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## **SOMAXON PROVIDES UPDATE ON NEW DRUG APPLICATION FOR SILENOR® (DOXEPIN) FOR THE TREATMENT OF INSOMNIA**

**SAN DIEGO, CA – April 7, 2009** – Somaxon Pharmaceuticals, Inc. (Nasdaq: SOMX), a specialty pharmaceutical company focused on the in-licensing, development and commercialization of proprietary branded pharmaceutical products for the treatment of diseases and disorders in the central nervous system therapeutic area, today provided an update on the status of its New Drug Application (NDA) for Silenor® (doxepin) for the treatment of insomnia.

Somaxon held a meeting with the Division of Neurology Products of the U.S. Food and Drug Administration (FDA) on April 6, 2009 to discuss the issues raised in the Complete Response Letter it previously received from the FDA relating to the Silenor NDA. 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. 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.

Based on the feedback it received at the meeting, Somaxon plans to conduct additional analyses of its clinical data focused on the durability of subjective sleep maintenance efficacy in adults with primary insomnia. The company will complete these analyses as soon as possible.

If the company believes that its additional data analyses demonstrate that Silenor can meet the FDA's criteria for approvability, it will include the analyses in a resubmission to the FDA. The FDA has indicated that the review cycle for any such resubmission would be six months from the date of the resubmission.

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.

“We believe that our meeting with the FDA resulted in increased clarity regarding the clinical efficacy evidence necessary to support a determination by the FDA that Silenor can be approved for the treatment of insomnia,” said Richard W. Pascoe, Somaxon’s president and chief executive officer. “In addition, the FDA acknowledged receipt of our previous submission of the data from our ECG study, and no additional safety issues were raised.”

### **Silenor Regulatory Background**

On February 25, 2009, Somaxon received a Complete Response Letter from the FDA for its NDA for Silenor for the treatment of insomnia. Based on its review, the FDA determined that the NDA could not be approved in the form submitted.

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. The FDA has not specifically requested that the company conduct additional clinical trials of Silenor. The company’s meeting with the FDA on April 6, 2009 was for the purpose of gaining a more complete understanding of the implications of the issues raised in the Complete Response Letter.

With respect to safety, the FDA noted in the Complete Response Letter that there were no adverse events observed in the clinical studies included in the NDA that would preclude approval, but asked the company to address the possibility that doxepin may prolong the cardiac QT interval. The company responded in March 2009 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 Silenor had no effect on QTc interval prolongation when administered at 6 mg or under exaggerated exposure conditions of 50 mg.

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 hydrochloride 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 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, which is a two-year carcinogenicity study in rats, 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 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 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 the clinical trials for Silenor, the timing of the interpretation of such results and the FDA's agreement with such interpretation; the potential for Somaxon to make a resubmission to the Silenor NDA; 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 to meet its obligations to parties with whom it contracts relating to financing activity, 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 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 Securities Exchange Act of 1934.*

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