



SOMAXON RECEIVES COMPLETE RESPONSE LETTER FROM THE FDA FOR SILENOR[®] NDA

SAN DIEGO, CA – December 7, 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 the company has received a Complete Response Letter from the U.S. Food and Drug Administration (FDA) for its New Drug Application (NDA) for Silenor[®] (doxepin) for the treatment of insomnia. Based on its review, the FDA has determined that the NDA cannot be approved in its present form. Somaxon previously received a Complete Response Letter for the NDA in February 2009, and it resubmitted the NDA in June 2009.

In the most recent Complete Response Letter, the FDA stated that the Silenor NDA did not meet the approval standard for efficacy due to a lack of robustness of sustained subjective sleep maintenance efficacy in adults with primary insomnia.

With respect to safety, the most recent Complete Response Letter did not raise any clinical safety issues. This is consistent with the February 2009 Complete Response Letter, in which the FDA noted that there were no adverse events observed in the clinical studies included in the NDA that would preclude approval. The most recent Complete Response Letter did request that the company submit an amended Risk Evaluation and Mitigation Strategy (REMS), including a Medication Guide to be distributed with the product, in any resubmission of the NDA.

Because the most recent Complete Response Letter did not contain any specific requirement to conduct any additional clinical work or other specific guidance to address the issue raised by the FDA, Somaxon believes that a meeting with the FDA will be necessary to discuss the basis for the FDA's decision and to seek such specific guidance. The company intends to schedule this meeting as soon as possible.

“We are disappointed in the decision because we believed that our June NDA resubmission adequately addressed the concerns raised by the FDA in its February Complete Response Letter,” said Richard W. Pascoe, Somaxon’s president and chief executive officer. “We have carefully reviewed the current Complete Response Letter and have requested a formal meeting with senior FDA leadership to discuss its conclusions.”

“In the February Complete Response Letter, the FDA acknowledged objective and subjective efficacy at the beginning and end of treatment in elderly patients, and at the beginning of treatment for non-elderly adult patients, and the most recent Complete Response Letter did not alter those conclusions,” continued Pascoe. “In addition, statistical significance on the primary endpoint and multiple secondary endpoints was achieved for all of our four Phase 3 clinical trials and both of our Phase 2 clinical trials for Silenor. We are consulting with our clinical and regulatory advisors and intend to take all steps we deem appropriate to seek approval and commercialization of this product candidate.”

About Silenor[®]

Silenor is a low-dose (3 mg, 6 mg) oral tablet formulation of doxepin hydrochloride that is patent protected for use in insomnia. Physicians have prescribed doxepin for more than 35 years for the treatment of depression and anxiety at dosages typically ranging from 75 mg to 300 mg per day. Based upon the controlled clinical trials of Silenor completed by Somaxon, the company believes that Silenor may be well tolerated by patients. In addition, the FDA has indicated that it will recommend that Silenor not be scheduled as a controlled substance.

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.

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. For example, statements regarding the review process for the NDA for Silenor and the company’s plans to seek the potential approval or commercialization of 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 its 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; 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; 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 submission of the results 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 successfully commercialize Silenor, if it is approved by the FDA; the potential to enter into and the terms of any commercial partnership or other 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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