



NeurogesX to Pursue Expanded U.S. Label for Qutenza(R) (capsaicin) 8% Patch in HIV-Associated Neuropathy

Targeting Supplemental New Drug Application in 1H 2011

SAN MATEO, Calif., Oct 18, 2010 /PRNewswire via COMTEX News Network/ -- NeurogesX, Inc. (Nasdaq: NGSX), a biopharmaceutical company focused on developing and commercializing novel pain management therapies, today announced plans to pursue a U.S. label expansion for Qutenza(R) (capsaicin) 8% patch to include patients with painful HIV-associated neuropathy (HIV-AN, also referred to as HIV-distal sensory polyneuropathy (HIV-DSP)).

Following a recent meeting with the U.S. Food and Drug Administration (FDA), NeurogesX plans to submit a supplemental new drug application (sNDA) in the first half of 2011. The submission will utilize data from two completed Phase 3 studies in patients with HIV-AN.

Anthony DiTonno, President and CEO, commented, "As a company, we are focused on addressing unmet medical needs in pain and have made significant progress towards this goal with the U.S. launch of Qutenza. Our decision to submit a supplemental NDA to address the HIV-AN patient population is important as there are currently no FDA approved treatments for HIV-AN. U.S. label expansion to include HIV-AN would reach a new segment of neuropathic pain patients while leveraging our U.S. sales force and their relationships with pain specialists."

Qutenza is currently indicated in the U.S. for the management of neuropathic pain associated with postherpetic neuralgia (PHN), and has been evaluated in two Phase 3 studies in patients with HIV-AN. The FDA has previously granted orphan drug designation for the use of capsaicin to treat painful HIV-AN and fast track designation for Qutenza for the treatment of painful HIV-AN.

HIV-AN 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. HIV-AN is the most common neurological complication of HIV infection, and many of these patients are afflicted with symptoms ranging from mild tingling to severe and excruciating pain.

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 (R) (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'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.

The Company's early-stage product pipeline includes pre-clinical compounds which are prodrugs of acetaminophen and various opioids. The Company has evaluated 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 about NeurogesX' plans to submit a supplemental NDA to the FDA and the timing of such submission; expected data to be included in such submission; additional market reach of expanding the Qutenza label to include treatment of pain associated with HIV-AN and the ability to use the U.S. sales force and other relationships to facilitate commercialization of Qutenza in the potential new indication. 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 submission of the supplemental NDA for Qutenza; data submitted may not be sufficient to support FDA approval of Qutenza in the treatment of pain associated with HIV-AN; 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 potential alternative therapies. 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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