



## **Somaxon Pharmaceuticals Announces Presentation of Silenor® Data at National Medical Meetings**

### **Researchers to present new analyses of Silenor® (doxepin) clinical data at the American Psychiatric Association, Associated Professional Sleep Societies and American Academy of Nurse Practitioners meetings**

**SAN DIEGO, CA - May 17, 2011** - Somaxon Pharmaceuticals, Inc. (NASDAQ: SOMX), a specialty pharmaceutical company, today announced that it will present new analyses of data from the Silenor Phase 3 clinical development program at the American Psychiatric Association (APA) 164<sup>th</sup> Annual Meeting, the Associated Professional Sleep Societies (APSS) 25<sup>th</sup> Annual Meeting and the American Academy of Nurse Practitioners (AANP) 26<sup>th</sup> National Conference.

"We are excited to be presenting these new analyses of Silenor data at these important medical meetings. By examining specific patient groups and patient-reported outcomes in our pivotal clinical trials, we hope to provide the medical community with further support for Silenor's utility in the treatment of insomnia characterized by difficulties with sleep maintenance," said Brian T. Dorsey, Somaxon's Senior Vice President, Technical Operations.

**A summary of the data presentations is as follows:**

#### **Somaxon's Poster Presentations at APA in Honolulu, HI on Tuesday, May 17<sup>th</sup>**

- APA Poster Presentation # NR10-45; **Improvement in Sleep Maintenance and Early Morning Awakenings in Adult and Elderly Patients with Insomnia Treated with Doxepin 3 and 6 mg**
- APA Poster Presentation # NR10-42; **Patient-Reported Symptom Improvement in Sleep Maintenance Endpoints in Adult and Elderly Patients with Insomnia Treated with Doxepin 3 and 6 mg**

#### **Somaxon's Poster Presentation at APSS in Minneapolis, MN on Monday, June 13<sup>th</sup>**

- APSS Poster Presentation # 198; **Improvement in Sleep Maintenance and Early Morning Awakenings in Adult and Elderly Patients with Insomnia Treated with Doxepin 3 and 6 mg**

#### **Somaxon's Oral Presentation at APSS in Minneapolis, MN on Wednesday, June 15<sup>th</sup>**

- APSS Abstract # 1051955: **Session 039; Patient-Reported Symptom Improvement in Sleep Maintenance Endpoints in Adult and Elderly Patients with Insomnia Treated with Doxepin 3 and 6 mg**

#### **Somaxon's Poster Presentations at AANP in Las Vegas, NV June 22<sup>nd</sup> - 26<sup>th</sup>**

- AANP Poster Presentation; **Improvement in Sleep Maintenance and Early Morning Awakenings in Adult and Elderly Patients with Insomnia Treated with Doxepin 3 and 6 mg**
- AANP Poster Presentation; **Patient-Reported Symptom Improvement in Sleep Maintenance Endpoints in Adult and Elderly Patients with Insomnia Treated with Doxepin 3 and 6 mg**
- AANP Poster Presentation; **Results from Clinical Trials Using Low-Dose Doxepin: Treatment Responders Defined by Categorical Criteria**

**About the Silenor Data**

- **Improvement in Sleep Maintenance and Early Morning Awakenings in Adult and Elderly Patients with Insomnia Treated with Doxepin 3 and 6 mg: Silenor 3 mg and 6 mg** demonstrated significant improvements in wake after sleep onset (WASO), subjective wake after sleep onset (sWASO) and sleep efficiency in the last quarter of the night (SE-LQ) that were consistent across four Phase 3 clinical trials and maintained at the final time point for all but one assessment. Across the clinical trials, these effects were not accompanied by clinically significant next day residual effects, and the dosages of Silenor were well-tolerated. These data suggest Silenor is effective and well tolerated for the treatment of both sleep maintenance (WASO and sWASO) and early morning awakenings (SE-LQ) in transient and chronic insomnia populations.
- **Patient-Reported Symptom Improvement in Sleep Maintenance Endpoints in Adult and Elderly Patients with Insomnia Treated with Doxepin 3 and 6 mg:** Across two Phase 3 clinical trials measuring subjective endpoints of sleep maintenance, Silenor 3 mg and 6 mg in adult patients and 3 mg in elderly patients achieved significant improvements that were sustained (up to three months) compared with placebo, in subjective wake after sleep onset (sWASO) and total sleep time (sTST). In both clinical trials, these effects were not accompanied by clinically significant next day residual effects and the dosages of Silenor were well-tolerated. These data suggest Silenor is effective and well tolerated for the treatment of insomnia characterized by sleep maintenance in both adult and elderly populations.
- **Results from Clinical Trials Using Low-Dose Doxepin: Treatment Responders Defined by Categorical Criteria:** An analysis of three Phase 3 clinical trials (two in adults and one in the elderly) demonstrated that Silenor treatment resulted in substantial increases in the percentage of subjects responding to treatment relative to placebo.

### About Silenor®

Silenor is a low-dose (3 mg and 6 mg) oral tablet formulation of doxepin, and is the first and only non-scheduled prescription sleep medication approved to treat insomnia characterized by difficulties with sleep maintenance. Sleep maintenance is defined as waking frequently during the night and/or waking too early and being unable to return to sleep. For more information, please visit [www.silenor.com](http://www.silenor.com).

### Important Safety Information

A doctor should be consulted if insomnia worsens or is not better within 7 to 10 days. This may mean that there is another condition causing the sleep problem.

Patients should be sure that they are able to devote 7 to 8 hours to sleep before being active again. Silenor should be taken within 30 minutes of bedtime. Patients should not take Silenor with alcohol or with other medicines that can cause drowsiness. Silenor should not be taken with or within two weeks after taking a monoamine oxidase inhibitor (MAOI). Patients should not take Silenor if they have untreated narrow angle glaucoma, if they have severe urinary retention, if they have severe sleep apnea or if they are allergic to any of the ingredients in Silenor. Until patients know how they will react to Silenor, they should not drive or operate machinery at night after taking Silenor, and they should be careful in performing such activities during the day following taking Silenor. Before taking Silenor, patients should tell their doctors if they have a history of depression, mental illness or suicidal thoughts. Patients should call their doctors right away if after taking Silenor they walk, drive, eat or engage in other activities while asleep. Drowsiness was the most common adverse event observed in clinical trials.

For more information, please see the complete Prescribing Information, including the Medication Guide, at [www.silenor.com](http://www.silenor.com) or [www.somaxon.com](http://www.somaxon.com).

### 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 to treat important medical conditions where there is an unmet medical need and/or high-level of patient dissatisfaction, currently in the central nervous system therapeutic area. Somaxon's product Silenor® (doxepin), now available by prescription in the United States, is indicated for the treatment of insomnia characterized by difficulties with sleep maintenance.

To be added to Somaxon Pharmaceuticals' email list, please visit <http://bit.ly/Somaxon-email-list>.

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 clinical data relating to Silenor and Somaxon's interpretation of such data 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, inadequate therapeutic efficacy or unexpected adverse side effects relating to Silenor that could result in recalls or product liability claims; other difficulties or delays in development, testing, manufacturing and marketing of Silenor; the timing and results of post-approval regulatory*

*requirements for Silenor, and the FDA's agreement with Somaxon's interpretation of such results; the market potential for insomnia treatments, and Somaxon's ability to compete within that market; Somaxon's ability to successfully enforce its intellectual property rights and defend its patents, including any developments relating to the recent submission of abbreviated new drug applications for generic versions of Silenor 3 mg and 6 mg tablets and related patent litigation; the possible introduction of generic competition of Silenor; the scope, validity and duration of patent protection and other intellectual property rights for Silenor; whether the approved label for Silenor is sufficiently consistent with such patent protection to provide exclusivity for Silenor; Somaxon's ability to successfully commercialize Silenor; Somaxon's reliance on its co-promotion partner, Procter & Gamble, and its contract sales force provider, Publicis, for critical aspects of the commercial sales process for Silenor; the performance of Procter & Gamble and Publicis and their adherence to the terms of their contracts with Somaxon; the ability of Somaxon's sales management personnel to effectively manage the sales representatives employed by Publicis; the ability of Somaxon to ensure adequate and continued supply of Silenor to successfully meet anticipated market demand; Somaxon's ability to raise sufficient capital to fund its operations, and the impact of any such financing activity on the level of its stock price; the impact of any inability to raise sufficient capital to fund ongoing operations, including any patent infringement litigation; Somaxon's ability to operate its business without infringing the intellectual property rights of others; and other risks detailed in Somaxon's prior press releases and periodic filings with the Securities and Exchange Commission.*

*Readers 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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