

SOMAXON REPORTS RESULTS NOT SIGNIFICANT IN TRIAL OF ORAL NALMEFENE IN PATHOLOGICAL GAMBLING- MENTAL HEALTH

somaxon

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Somaxon Pharmaceuticals, Inc. (SOMX) announced results from the company's phase 2/3 clinical trial evaluating 20 mg and 40 mg of oral nalmefene hydrochloride, an opiate antagonist, in patients with a diagnosis of pathological gambling.

Nalmefene did not demonstrate a statistically significant difference compared to placebo on the primary endpoint, mean PG-YBOCS (Yale Brown Obsessive Compulsive Scale modified for Pathological Gambling) as measured at week 12 of the treatment period, for either of the doses studied. In addition, neither dose achieved statistical significance on the secondary endpoints in the trial. The most frequently reported adverse events were insomnia, nausea and dizziness. Elevation in liver enzymes was observed in some nalmefene-treated patients.

Somaxon intends to further assess the results from this clinical trial, both internally and with its licensor. Somaxon also intends to assess the previously reported results from its phase 2 clinical trial evaluating nalmefene for smoking cessation before making determinations regarding the future of the nalmefene program.

Somaxon has previously reported positive results of three phase 3 clinical trials evaluating Silenor for the treatment of insomnia. The company expects results from its remaining phase 3 clinical trial for Silenor in December of this year. Assuming that this final ongoing phase 3 clinical trial and the planned preclinical studies for Silenor are successful and proceed as currently scheduled, Somaxon expects to file a new drug application (NDA) with the U.S. Food and Drug Administration (FDA) for Silenor in the third quarter of 2007. This timing assumes that the initial NDA submission will include all of the data from the company's completed genotoxicity and ongoing reproductive toxicology studies requested by the FDA, but that the FDA will allow the company to submit the data from the requested carcinogenicity studies at a later date.

The FDA has previously indicated to Somaxon that depending on the outcome of the genotoxicity studies, it may be flexible as to the timing of the conduct of the carcinogenicity studies, including the potential that the data from those studies may be submitted as a post-NDA approval commitment. The company has submitted the results of the genotoxicity studies to the FDA and is awaiting a response; as the company previously reported, no signal indicative of genotoxicity was observed in any of those studies.

Headquartered in San Diego, California, Somaxon Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on treatment of diseases and disorders in the fields of psychiatry and neurology.