

# Centrexion Therapeutics Announces Completion of Patient Enrollment in Pivotal Phase 3 Clinical Trial of CNTX-4975 for the Treatment of Moderate to Severe Knee Osteoarthritis Pain

**BOSTON, Mass.**, December 5, 2018 – Centrexion Therapeutics Corporation, a company focused on developing non-opioid, non-addictive therapeutics for the treatment of chronic pain, today announced completion of patient enrollment ahead of schedule in its pivotal Phase 3 VICTORY-1 trial, a randomized, double-blind, placebo-controlled, 325-patient, 52-week clinical trial to evaluate the safety and efficacy of a single intra-articular injection of CNTX-4975 in subjects with chronic moderate-to-severe knee osteoarthritis (OA) pain. Topline results from VICTORY-1 are expected to be reported in the first quarter of 2020.

CNTX-4975 is an ultra-pure, synthetic form of trans-capsaicin that is injected directly into the joint where the pain stimulus originates. It is designed to harness the natural analgesic power of capsaicin through a proprietary injectable therapeutic candidate intended to provide durable pain relief within days of administration. CNTX-4975 is designed to induce a localized degeneration of pain sensing fibers without affecting other sensory nerve fibers. In January 2018, CNTX-4975 received Fast Track designation by the U.S. Food and Drug Administration (FDA) for the treatment of moderate to severe pain associated with knee OA.

"The completion of patient enrollment in VICTORY-1 is an important milestone not only for Centrexion, but also for patients with chronic knee OA pain who seek better treatment options," said Jeffrey B. Kindler, chief executive officer of Centrexion Therapeutics. "VICTORY-2, the second pivotal trial which includes repeat dosing, is also underway, with site initiation and enrollment progressing as anticipated. The OA-303 open label, eight-week study in 850 subjects is enrolling on schedule and we expect to have topline results reported in 2019."

Randall Stevens, M.D., chief medical officer of Centrexion, said, "We have designed the OA-303 study to provide additional information beyond just fulfilling the required safety database. The study design includes efficacy readouts in additional patient populations such as injection of CNTX-4975 in both knees in patients with bilateral knee OA pain and patients with prior knee joint replacement in the non-index knee. It will also evaluate variations of the CNTX-4975 administration procedure designed to enable physicians to select options that best fit their practice dynamics and patient needs."

## About the Pivotal Phase 3 VICTORY-1 Trial

The pivotal 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 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 at Week 12 include improvement in the 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), functional outcomes and quality of life measures.

### **About CNTX-4975**

CNTX-4975, Centrexion's most advanced product candidate, is an investigational synthetic, ultra-pure intra-articular injection of trans-capsaicin for the treatment of moderate to severe pain associated with knee OA. CNTX-4975 is designed to be administered directly into the joint where the pain stimulus originates and to selectively and locally target and disrupt the signaling of pain-sensing nerve fibers. In January 2018CNTX-4975 was granted Fast Track Designation by the U.S. Food and Drug Administration for the treatment of pain associated with knee OA.

## **About Centrexion Therapeutics**

Centrexion is a late clinical-stage biopharmaceutical company focused on becoming the leader in identifying, developing and commercializing novel, non-opioid and non-addictive therapies to address the large unmet medical need for the treatment of chronic pain. Centrexion's website address is http://www.centrexion.com.

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