



Centrexion Therapeutics Announces Fast Track Designation Granted by FDA to CNTX-4975 for Treatment of Morton's Neuroma

– CNTX-4975 has potential to be the first non-surgical FDA-approved treatment for orphan disease, painful foot nerve disorder –

Baltimore – November 15, 2016 – Centrexion Therapeutics, a company focused on advancing the treatment of chronic moderate to severe pain with one of the largest exclusively pain-focused pipelines of non-opioid therapies in active development, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to CNTX-4975 for the treatment of Morton's neuroma, a rare, painful nerve disorder in the foot. CNTX-4975, Centrexion's proprietary lead pipeline candidate, is a highly potent, ultrapure, synthetic form of capsaicin (originally derived from the chili plant), called trans-capsaicin, that is designed to be injected directly into the site of pain to provide rapid onset analgesia and a long duration of relief.

Centrexion Therapeutics successfully completed a Phase 2b randomized, double-blind, placebo-controlled, parallel group, single-injection study in patients with Morton's neuroma. An open-label, multiple-dose extension study is ongoing. The FDA previously granted CNTX-4975 orphan drug designation for the treatment of Morton's neuroma pain.

"The FDA's Fast Track designation of CNTX-4975 recognizes the need for a safe and effective treatment for the painful condition of Morton's neuroma that controls pain, but leaves other sensations intact, and could help us expedite the development of this novel, non-opioid pain treatment," said Randall M. Stevens, M.D., chief medical officer for Centrexion Therapeutics. "CNTX-4975 has the potential to become the first non-surgical approach approved by the FDA to treat Morton's neuroma. With today's announcement of Fast Track designation and the orphan drug designation CNTX-4975 previously received, we are excited to continue building on the momentum of our CNTX-4975 program with the upcoming completion of our Phase 2 open-label, multiple-dose study and initiation of a Phase 3 trial in Morton's neuroma."

The FDA's Fast Track process is designed to facilitate the development and expedite the review of drugs used to treat serious conditions and fill an unmet medical need. Fast Track designation enables a company to have early and frequent communication with the FDA throughout the drug development and review process, often leading to earlier drug approval.

About Morton's Neuroma

Morton's neuroma involves a thickening of the tissue around one of the nerves leading to the toes. This can cause a sharp, burning pain in the foot and stinging, burning or numbness in the toes, especially when walking. Repetitive strain on the front of the foot, such as wearing high-heeled shoes or long-distance running, has been linked to the development of Morton's neuroma. Although some people can experience relief by switching to lower-heeled shoes with wider toe boxes or by using orthotics, many require medical intervention for the pain. The current standard of care is a corticosteroid



injection. If a corticosteroid injection fails, one of the only options is surgery to remove the nerve containing the neuroma, resulting in numb toes at the site of removal. There are currently no FDA-approved treatments for Morton's neuroma.

About CNTX-4975

CNTX-4975 is a highly potent, ultrapure, synthetic form of injectable trans-capsaicin. It works by selectively targeting the capsaicin receptor (TRPV1) to rapidly inactivate the local pain fibers transmitting signals to the brain. With a short half-life, trans-capsaicin is cleared from the body within 24 hours. This approach provides pain relief that can last for months until the ends of the local pain fibers regenerate, while leaving the rest of the nerve fiber functioning as normal, and without the risks of toxicities of NSAIDs or the side effects, including abuse and addiction, associated with opioid treatments.

In addition to the ongoing open-label, multiple-dose extension trial in patients with Morton's neuroma pain, CNTX-4975 is currently being evaluated in a Phase 2b study for the treatment of chronic moderate to severe pain from knee osteoarthritis (OA) in humans and in a double-blind trial in pet dogs with OA.

About Centrexion Therapeutics

Centrexion Therapeutics, Corp. is focused on advancing the treatment of chronic moderate to severe pain with one of the largest exclusively pain-focused pipelines of non-opioid therapies in active development. Centrexion Therapeutics recognizes the needs of over a quarter of a billion patients living with chronic pain worldwide, and aims to develop new, safer and more effective therapies that overcome the limitations and challenges associated with current pain treatments. Founded by world-renowned leaders in drug development and well-funded by key investors, Centrexion Therapeutics is building a pain treatment powerhouse to address the substantial and growing global chronic pain epidemic.

For more information about Centrexion, visit <http://www.centrexion.com>.

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