NEUROGESX

NeurogesX Reports Positive Phase 2 Results for NGX-1998 for Treatment of Postherpetic Neuralgia

Study Results Support 5 Minute Application of Topical Liquid Capsaicin Formulation

Conference Call Today at 8:30am (ET)

SAN MATEO, Calif., Nov. 8, 2011 (GLOBE NEWSWIRE) -- NeurogesX, Inc. (Nasdaq:NGSX), a biopharmaceutical company focused on developing and commercializing novel pain management therapies, announced today positive top-line results from its Phase 2 clinical study of NGX-1998, a topical liquid formulation of high-concentration capsaicin, in patients with postherpetic neuralgia (PHN). The Company believes that the data support moving forward to a Phase 3 clinical development program following an End-of- Phase 2 meeting with the Food and Drug Administration for NGX-1998, which NeurogesX believes could occur in the first half of 2012.

The 12-week, multicenter, randomized, double-blinded, placebo-controlled clinical trial met its protocol-specified objectives, which include the primary endpoint of a percentage change from baseline vs. placebo in a patient-reported numeric pain rating scale (NPRS) score during Weeks 2 through 8. A total of 183 patients were enrolled in the Phase 2 study. Patients were randomized into one of three groups: NGX-1998 capsaicin 10% solution, NGX-1998 capsaicin 20% solution or placebo, according to an unequal allocation scheme of 2:2:1. NGX-1998 exhibited a dose response. Although no topical anesthetic was used during the second stage of the study the patients were able to tolerate the treatment procedure. No patients discontinued the study due to adverse events, and the incidence of adverse events and serious adverse events in patients treated with NGX-1998 were similar to the placebo-treated group.

Mark S Wallace, MD, an investigator in the study, commented, "These top-line data are promising and suggest that a 20% formulation of NGX-1998 may provide similar efficacy and safety as Qutenza, with only a five-minute procedure time, and without the need for a topical anesthetic pretreatment. This data adds to the body of clinical evidence that prescription-strength topical capsaicin treatment can produce long-term relief from certain neuropathic pain conditions. Reduction in pain scores following treatment with NGX-1998 was maintained over the course of the 12-week study."

Dr. Wallace is a Professor of Clinical Anesthesiology and the Chief of the Division of Pain Medicine in the Department of Anesthesiology and the Director of the Division of Clinical Research at University of California at San Diego ("UCSD").

Dr Stephen J. Peroutka, who will become the Executive Vice President and Chief Medical Officer of NeurogesX on November 9, 2011, concluded, "NGX -1998 represents a significant advance in our ongoing efforts to optimize the short term delivery of capsaicin in order to achieve long term analgesic efficacy. We are very pleased with these top-line results. We believe that this study provides initial evidence that NGX-1998 is a safe and effective analgesic following a five minute administration, without the use of a topical anesthetic. We also believe that the study suggests a dose response and separation from inert placebo, which is an important observation that will help us to design our Phase 3 program for NGX-1998. Additionally, we believe that these results will support our initiative to establish a partnership for NGX-1998 in the United States and other markets."

Conference Call Details

The conference call will be held, Tuesday, November 8, 2011 at 8:30 a.m. ET (5:30 a.m. PT). To participate, please dial 1-877-407-0784 or 1-201-689-8560 (International). Slides to be presented live on the call will be available beginning at 7:30 a.m ET. They can be accessed here, or on the Events page under the Investor Relations section of the Company website, www.neurogesx.com.

A replay of the conference call will be available beginning November 8, 2011 at 11:30 a.m. ET (8:30 a.m. PT) and ending on November 15, 2011, by dialing 1-877-870-5176 (USA) or 1-858-384-5517 (International), PIN Number: 382935.

About the Phase 2 Trial for NGX-1998

The Phase 2 clinical study design included two stages. The first stage was designed to determine the shortest tolerable anesthetic pretreatment regimen. The results of this stage of the study indicated that no topical anesthetic was required to achieve the study's tolerability goal. The second stage was designed to evaluate two NGX-1998 dose concentrations using the pretreatment regimens determined during stage 1. The objective of the second stage was to select an appropriate concentration of NGX-1998 for further evaluation in a Phase 3 clinical program.

About NeurogesX, Inc.

NeurogesX, Inc. (Nasdaq:NGSX) is a San Francisco Bay Area-based biopharmaceutical company focused on developing and commercializing novel pain management therapies. NeurogesX was founded on the concept that use of prescription-strength capsaicin could help manage the pain associated with neuropathic pain conditions. Since its inception, NeurogesX has leveraged its passion to help people with pain to efficiently develop this concept, resulting in the commercial launch of Qutenza (capsaicin) 8% patch in 2010. The Company continues to apply its knowledge and expertise in the development of other novel treatments for pain.

The Company's lead product, Qutenza, is a localized dermal delivery system containing prescription strength capsaicin that is currently approved in the United States and the European Union. Qutenza is now available in the United States for the management of neuropathic pain associated with postherpetic neuralgia (PHN). In Europe, Qutenza is being marketed by Astellas Pharma Europe Ltd. (Astellas), the European affiliate of Tokyo-based Astellas Pharma Inc., for the treatment of peripheral neuropathic pain in non-diabetic adults, either alone or in combination with other medicinal products for pain. The Company has submitted a supplemental new drug application (sNDA) to expand the U.S. label for Qutenza for the management of pain due to HIV-associated peripheral neuropathy (HIV-PN), also known as HIV-associated neuropathy (HIV-AN) and HIV-distal sensory polyneuropathy (HIV-DSP).

The Company's most advanced product candidate, NGX-1998, is a topically applied liquid formulation containing a high concentration of capsaicin designed to treat pain associated with neuropathic pain conditions such as PHN. NGX-1998 has completed one Phase 2 study in PHN patients and three Phase 1 studies.

The Company's early-stage pipeline includes pre-clinical compounds which include a number of prodrugs of acetaminophen. The Company has evaluated certain of these compounds *in vitro* and *in vivo*.

Forward Looking Statement

This press release contains forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995 (the Act). NeurogesX disclaims any intent or obligation to update these forward-looking statements, and claims the protection of the Safe Harbor for forward-looking statements contained in the Act. Examples of such statements include but are not limited to statements regarding: the potential for a Phase 2 meeting with the FDA, including the timing of such meeting; the potential safety and efficacy of NGX-1998[, including as compared to Qutenza]; plans with respect to a potential Phase 3 program for NGX-1998; plans to seek a partnership for NGX-1998 in the United States and other markets; and the timing of Dr. Peroutka assuming the position of Executive Vice President and Chief Medical Officer. Such statements are based on management's current expectations, but actual results may differ materially due to various risks and uncertainties, including, but not limited to: difficulties or delays in further clinical development of NGX-1998; NGX-1998, or NeurogesX approved product Qutenza, may have unexpected adverse side effects; unexpected or increased expenses in the continued development of NGX-1998 or Qutenza; market acceptance of NeurogesX's existing product Qutenza; and difficulties in maintaining adequate funding or other resources for NeurogesX operations and development of NGX-1998. For further information regarding these and other risks related to NeurogesX' business, investors should consult NeurogesX' filings with the Securities and Exchange Commission.

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