NEUROGESX

NeurogesX Submits Supplemental New Drug Application for Qutenza(R) (capsaicin) 8% Patch for HIV-Associated Peripheral Neuropathy (HIV-PN)

- *Received U.S. FDA Orphan Drug and Fast Track Designations for the Potential Use of Qutenza to Treat Painful HIV-PN*
- *Qutenza Currently Approved by U.S. FDA for the Management of Neuropathic Pain Associated With Postherpetic Neuralgia (PHN)*

SAN MATEO, Calif., Sept. 8, 2011 (GLOBE NEWSWIRE) -- NeurogesX, Inc. (Nasdaq:NGSX), a biopharmaceutical company focused on developing and commercializing novel pain management therapies, today announced it submitted a supplemental new drug application (sNDA) to the U.S. Food and Drug Administration (FDA) seeking to expand the label for Qutenza® (capsaicin) 8% patch to include an indication 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 sNDA seeks approval for a 30-minute application of Qutenza for the treatment of neuropathic pain associated with HIV-PN. As part of the application, NeurogesX is also requesting a Priority Review designation. FDA Priority Review status is given to drug candidates that offer major advances in treatment, or provide a treatment where no adequate therapy exists, and accelerates the standard review time from ten months to six months. Qutenza is approved by the FDA as a 60-minute application for the management of neuropathic pain associated with postherpetic neuralgia (PHN), as well as by the European Commission for the treatment of peripheral neuropathic pain in non-diabetic adults either alone or in combination with other medicinal products for pain in all 27 countries of the European Union.

"This is an important step forward as we pursue our strategy to obtain broader market access for Qutenza through the expansion of approved indications," said Anthony DiTonno, President and CEO of NeurogesX. "An approval for this indication would be particularly meaningful as the treatment of HIV-PN represents a significant unmet medical need in the HIV community. Currently, no FDA approved drugs are available to treat this complication."

Mr. DiTonno continued, "Additionally, as Qutenza is a topical treatment with minimal systemic absorption, it is expected to have minimal risk of drug-drug interactions, a feature that is particularly important in this patient population."

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 a prescription strength capsaicin, is approved by the U.S. Food and Drug Administration (FDA) for the management of neuropathic pain associated with postherpetic neuralgia (PHN).

Clinical studies have shown that a single one-hour Qutenza application can provide three months relief from pain associated with postherpetic neuralgia (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 subsidiary of Tokyo-based Astellas Pharma Inc.

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 subsidiary 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 three Phase 1 studies and patient enrollment and dosing has been completed in a 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, including the potential for Priority 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); and the potential benefits of Qutenza (including expectations regarding potential minimal drug-drug interactions of Qutenza and the importance of such factor to the patient population). 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 Priority Review for or 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; and unexpected or increased expenses in the commercialization and continued development of Qutenza or the 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.

CONTACT: NeurogesX, Inc.

Stephen Ghiglieri

Executive Vice President, COO

and CFO

(650) 358-3310

sghiglieri@neurogesx.com

The Ruth Group

Stephanie Carrington (investors)

(646) 536-7017

scarrington@theruthgroup.com

Victoria Aguiar (media)

(646) 536-7013

vaguiar@theruthgroup.com

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