



Centrexion Therapeutics Announces Completion of Patient Enrollment in VICTORY-3 Phase 3 Open-Label Clinical Trial of CNTX-4975 in Patients with Moderate-to-Severe Osteoarthritis Knee Pain

- CNTX-4975 Phase 3 clinical development program fully enrolled -

- VICTORY-1 pivotal and VICTORY-3 open-label topline results expected in Q1 2020; VICTORY-2 pivotal results expected in Q3 2020 -

BOSTON, Mass.,” September 17, 2019 – Centrexion Therapeutics Corporation, a company focused on developing non-opioid, non-addictive therapies for the treatment of chronic pain, today announced completion of patient enrollment in its third Phase 3 trial, VICTORY-3. VICTORY-3 is a randomized, open-label, single injection (per knee), eight-week study of 857 participants designed to streamline and optimize CNTX-4975 administration procedure and patient comfort as well as to evaluate the efficacy and safety of an injection of 1.0 mg of CNTX-4975 in patients with chronic moderate-to-severe knee osteoarthritis (OA) pain in one or both knees. Topline results from VICTORY-3 are expected to be reported in the first quarter of 2020.

VICTORY-3 will evaluate the comfort and ease of use of five different cooling treatment regimens: Breg cooling, gel pack cooling, shortened gel pack cooling and single needle injection gel pack cooling with two different strengths of lidocaine (2% and 1%).

CNTX-4975 is an investigational synthetic, ultra-pure intra-articular injection of trans-capsaicin that is designed to be injected directly into the site of pain. It harnesses the natural analgesic power of trans-capsaicin to provide durable and targeted pain relief, with onset of response by the second day after injection. Through its targeted delivery and highly selective method of action, CNTX-4975 is designed to manage pain without disrupting other nerve functions. 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.

“We are pleased to have completed patient enrollment in VICTORY-3 as this is an important milestone in our Phase 3 registrational clinical development program for CNTX-4975,” said Jeffrey B. Kindler, chief executive officer of Centrexion Therapeutics. “We are encouraged by the consistency of the positive results across the program and look forward to reporting on the results of VICTORY-3 and the first pivotal trial VICTORY-1 in Q1 of 2020. In Q3 of next year, we expect to report the results of the second pivotal trial VICTORY-2.”

“In VICTORY-3, we are continuing to evaluate variations of the CNTX-4975 administration procedure designed to maximize the physician and patient experience and convenience. We are very pleased to have already reported interim data demonstrating pain reductions similar to those observed in the Phase 2 trial.” said Randall M. Stevens, M.D., chief medical officer of Centrexion. “In VICTORY-3, more than 80% of patients with bilateral painful knee OA returned for the second treatment in the other knee one week later, which we believe is supportive of a new therapeutic option which may provide well tolerated pain relief to patients with moderate-to-severe osteoarthritis knee pain.”

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 repeat doses, administered six months apart. The primary endpoint of both studies 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.

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 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. 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, 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 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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