



Contacts: Jeff Raser
SVP, Sales and
Marketing
(858) 480-0404

Rob Whetstone
PondelWilkinson, Inc.
(310) 279-5963

Somaxon Pharmaceuticals Provides Update on SILENOR™ Development Program for the Treatment of Insomnia

- **Preclinical testing required by the FDA**
- **Anticipated NDA filing now third quarter of 2007**
- **Results from at least two of remaining three Phase 3 trials expected by end of 2006**

SAN DIEGO, CA – July 19, 2006 – Somaxon Pharmaceuticals, Inc. (NASDAQ: SOMX) today is providing information on its development program for SILENOR™ (doxepin HCl), its lead drug candidate currently in Phase 3 clinical trials for the treatment of insomnia. The company is updating information regarding the preclinical testing program for SILENOR™ recently requested by the U.S. Food and Drug Administration (FDA). Based on this information, the company is also updating the anticipated timing of its potential New Drug Application (NDA) submission for SILENOR™. The company is also providing a status update on its ongoing Phase 3 clinical program.

Preclinical Program and NDA Filing Update

As the company previously disclosed, in connection with a planned pre-NDA meeting for SILENOR™, the FDA requested that Somaxon develop and submit a proposal relating to the scope and timing of additional preclinical work regarding SILENOR™. Somaxon submitted the proposal to address the FDA's request, to which the FDA has now responded.

Based on this correspondence, Somaxon has initiated a preclinical program consisting of standard genotoxicity, reproductive toxicology and carcinogenicity studies. The FDA has indicated that the data from the genotoxicity studies and reproductive toxicology studies should be included in the original NDA for SILENOR™. Depending on the results of the genotoxicity studies, the FDA has indicated flexibility on the timing of submission of data from the carcinogenicity studies, including the potential that the FDA may allow the data from those studies to be submitted post-approval.

Based on this information, the company anticipates that an NDA submission for SILENOR™ could occur in the third quarter of 2007, provided that the ongoing and planned clinical and preclinical studies are successful and proceed as currently scheduled.

The requirement to conduct these additional studies was unexpected. The company intends to seek approval for SILENOR™ under the 505(b)(2) regulations, and prior written guidance from the FDA acknowledged that such additional preclinical testing would not be necessary. The company believes that the FDA's request was not in response to any specific safety concern arising from ongoing or completed SILENOR™ clinical trials.

Phase 3 Clinical Program

Somaxon initiated a program of four Phase 3 clinical trials in insomnia that are targeted to collectively enroll approximately 1,200 patients. The first of these Phase 3 clinical trials, a study evaluating the efficacy and safety of nightly administration of 3 mg and 6 mg of SILENOR™ in 229 adult patients with primary sleep maintenance insomnia, has been completed. The company announced the results from this clinical trial in April 2006. Doses of 3 mg and 6 mg of SILENOR™ achieved sustained, statistically significant improvements relative to placebo on the trial's primary endpoint, Wake After Sleep Onset (WASO), an objective measure of sleep maintenance. Both doses of SILENOR™ also showed statistically significant improvements relative to placebo on the key secondary endpoints Latency to Persistent Sleep (LPS), Total Sleep Time (TST) and Sleep Efficiency (SE). SILENOR™ was well tolerated, and rebound insomnia, withdrawal effects, memory impairment, weight gain and anticholinergic effects were not observed. In addition, no significant next day hangover effects were reported.

The company has also completed enrollment in a three month clinical trial evaluating the efficacy and safety of nightly administration of 1 mg and 3 mg of SILENOR™ in elderly patients with

primary sleep maintenance insomnia. The trial is being conducted in a sleep laboratory setting using Wake After Sleep Onset (WASO) as the primary endpoint. Results from this clinical trial are expected in the fourth quarter of 2006.

The company has also completed enrollment in a clinical trial evaluating the efficacy and safety of a single dose administration of 6 mg of SILENOR™ in patients with induced transient insomnia. Latency to Persistent Sleep (LPS) is the primary endpoint in this trial, and results are expected in the fourth quarter of 2006.

Enrollment is progressing in the remaining Phase 3 clinical trial, which is a four week study to evaluate the efficacy and safety of nightly administration of 6 mg of SILENOR™ in elderly patients. This trial is being conducted in an outpatient setting, and the primary endpoint is subjective Total Sleep Time (sTST). Enrollment is expected to be completed in the third quarter of 2006, and the company anticipates results in late 2006 or early 2007.

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 low 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 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 (H₁) antagonist. H₁ blocking has been demonstrated to reduce wakefulness and is thought to promote the initiation and maintenance of sleep.

While SILENOR™ is known to be a potent blocker of H₁, at the low doses that are being investigated for insomnia it does not appear to exhibit the undesirable side effects noted at higher doses of doxepin.

About Somaxon Pharmaceuticals, Inc.

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 in 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.

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.*

###