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**SOMAXON RESUBMITS NEW DRUG APPLICATION FOR  
SILENOR® (DOXEPIN) FOR THE TREATMENT OF INSOMNIA**

**SAN DIEGO, CA – June 4, 2009** – Somaxon Pharmaceuticals, Inc. (Nasdaq: SOMX), a specialty pharmaceutical company focused on the in-licensing, development and commercialization of proprietary branded pharmaceutical products and late-stage product candidates for the treatment of diseases and disorders in the central nervous system therapeutic area, today announced that it has resubmitted its New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for Silenor® (doxepin) for the treatment of insomnia.

The resubmission includes additional statistical analyses of the company's clinical data relating to the durability of subjective sleep maintenance efficacy. It also includes the results of the company's completed clinical trial of doxepin that evaluated the potential for electrocardiogram, or ECG, effects. The results of that clinical trial demonstrated that Silenor had no effect on QT interval prolongation when administered at 6 mg or under exaggerated exposure conditions of 50 mg. The FDA has indicated that the review cycle for the resubmission will be six months.

“We believe that this resubmission fully addresses all of the issues raised in the Complete Response Letter that we received from the FDA on February 25, 2009 and further clarified in our meeting with the FDA on April 6,” said Richard W. Pascoe, Somaxon's president and chief executive officer. “We are confident that the additional clinical efficacy data analyses included in the resubmission demonstrate sustained subjective sleep maintenance efficacy in adults. Based on those analyses, as well as the favorable results from our ECG study, we believe that the resubmission can support a determination by the FDA that Silenor be approved for the treatment of insomnia.”

“Silenor is highly differentiated from currently available insomnia treatments and has significant commercial potential, if it is approved by the FDA,” continued Pascoe. “With this potential in mind, we intend to advance our current discussions relating to a commercial partnership for Silenor, with the goal of entering into an agreement that will maximize the commercial success of Silenor, if it is approved by the FDA. In addition, during June we intend to seek to raise cash in an amount sufficient to fund our operations at least through the FDA review period.”

### **Silenor Regulatory Background**

On February 25, 2009, Somaxon received a Complete Response Letter from the FDA relating to its NDA for Silenor for the treatment of insomnia. Based on its review, the FDA determined that the NDA could not be approved in its then-current form. In the Complete Response Letter, the FDA raised a number of issues relating to the interpretation of the efficacy data contained in the Silenor NDA and indicated that the FDA was open to a discussion of these concerns.

With respect to safety, the FDA noted that there were no adverse events observed that would preclude approval, but asked the company to address the possibility that doxepin may prolong the cardiac QT interval. Somaxon responded by submitting to the FDA the results of its completed clinical trial of doxepin that evaluated the potential for ECG effects. The results of this clinical trial demonstrated that doxepin had no effect on QT interval prolongation when administered at 6 mg or under exaggerated exposure conditions of 50 mg.

Somaxon held a meeting with the FDA on April 6, 2009 to discuss the issues raised in the Complete Response Letter. In the meeting, the FDA stated that to obtain approval of a chronic insomnia treatment, objective and subjective efficacy must be established in adult and elderly patient populations, and efficacy must be shown both at the beginning of treatment and on a persistent basis, defined as at least one month. No additional safety issues were raised in the meeting, and the FDA has not requested that the company conduct additional clinical trials of Silenor.

Based on the feedback it received at the meeting, Somaxon conducted additional analyses of its clinical data, focusing on the durability of subjective sleep maintenance efficacy in adults with primary insomnia, and included them in its resubmission to the FDA.

In addition, based on the Complete Response Letter and its meeting with the FDA, Somaxon will no longer pursue approval of a 1 mg dose of Silenor, nor will it seek approval of a statement in the

indication section of the label that clinical trials of Silenor have demonstrated improvement in sleep onset.

Somaxon submitted the NDA for Silenor under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, which allows the company to rely on published literature reports or the FDA's findings of safety and efficacy for other formulations of doxepin that have previously been approved by the FDA. The NDA includes the data from Somaxon's completed clinical development program for Silenor, which included six randomized, double-blind, placebo-controlled, multi-center clinical trials designed to assess the efficacy and safety of Silenor for the treatment of insomnia. All of the clinical trials demonstrated statistically significant differences relative to placebo on their primary endpoints and multiple secondary endpoints. Four of these were Phase 3 clinical trials.

The NDA submission also includes data from Somaxon's non-clinical development program, including the genotoxicity, reproductive toxicology and 26-week transgenic mouse carcinogenicity studies of Silenor, which were undertaken based on a previous request from the FDA. The company continues to plan to submit the results of its standard two-year carcinogenicity study as a post-approval commitment. Somaxon initiated that study in August 2007 and expects data from the study in the first quarter of 2010.

#### **About Somaxon Pharmaceuticals, Inc.**

Headquartered in San Diego, CA, Somaxon Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on the in-licensing, development and commercialization of proprietary branded pharmaceutical products and late-stage product candidates for the treatment of diseases and disorders in the central nervous system therapeutic area. Somaxon has submitted a New Drug Application for its product candidate, Silenor® (doxepin) to the U.S. Food and Drug Administration.

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. For example, statements regarding the review process and the potential approval of the NDA for Silenor, including the conduct and the interpretation of the results of additional analyses of Silenor clinical data contained therein, the intention to seek additional funding and discussions with potential commercial partners 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, Somaxon's interpretation of its communications and interactions with the FDA relating to the requirements for approval of the NDA for Silenor, and the FDA's agreement with such interpretation; Somaxon's interpretation of the results of clinical trials for Silenor, the timing of the interpretation of such results and the FDA's agreement with such interpretation; the potential for Silenor to receive regulatory approval for one or more indications on a timely basis or at all; the potential for the FDA to impose non-clinical, clinical or other requirements to be completed before or after regulatory approval*

*of Silenor; Somaxon's ability to demonstrate to the satisfaction of the FDA that potential NDA approval of Silenor is appropriate prior to the completion of standard, long-term carcinogenicity studies, given the context of completed trials and pending studies; the timing and results of non-clinical studies for Silenor, and the FDA's agreement with Somaxon's interpretation of such results; Somaxon's ability to raise sufficient capital to meet FDA requirements and otherwise fund its operations, and the impact of any such financing activity on the level of Somaxon's stock price; the impact of any inability to raise sufficient capital to fund ongoing operations, including the potential to be required to restructure the company or to be unable to continue as a going concern; Somaxon's ability to successfully commercialize Silenor, if it is approved by the FDA; the potential to enter into and the terms of any strategic transaction relating to Silenor; the scope, validity and duration of patent protection and other intellectual property rights for Silenor; whether any approved label for Silenor is sufficiently consistent with such patent protection to provide exclusivity for Silenor; Somaxon's ability to operate its business without infringing the intellectual property rights of others; inadequate therapeutic efficacy or unexpected adverse side effects relating to Silenor 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; the market potential for insomnia treatments, and Somaxon's ability to compete within that market; and other risks detailed in Somaxon's prior press releases as well as in its 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 press release to reflect events or circumstances after the date hereof. This caution is made under the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934.*

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