Centrexion Therapeutics Announces Completion of Patient Enrollment in Pivotal Clinical Trial of Repeat Doses of CNTX-4975 in Patients with Moderate to Severe Osteoarthritis Knee Pain

BOSTON, Mass., June 5, 2019 – 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 in its second pivotal trial, VICTORY-2, a randomized, double-blind, placebo-controlled, repeat injection at 6 months, 52-week study to evaluate the efficacy and safety of intra-articular (IA) injections of CNTX-4975 in 332 participants with chronic moderate-to-severe knee osteoarthritis (OA) pain. The VICTORY-2 clinical trial commenced in September 2018.

CNTX-4975 is an investigational synthetic, ultra-pure, IA injection of trans-capsaicin that is designed to be injected directly into the site of pain. It harnesses the natural analgesic power of 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-2 ahead of schedule. This is the second pivotal trial and is evaluating a repeat IA injection of CNTX-4975, six months apart, for patients with chronic knee OA pain in need of additional long-term effective treatment options. We anticipate reporting top line results in the second half of next year," said Jeffrey B. Kindler, chief executive officer of Centrexion Therapeutics. "As previously reported, our other pivotal trial, VICTORY-1, completed enrollment in December last year and is expected to report out in the first quarter of 2020. Our third trial, VICTORY-3, the open label study, is progressing well, with reporting of results expected in the second half of this year."

Randall Stevens, M.D., chief medical officer of Centrexion Therapeutics, said, "The VICTORY-2 study is designed to provide important information to patients, physicians and regulators, about one-year safety and efficacy of repeat dosing of CNTX-4975. The VICTORY-3 open label study evaluates CNTX-4975 in a variety of patients, including those with painful osteoarthritis in both knees and with prior knee joint replacement but with knee OA pain in the other knee. VICTORY-3 will evaluate variations of the CNTX-4975 administration procedure designed to optimize physician and patient convenience and experience."

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 safety 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 United States, 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 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.

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