NEUROGESX

NeurogesX Receives FDA Acceptance for Review of sNDA for Qutenza(R) (capsaicin) 8% Patch for HIV-Associated Peripheral Neuropathy (HIV-PN)

Priority Six Month Review Granted - PDUFA Date of March 7, 2012

SAN MATEO, Calif., Nov. 14, 2011 (GLOBE NEWSWIRE) -- NeurogesX, Inc. (Nasdaq:NGSX), a biopharmaceutical company focused on developing and commercializing novel pain management therapies, today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the Company's supplemental new drug application (sNDA) for Qutenza® (capsaicin) 8% for the management of neuropathic pain associated with HIV-associated peripheral neuropathy (HIV-PN). The FDA has granted Qutenza a priority six month review classification, assigning a Prescription Drug User Fee Act (PDUFA) action date of March 7, 2012.

"The FDA's filing and priority review of our sNDA for Qutenza in HIV-PN is a significant achievement for NeurogesX as we seek to expand our pain management franchise," said Anthony DiTonno, President and CEO of NeurogesX. "This takes us another step forward in our effort to provide lasting relief from one of the most challenging chronic pain conditions. We look forward to our continued discussion with the FDA during the review of this application."

The Qutenza sNDA seeks approval for a 30-minute application for the treatment of neuropathic pain associated with HIV-PN. Qutenza is currently FDA approved as a 60-minute application for the management of neuropathic pain associated with postherpetic neuralgia (PHN). If approved, the company believes that Qutenza would be the first and only product approved to treat HIV-PN in the United States.

About HIV-PN

HIV-PN is the most common neurological complication of HIV infection. Many patients with HIV are afflicted with symptoms ranging from mild tingling to severe and excruciating pain. HIV-PN is thought to be caused by multiple factors related to HIV infection including injury of sensory neurons by HIV virus proteins, the immune system's fight against HIV and some antiretroviral drugs.

About Qutenza

Qutenza (capsaicin) 8% patch, a localized dermal delivery system containing prescription strength capsaicin, is approved by the U.S. Food and Drug Administration (FDA) for the management of neuropathic pain associated with PHN.

Clinical studies have shown that a single one-hour Qutenza application can provide three months relief from pain associated with PHN, the nerve pain that can occur after shingles.

In clinical trials, serious adverse reactions included application-associated pain and increase in blood pressure. The most common treatment-emergent adverse reactions (greater than or equal to 5 percent of Qutenza patients and greater than control) were application-site erythema, application-site pain, application-site pruritus, and application-site papules.

Qutenza is also approved in the European Union and is marketed by Astellas Pharma Europe Ltd. (Astellas), the European affiliate of Tokyo-based Astellas Pharma Inc. In Europe, Qutenza is approved for peripheral neuropathic pain in non-diabetic adults, which includes HIV-PN.

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) previously referred to 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 three Phase 1 clinical trials and one Phase 2 clinical trial in PHN patients.

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*.

Safe Harbor 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 timing of FDA review for the sNDA submission seeking expansion of the U.S. label for Qutenza to include management of pain due to HIV-associated peripheral neuropathy (HIV-PN); that if approved by the FDA, Qutenza is expected to be the first and only product approved in the United States to treat HIV-PN; and the potential benefits of Qutenza. 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 the further development of Qutenza for additional indications, including difficulties or delays in receipt of FDA approval of the sNDA to expand the U.S. label for Qutenza for the management of pain due to HIV-PN; market acceptance of Qutenza in already approved indications may not be sufficient to support further pursuit of an expanded label for Qutenza, including as a result of physician or patient reluctance to use Qutenza; Qutenza and NeurogesX' other product candidates may have unexpected adverse side effects; unexpected or increased expenses in the commercialization and continued development of Qutenza or the development of NGX-1998; and the potential for other products to receive approval by the FDA for treatment of HIV-PN prior to any approval of Qutenza for such indication. 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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Source: NeurogesX

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