

Centrexion Therapeutics Announces Fast Track Designation Granted by FDA to CNTX-4975 for Treatment of Knee Osteoarthritis Pain

BOSTON, Mass., January 16, 2018 – <u>Centrexion Therapeutics Corporation</u>, a company focused on developing non-opioid, non-steroidal therapeutics for the treatment of chronic pain, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to CNTX-4975 for the treatment of pain associated with knee osteoarthritis. CNTX-4975, Centrexion's Phase 3 ready lead therapy, is a synthetic, ultra-pure injection of trans-capsaicin designed to be injected directly into the painful joint to provide rapid and durable pain relief.

"This is an important milestone for both Centrexion and the millions of people suffering from pain associated with knee osteoarthritis. With the Fast Track approval, we look forward to additional interactions with the FDA to optimize the development of this novel, non-opioid, non-addictive pain treatment," said Randall M. Stevens, M.D., chief medical officer for Centrexion Therapeutics. "Osteoarthritis is a rapidly escalating public health issue projected to affect nearly 67 million Americans by 2030¹ – it is absolutely critical that we continue to advance new pain treatments like CNTX-4975 that have the potential to relieve pain and improve stiffness and function, while avoiding the significant challenges and side effects of currently available therapies. We look forward to building on the momentum of our CNTX-4975 program with the initiation of our Phase 3 program in patients with moderate to severe knee osteoarthritis in the first quarter of 2018."

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

CNTX-4975 is Phase 3 ready for the treatment of two chronic pain conditions: osteoarthritis pain of the knee and pain associated with Morton's neuroma, a rare, painful foot condition. The FDA previously granted CNTX-4975 orphan drug designation and Fast Track designation for the treatment of Morton's neuroma pain. In the Phase 2b TRIUMPH clinical trial, treatment with CNTX-4975 resulted in one of the largest reductions of pain associated with knee osteoarthritis reported in any placebo controlled clinical trial.

About CNTX-4975

CNTX-4975 is based on Centrexion's proprietary STRATI[™] technology (Synthetic TRans cApsaicin ulTra-pure Injection), a highly potent, ultrapure, synthetic form of transcapsaicin (a medicine traditionally derived from the chili plant). CNTX-4975 is designed to be injected directly into the site of pain to provide rapid onset, large reduction and long duration of relief from moderate to severe pain without affecting touch sensibility or position sense.

CNTX-4975 works by targeting the capsaicin receptor (TRPV1) to selectively and rapidly inactivate the local pain fibers transmitting signals to the brain. With a short half-life, CNTX-4975 is cleared from the body within 24 hours. This approach is designed to provide pain relief that can last for months until the ends of the local pain fibers regenerate, while maintaining normal sensation, such as touch, pressure and position, and without the risks of toxicities of NSAIDs and injected corticosteroids, or the side effects, including abuse and addiction, associated with opioid treatments.

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, non-addictive therapies in active development. Centrexion Therapeutics recognizes the needs of over a quarter of a billion people 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.

1. Hootman JM, Helmick CG. Projections of US prevalence of arthritis and associated activity limitations. Arthritis Rheum. 2006;54:226-9.

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