



## **Centrexion Therapeutics Announces Issuance of U.S. Composition of Matter Patent for Lead Pipeline Candidate CNTX-4975**

*-- Patent Underpins CNTX-4975 Formulation Technology and Provides Intellectual Property Protection into 2037 --*

**BOSTON, Mass.**, December 3, 2019 – Centrexion Therapeutics Corporation, a company focused on developing non-opioid, non-addictive therapies for the treatment of chronic pain, today announced that the U.S. Patent and Trademark Office has issued a composition of matter patent (Patent No. 10,493,047) entitled “Stable Aqueous Capsaicin Injectable Formulations and Medical Uses Thereof,” which provides coverage for the formulation of capsaicin used in the company’s CNTX-4975 product candidate. The patent describes and claims an aqueous, injectable, ready-to-use formulation of capsaicin.

CNTX-4975, the company’s lead product candidate, is an investigational synthetic, proprietary, ultra-pure intra-articular injection of a selective TRPV1 agonist (capsaicin) currently in pivotal clinical trials for the treatment of moderate-to-severe pain associated with knee osteoarthritis (OA).

“We are extremely pleased with the issuance of this patent for CNTX-4975 that supports the easy-to-use, room temperature-stable, prefilled syringe for administration, and believe it is an important milestone for Centrexion,” said Jeffrey B. Kindler, chief executive officer of Centrexion Therapeutics. “As we complete our pivotal clinical trials for CNTX-4975 for moderate-to-severe pain associated with knee OA, this additional protection is an important component in establishing a solid foundation for a successful commercialization plan.”

CNTX-4975 is designed to be administered directly into the joint (intra-articular [IA]) where the pain stimulus originates, and to selectively and locally target and disrupt the signaling of specific TRPV1 pain-signaling nerve fibers within the joint. In January 2018, CNTX-4975 was granted Fast Track designation by the U.S. Food and Drug Administration for the treatment of moderate-to-severe pain associated with knee OA. Centrexion has completed patient enrollment in all three studies comprising the Phase 3 VICTORY clinical program and expects to report the results of VICTORY-1 and VICTORY-3 in the first quarter of 2020. Centrexion anticipates reporting the results of the second pivotal trial, VICTORY-2, in the third quarter of 2020.

### **About the Phase 3 VICTORY Program**

The Phase 3 VICTORY clinical program consists of three trials. VICTORY-1 and VICTORY-2 are pivotal, randomized, double-blind, placebo-controlled, 52-week clinical trials to evaluate the efficacy and safety of intra-articular (IA) injections of CNTX-4975 in people with chronic, moderate-to-severe pain resulting from knee osteoarthritis (OA). VICTORY-1 is a 332-patient, single IA dose trial to evaluate a single injection of CNTX-4975. VICTORY-2 is a 331-patient trial that includes a repeat dose, administered six months after the first IA injection. The primary endpoint of both trials is the change in pain with walking measured at Week 12, using the numeric pain rating scale (NPRS [0-10]). Secondary endpoints at Week 12 include improvement in the average pain,



stiffness and function (subparts A, B and C of the Western Ontario and McMaster Universities Osteoarthritis Index, WOMAC) measured at Week 12. Additional secondary endpoints will be measured out to week 52, including other variables such as patient global impression of change (PGIC), functional outcomes, quality of life measures and change in knee radiographs from baseline to Week 52.

VICTORY-3 trial is an open label, eight-week trial to evaluate the tolerability of a single IA injection of 1.0 mg of CNTX-4975 in 856 patients with chronic moderate-to-severe pain resulting from knee OA. In addition to expanding the safety database for CNTX-4975, VICTORY-3 is evaluating three patient groups (single painful knee, single painful knee with the opposite knee having a joint replacement, and bilateral painful knee OA where both knees are treated) as well as variations of the procedure pain control technique designed to enable physicians to select options that could best fit their practice dynamics and patient needs if CNTX-4975 is approved.

Patients enrolled in the Phase 3 VICTORY program were permitted to enter the trials on their oral standard of care analgesics for their painful knee OA, such as NSAIDs and an opioid.

#### **About Osteoarthritis**

Osteoarthritis (OA) is the most common joint disease in the U.S., currently affecting more than 30 million Americans, according to the U.S. Centers for Disease Control. OA occurs when cartilage, the tissue that envelops the structural bones within a joint, gradually deteriorates. These changes cause pain, swelling and problems moving the joint. Although OA can affect any joint, it most often affects joints in the knees, hips, lower back and neck, small joints of the fingers and the bases of the thumb and big toe. Over time, patients with knee OA tend to become inactive due to pain and joint stiffness and reduced function.

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

CNTX-4975, Centrexion's most advanced product candidate, is an investigational synthetic, proprietary, ultra-pure intra-articular injection of a selective TRPV1 agonist (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 TRPV1 pain-signaling nerve fibers. In January 2018, CNTX-4975 was granted Fast Track Designation by the U.S. Food and Drug Administration for the treatment of moderate-to-severe pain associated with knee OA.

#### **About Centrexion Therapeutics Corporation**

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.

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