



## **Centrexion Therapeutics Announces First Patient Dosed in Phase 3 Trial of CNTX-4975 for the Treatment of Moderate to Severe Knee Osteoarthritis Pain**

**BOSTON, Mass.**, February 21, 2018 – [Centrexion Therapeutics Corporation](#), a company focused on developing non-opioid, non-steroidal therapeutics for the treatment of chronic pain, today announced that the first patient has been dosed in its Phase 3 VICTORY-1 clinical trial of CNTX-4975, a synthetic, ultrapure injection of trans-capsaicin, for the treatment of chronic moderate to severe pain due to knee osteoarthritis (OA). CNTX-4975 is a highly differentiated, novel, non-opioid therapy that is designed to be injected directly into the painful joint to potentially provide fast-acting and long-lasting pain relief without the risk of abuse and addiction. CNTX-4975 was recently granted Fast Track designation by the U.S. Food and Drug Administration (FDA) for the treatment of moderate to severe pain associated with knee OA.

In the Phase 2b TRIUMPH clinical trial, treatment with a single injection of CNTX-4975 resulted in one of the largest reductions of pain associated with knee OA reported in any placebo-controlled clinical trial. The data showed statistically significant reduction in pain with walking, compared to placebo, beginning at Week 1, and continuing through six months.

“Chronic osteoarthritis pain is an important and rapidly growing public health issue. To improve the quality of life for the millions of people suffering from this condition, we must continue to explore novel approaches that lead to effective and safe therapeutic alternatives,” said Jeffrey B. Kindler, chief executive officer, Centrexion Therapeutics. “The initiation of our Phase 3 development program, with the dosing of the first patient, is a major milestone for both Centrexion and patients with chronic moderate to severe knee OA pain who are seeking better treatment options. We believe that CNTX-4975, which provided substantial, rapid onset pain reduction in patients with moderate to severe OA pain in previous clinical studies, has the potential to be a highly effective therapy that avoids the significant challenges, side effects and potential risks associated with currently available therapies.”

### **About the Phase 3 VICTORY-1 Trial**

The Phase 3 trial is a randomized, double-blind, placebo-controlled, 52-week study to evaluate the safety and efficacy of a single injection of CNTX-4975 in people with chronic moderate to severe OA knee pain. The study will enroll approximately 325 patients aged 40 to 95 years of age. The primary endpoint of the study is the change in pain with walking measured at Week 12, using the Numeric Pain Rating Scale (NPRS). Secondary endpoints include change in pain with walking (Area Under the Curve [AUC]) and change in average knee stiffness and function (Western Ontario and McMaster Universities Osteoarthritis Index [WOMAC B, stiffness and WOMAC C, functional scale]) measured at Week 12. Additional secondary endpoints will be measured out to week 52, including change in knee pain (WOMAC A), knee stiffness and function (WOMAC B and C, respectively), patient global impression of change (PGIC) for the treated knee and quality of life measures.

More information about VICTORY-1 can be found at <http://www.centrexion.com> or [www.clinicaltrials.gov](http://www.clinicaltrials.gov) under trial identifier NCT03429049.

### **About Osteoarthritis**

Osteoarthritis (OA) is the most common form of arthritis, affecting approximately 14 million people in the United States. OA occurs when the protective cartilage on the ends of the bones wears down over time, and the bone around the joints harden and form edges. These changes cause pain, swelling and problems moving the joint. OA also causes an inflammatory process to occur in the affected joint, further damaging the cartilage. Although OA can damage the majority of joints in the body, it most commonly affects joints in the knees, hips, hands and spine. OA can cause pain severe enough that patients

experience difficulty walking, climbing stairs or even rising from a chair. Despite currently available therapies, many patients opt for total joint replacement to manage the painful condition.

#### **About CNTX-4975**

CNTX-4975 is based on Centrexion's proprietary STRATI™ technology (Synthetic TRans cApsaicin ulTra-pure Injection), a highly potent, ultra-pure, synthetic form of trans-capsaicin. 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 joint 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. In January 2018, CNTX-4975 was granted Fast Track designation by the U.S. Food and Drug Administration for the treatment of pain associated with knee osteoarthritis.

#### **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 Therapeutics, visit <http://www.centrexion.com>.

1. Deshpande, B., et al. Number of Persons With Symptomatic Knee Osteoarthritis in the US: Impact of Race and Ethnicity, Age, Sex, and Obesity. *Arthritis Care & Research*. Published online November 3, 2016

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