scheduled, Somaxon plans to file the NDA for SILENOR™ in the third quarter of 2007.

In April 2006, Somaxon announced the results of its first Phase 3 clinical trial for SILENOR™ which demonstrated statistically significant improvements in sleep maintenance and sleep onset compared to placebo. Incidences of adverse events were comparable to placebo. The company also recently completed enrollment in its remaining three Phase 3 clinical trials for SILENOR™. These include a transient insomnia trial, an elderly three month polysomnography (PSG) trial and an elderly outpatient trial. Results from each of these trials are expected in late 2006.

Ken Cohen, Somaxon's President and CEO stated, "We are pleased with both the progress and results to date from the preclinical work requested by the FDA for SILENOR™. We look forward to reporting on the results from our three remaining Phase 3 clinical trials for SILENOR™ in the fourth quarter of this year."

#### **About SILENOR™**

SILENOR™ is a low-dose (1 mg, 3 mg, 6 mg) oral tablet formulation of doxepin HCl that is patent protected for its use in insomnia. Doxepin has been prescribed for more than 35 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 dry mouth, dry eyes and other anticholinergic effects. However, at the doses used in SILENOR™ in controlled clinical trials completed by Somaxon to date, 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 leading prescription insomnia treatments in that the effects are mediated through the histaminergic system. Histamine blocking has been demonstrated to reduce wakefulness and is thought to promote the initiation and maintenance of sleep.

#### **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™ (doxepin HCl), is in Phase 3 clinical trials for the treatment of insomnia. Nalmefene HCl is in a Phase 2/3 clinical trial for pathological gambling and has completed a pilot Phase 2 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](http://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 results which may be observed in the preclinical studies and pending clinical trials for SILENOR™; the potential for the FDA to require additional preclinical work or other clinical requirements to support an NDA submission for SILENOR™ or to be completed after regulatory approval; the timing of receipt of trial results and any NDA submission; unexpected adverse side effects or inadequate therapeutic efficacy of SILENOR™ that could delay or prevent regulatory filings and approval; the scope and validity of patent protection for SILENOR™; Somaxon's ability to attract and retain key personnel; and other risks detailed in Somaxon's prior press releases as well as in periodic filings with the Securities and Exchange Commission.*

*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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