Somaxon Pharmaceuticals Announces Positive Results in a Phase II Dose-Finding Study of Low-Dose Doxepin in Elderly Patients with Primary Sleep Maintenance Insomnia

SAN DIEGO, CA – April 21, 2005 -- Somaxon Pharmaceuticals Inc., a specialty pharmaceutical company focused on developing and marketing products for the treatment of neuro-psychiatric disorders, today announced that low-dose doxepin demonstrated statistically significant results in a Phase II dose-finding study in elderly patients with primary sleep maintenance insomnia. Low-dose doxepin demonstrated efficacy in its primary endpoint, Wake Time During Sleep (WTDS) at all doses studied, 1 mg, 3 mg and 6 mg. Low-dose doxepin also demonstrated efficacy in all secondary sleep maintenance endpoints as well as patient reported outcomes. In all dose groups, there were no differences in adverse events and no statistically significant next day residual effects with low-dose doxepin versus placebo.

Results

- Doxepin 1 mg, 3 mg and 6 mg demonstrated statistically significant improvement in the primary endpoint by polysomnography (PSG)-defined Wake Time During Sleep (WTDS) vs. placebo ($p \leq 0.0001$ for 1 mg 3 mg and 6 mg).
- Doxepin 1 mg, 3 mg, and 6 mg demonstrated statistically significant improvement in the secondary endpoints of PSG-defined Wake After Sleep Onset (WASO), Sleep Efficiency (SE) and Total Sleep Time (TST) vs. placebo.
- Latency to Persistent Sleep (LPS) showed a dose-dependent reduction, though not statistically significant vs. placebo. Latency to Sleep Onset (LSO) demonstrated statistical significance vs. placebo in one dose group.
- Doxepin demonstrated statistical significance vs. placebo in Subjective Total Sleep Time (sTST), and Subjective Wake After Sleep Onset (sWASO).
- Sleep Quality (SQ) was also statistically significantly improved for all dose groups.

Somaxon President and Chief Executive Officer Ken Cohen stated, “We are extremely pleased with the results from our second Phase II study with low-dose doxepin in elderly patients with sleep maintenance insomnia. In January we reported positive data on a similar dose-finding study in adults with primary sleep maintenance insomnia. On the basis of these encouraging results, we are preparing to enter Phase III clinical trials in which we will evaluate the safety and efficacy of low-dose doxepin in both adult and elderly patients with insomnia. We expect our first Phase III trial to commence by the middle of 2005.”

Study Design

The Phase II study was a randomized, multi-center, double-blind, placebo-controlled, four-way cross-over, dose response study of 71 per protocol elderly patients aged 65-84 years who were diagnosed with primary chronic sleep maintenance insomnia. Three dose levels of doxepin (1 mg, 3 mg, 6 mg) were assessed in a PSG sleep laboratory setting. The primary endpoint was Wake Time During Sleep (WTDS). Among the secondary endpoints measured were Wake After Sleep Onset (WASO), Total Sleep Time (TST), Wake Time After Sleep (WTAS) as well several patient reported outcomes. Safety and tolerability were also assessed.

About Doxepin

Doxepin HCL is a tricyclic compound currently approved for the treatment of depression. The recommended daily dose for the treatment of depression ranges from 75 mg to 300 mg. Doxepin, unlike all FDA approved products for the treatment of insomnia is not a Schedule IV controlled substance.

About Insomnia

Insomnia is a growing health problem in the United States. It is believed that more than 10 million people suffer from chronic insomnia and up to an additional 50 million people suffer from some form of insomnia each year. Sleep maintenance insomnia is a significant problem. In the National Sleep Foundation's Sleep in America Poll 2005, 42 percent of survey respondents reported they awoke frequently during the night, 22 percent of adults report waking too early and not being able to return to sleep and 38 percent surveyed reported waking and feeling unrefreshed.

About Somaxon Pharmaceuticals

Headquartered in San Diego, Somaxon Pharmaceuticals is a specialty pharmaceutical company focused on developing and commercializing products for the treatment of neuro-psychiatric disorders. The company has several product candidates in development. The most advanced clinical program focuses on the evaluation of low-dose doxepin for the treatment of insomnia, a condition that, according to the National Sleep Foundation's, Sleep in America Poll affects more than 50 million Americans. The company anticipates that Phase III clinical trials evaluating low doses of doxepin for insomnia will begin in mid 2005.

A Phase II clinical trial with oral nalmefene for the treatment of pathological gambling was completed by Somaxon's strategic partner, BioTie Therapies Corp. in 2003. Pathological gambling is a growing health concern that has been recognized in the Diagnostic and Statistical Manual of Mental Disorders of the American Psychiatric Association since 1980. It is estimated that in North America there are approximately 3 million pathological gamblers. Pathological gambling is designated as an Impulse

Control Disorder (ICD). Impulse Control disorders are similar to other addictions and include pyromania, kleptomania, and intermittent explosive disorder. Pathological gambling and other ICDs represent a significant unmet medical need as there is no approved drug therapy to treat these disorders. Somaxon is planning to initiate studies of oral nalmefene in both pathological gambling and nicotine dependence in 2005.

The Company also has in-licensed the worldwide rights to the use of acamprosate, a GABA-A agonist and NMDA antagonist, for the treatment of movement disorders and other conditions and is initiating product development work on this compound.

For more information, please contact Ken Cohen, President and CEO (858.509.3670) or 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 may be 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, statements about: the progress and timing of its clinical trials; difficulties or delays in development, testing, obtaining regulatory approval, producing and marketing its products; unexpected adverse side effects or inadequate therapeutic efficacy of its product candidates that could delay or prevent product development or commercialization, or that could result in recalls or product liability claims; the scope and validity of patent protection for its product candidates; competition from other pharmaceutical or biotechnology companies; and its ability to obtain additional financing to support its operations. 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.