



## **Centrexion Therapeutics to Present New Positive Clinical Trial Results on Streamlined CNTX-4975 Administration Techniques**

-- *Administration procedure designed to optimize physician and patient experience and convenience --*

-- *Company also shares interim analysis of 719 patients in VICTORY-3 Phase 3 open-label trial indicating the studied streamlined administration procedures maintain patient comfort --*

-- *Data to be presented at the 2019 Florida Society of Interventional Pain Physicians Conference --*

**BOSTON, Mass.**, July 18, 2019 – Centrexion Therapeutics Corporation, a company focused on developing non-opioid, non-addictive therapeutics for the treatment of chronic pain, today announced that it will present new data from clinical trials of CNTX-4975, including an assessment of refinements of the company's proprietary method for CNTX-4975 administration, at the 2019 Florida Society for Interventional Pain Physicians Conference (FSIPP), taking place July 18-21, 2019 in Hollywood, Florida.

"This open-label trial in patients with bilateral, painful knee osteoarthritis (OA), tested shorter durations of cooling and different types of cooling methods, including readily available devices such as ice-gel packs, as well as using one- or two- intra-articular (IA) injection techniques for lidocaine and 1.0 mg of CNTX-4975," said Randall M. Stevens, M.D., chief medical officer of Centrexion. "We are pleased with the newest results, which are consistent with other clinical trials, which showed that the refinements to our proprietary technique for IA) injection of CNTX-4975 for painful knee OA were able to reduce post-procedure discomfort."

In this presentation of the clinical trial, 10 patients with bilateral painful knee OA received an IA injection of CNTX-4975 in the first knee, followed by a treatment of the second knee seven days later.

- Mean pain with walking scores decreased from 5.9 at baseline to 1.6, using the Numeric Pain Rating Scale (NPRS; 0-10) at day 42, for a 73% pain reduction ( $P<0.001$ , two-tailed, paired  $t$  test).

- Five to six weeks post-procedure, seven patients reported a pain level ≤2, and three patients reported no pain in either knee.
- All patients reported improvement in both knees using the Patient Global Impression of Change.

These results are consistent with the pain reductions reported in the Phase 2 double-blind, randomized, controlled trial evaluating a single injection of CNTX-4975 1.0 mg in patients with moderate-to-severe OA knee pain (TRIUMPH)<sup>1</sup>.

### **Ongoing Assessment of Methods to Optimize the CNTX-4975 Administration Procedure**

Two cooling devices are being assessed in the ongoing Phase 3 VICTORY-3 open label, 8-week clinical trial to manage post-procedure comfort: an ice-water cooling pump with a knee wrap and an ice-gel pack knee wrap. This study also investigates shorter cooling times and the use of one- or two-injection techniques for lidocaine and 1.0 mg of CNTX-4975. In total, five variants of the administration procedure are incorporated into the trial.

- An interim analysis based on data from 719 patients (1,087 knees treated) of the planned 850, suggests overall post-procedure discomfort across the groups has been well managed and similar to that observed with the 1.0 mg CNTX-4975 group in the TRIUMPH trial.
- The average overall post-procedure discomfort 30-minutes after treatment was similar to or less than the average overall baseline knee pain at rest before the procedure and ranged from 1.4 to 2.0 (0-4 scale), depending on the group.
- IA injection technique using a single needle with lidocaine and CNTX-4975 injections separated by three minutes was as well tolerated as lidocaine and CNTX-4975 given with two separate injections, separated by 30 minutes of cooling.

“In this ongoing Phase 3 VICTORY-3 trial, we have interim data that show reductions in pain with walking similar to those observed in the Phase 2 trial. In particular, as with prior trials, patients with moderately severe to severe pain on average experienced a reduction to mild pain. More than 80% of patients with bilateral painful knee OA received the second treatment into the other painful OA knee one week later. In addition, of the bilateral subjects that did not have the other knee treated, the majority indicated that they were mostly or completely satisfied with the first procedure,” continued Dr. Stevens. “We intend to continue to evaluate variations of the CNTX-4975 administration procedure designed to optimize the physician and patient experience and convenience.”

Details of the abstracts and poster presentations are listed below.

**Title:** Efficacy of Bilateral Intra-articular CNTX-4975 Injection for Management of Painful Knee Osteoarthritis

**Presentation Time:**

Friday, July 19: 10:15am – 10:45am, 3:30pm – 4:00pm

Saturday, July 20: 10:00am – 10:30am, 3:00pm – 3:30pm

**Location:** Diplomat 1-3

**Online publication:**

<https://www.fsipp-conference.com/pdf/FSIPP 2019 Educational Guide.pdf>

**Title:** Assessment of Cooling Methods for Reducing Procedural Pain Associated With CNTX-4975 Injection for the Management of Painful Knee Osteoarthritis

**Presentation Time:**

Friday, July 19: 10:15am – 10:45am, 3:30pm – 4:00pm

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### About the Phase 3 VICTORY Program

The Phase 3 VICTORY clinical program consists of three studies. 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 dose study to evaluate a single injection of CNTX-4975. VICTORY-2 is a 332-patient study evaluating a repeat dose, administered 6 months after the first dose. The primary endpoint of both studies 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 knee stiffness and function (Western Ontario and McMaster Universities Osteoarthritis Index [WOMAC B, stiffness and WOMAC C, functional scale]). 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), the Knee Injury and Osteoarthritis Scale, and additional patient reported outcome measures. The VICTORY-3 trial is an open label, 8-week trial to evaluate the safety of a single IA injection of 1.0 mg of CNTX-4975 into one or two knees in 850 patients with chronic moderate-to-severe pain resulting from knee OA. In addition to expanding the safety database for CNTX-4975, VICTORY-3 is also evaluating 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.

## **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, with similar prevalence in Europe. 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 and 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, ultra-pure intra-articular injection of trans-capsaicin for the treatment of moderate to severe pain associated with knee osteoarthritis (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 2018, CNTX-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.

<sup>1</sup> Stevens, RM Controlled Clinical Trial of Intra-Articular CNTX-4975 (trans-capsaicin) for Pain Associated with Osteoarthritis of the Knee, *Arthritis Rheumatol.* 2019 Mar 19.  
<https://onlinelibrary.wiley.com/doi/epdf/10.1002/art.40894>

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