A Study to Evaluate the Safety and Efficacy of CNTX-6970 in Subjects With Knee Osteoarthritis Pain.

Status: Recruiting

Eligibility Criteria

Age: 4 years to 80 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

A subject will be eligible for study participation if they meet all of the following criteria: 1. Individuals between 40 and 90 years of age (inclusive) at the time of the Screening Visit. 2. Willing to use a mobile smart device during the study period. Individuals who do not have access to a mobile device will be provided with one for the duration of the study and trained in its use. 3. Can understand the nature of the study and protocol requirements and is willing to comply with study drug administration requirements and discontinue prohibited concomitant medications. 4. Radiography of both knees with a posterior-anterior, fixed-flexion view taken during the Screening visit. The Index knee must show evidence of chronic OA with a K-L Grading Scale of 1, 2, 3, or 4. Such evidence will be provided by a central reading of the radiography of both knees from an expert radiologist of the CCC of EPPIC-Net. 5. Moderate to severe pain in the Index knee associated with OA and stable for a minimum of 6 months prior to Screening in the opinion of the investigator. 6. Confirmation of OA of the index knee: American College of Rheumatology (ACR) diagnostic criteria. 7. Subjects must have failed 2 or more prior therapies. Failure is deemed to be inadequate relief in the opinion of the investigator. 8. Body mass index (BMI) of ≤ 40 kg/m2. 9. Willing to refrain from illicit drug use during the study, and to have illicit drug testing at screening and at later time points. A subject will be excluded from the study if they meet any of the following criteria: 1. Any form of joint replacement surgery, open surgery, or arthroscopic surgery of the index knee/knee joint with 12 months of Screening. 2. Any painful condition(s) of the index knee due to disease other than OA. For example, periarticular or referred pain involving the index knee, or from joint disease other than OA associated with the index knee. 3. Other chronic pain anywhere in the lower extremities (e.g. hips, legs, feet) that is equal or greater in intensity or impairment than index knee pain or that requires the use of analgesic medications. This includes radicular low back pain with radiation to the knee. 4. Documented history of neuropathic arthropathy in the knee. 5. Significant instability (e.g., cruciate ligament tear or rupture or previous repair) within the past 5 years or current misalignment (>10 degrees varus or valgus) of the index knee. 6. Plans to have surgery, invasive procedures, or intra-articular (IA) injections of the index knee or procedure or surgery otherwise contraindicated for study participation while in the study. a. Concomitant Medications for Pain

•i. Continuous use of one of the following medications prescribed for pain: tramadol, gabapentin, duloxetine, pregabalin, milnacipran, or tricyclic antidepressants that is: 1. chronic for at least 12 weeks; and 2. at a stable dose for at least 4 weeks before Screening ii. Intermittent use of opioids that is: 1. ongoing for at least 4 weeks before Screening; 2. at a frequency no more than 4 days/week; and 3. not be taken within 24 hours of a study visit iii. As needed use of acetaminophen b. Concomitant Medications for Non-Pain Indications That May Impact Pain

•i. Continuous use of medication for non-pain indications that are known to potentially impact pain, e.g. duloxetine for depression, that is at a stable dose for at least 12 weeks prior to Screening. 7. Corticosteroid injection in the index knee within 90 days of Screening or during study participation. 8. Received IA viscosupplementation (e.g., Synvisc®, Hyalgan®) within 90 days of Screening or any time during study participation. 9. History of clearly documented allergic reaction to celecoxib (Celebrex®), or to sulfa drugs. 10. Use of an investigational medication within 30 days of Screening, or 5 pharmacokinetic or pharmacodynamic half-lives (whichever is longer) or scheduled to receive such an agent while participating in the current study. 11. Current therapy with any immunosuppressive therapy, including corticosteroids (>5 mg/day of prednisone).

Conditions & Interventions

Interventions:
Drug: Celecoxib, Drug: CNTX-6970, Drug: Placebo
Conditions:
Knee Osteoarthritis

More Information

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