

# CORE Orthopaedic Medical Center / Research

## 1-Zimmer- RCT Subchondroplasty

Prospective Efficacy Evaluation of Subchondroplasty™ for the Treatment of Defects Associated with Bone Marrow Lesions.

Inclusion:

- 1- Patient Male and Female age 30-75 Years old
- 2- BMI < 40
- 3- Subject has experienced pain in the knee for at least 3 months
- 4- BML(Bone marrow Lesions) is confirmed on T2 weighted MR imaging by presence of white signal
- 5- Subject has single BML of Tibia, Single BML of femur, or adjoining BML's of tibia & femur.
- 6- Subject is a candidate for knee arthroscopy due to mechanical symptoms, meniscus tear, loose body and/or synovitis
- 7- The contralateral(non-study)knee is stable and functional
- 8- Baseline KOOS pain subscore is ≤ 65
- 9- Subject's ACL and PCL ligaments are intact
- 10- Subject's has failed conservative treatment

Exclusion:

- 1- Surgeon deems subject's pain to be primarily related to an alternate condition such as a baker cyst, synovitis, Meniscal pathology
- 2- BML caused by acute trauma
- 3- Subject is not neurologically intact( sensory, motor, and reflex deficit)
- 4- Preoperative KOOS pain scale should be moderate to extreme pain for any one of the questions from P2 through P9
- 5- Subject with primary bone tumor in the knee area
- 6- Subject is accepting worker's compensation

## 2-Ceterix Orthopaedics, Inc.

A Prospective, Non-randomized, Multi-Center Investigation of All- Suture-based Repair of Horizontal Meniscal Tears (STITCH Study)

Inclusion:

- 1- Patient Male and Female age 18-60 Years old
- 2- History Indicative of Meniscal Pathology(e.g., pain, mechanical symptoms described as locking, clicking or giving way)
- 3- If prior ligament reconstruction, the study knee is clinically stable
- 4- Preoperative MRI and X-rays evidence with a horizontal/ oblique meniscus tear in the symptomatic compartment within 6 months.

Exclusion:

- 1- Arthritis in the study Knee (kellgren- Lawrence Grade 3 or higher.
- 2- BMI ≥35 kg/m2
- 3- Previous meniscal repair or meniscectomy of the study Meniscus
- 4- Malalignment of the study knee >5 degree and /or requiring osteotomy and/ or correction
- 5- History of constitutional/ systemic inflammatory/ arthritis problem or pain condition, history of knee infection, vascular condition of legs, benign neoplasms of knee, hepatitis, HIV, drug/alcohol abuse, tobacco abuse, cancer.

## 3-Depuy Synthes Mitek Sports Medicine / Monovisc Hip Injection

A Pivotal Study Comparing Two Injections of Monovisc to Two Injections of Saline in Patients with Osteoarthritis of the Hip

Inclusion:

- 1- Male or Female ≥40 years old
- 2- Clinical or Radiographic diagnosis of hip osteoarthritis in the target hip, with a Kellgren Lawrence grade of 2 or 3
- 3- Walking pain NRS ≥4 and ≤8

Exclusion:

- 1- Radiographic evidence of osteonecrosis in the target Hip
- 2- NRS walking pain ≥3 the contralateral hip
- 3- Clinically diagnosed osteoarthritis in either knee resulting in walking pain greater than NRS 5
- 4- Any major surgery, arthroplasty, or arthroscopy of the lower extremities in the past 6 months, or planned surgery during the study
- 5- Intra-articular steroid or hyaluronan injection of the target hip within the last 26 weeks

## **4-Ampion / Intra-Articular injection of Ampion in Adult with knee pain due to severe OA- One injection**

### **Inclusion:**

- 1- Male or Female, 40 to 85 years old
- 2- Must be Ambulatory
- 3- Study knee must have a clinical diagnosis of OA supported by radiological evidence of Grade 4
- 4- Moderate to moderate-severe OA pain in the study Knee (rating of at least 1.5 on the WOMAC A-C
- 5- WOMAC A, pain subscale < 1.5 in the contralateral Knee

### **Exclusion:**

- 1- Presence of tense effusions
- 2- NO IA injected medications in the study Knee at least 12 weeks prior to baseline
- 3- NSAID's are not permitted during the study; Acetaminophen is available as a rescue medication
- 4- No topical treatment on the study knee during the study
- 5- No major injury to the study knee within the 12 months prior to screening

## **5-CREATE-1 Study: CRPS- to assess the efficacy and safety of AXS-02 (Disodium Zoledronate Tetrahydrate) Administered orally.**

### **Inclusion:**

- 1- Male or Female at least 18 years of age
- 2- Has a confirmed diagnosis of CRPS-1 according to the new criteria from international Association for the study of pain
- 3- Has CRPS-1 in one upper or lower limb
- 4- Has a weekly average baseline pain intensity score  $\geq 5$  based on an 11-point NRS in the affected limb
- 5- Has been diagnosis with CRPS-1 within 6 months of the time of screening
- 6- Has failed trials of at least 2 available treatment modalities

### **Exclusion:**

- 1- Has a documented history or diagnosis of peripheral neuropathy, including diabetic neuropathy or other metabolic or toxic neuropathy
- 2- Has a type 1 diabetes mellitus , or poorly controlled type II diabetes mellitus
- 3- Is unable to stand or sit upright for at least 30 minutes
- 4- Is on chronic opioid therapy within 4 weeks of randomization
- 5- Received treatment with calcitonin within 3 months before study entry
- 6- Received a sympathetic nerve block within 4 weeks prior to Baseline (day 1)
- 7- Received treatment with high -dose oral or parenteral steroids (0.5 to 1 mg/kg per day orally) within the last 3 months

## **6-nSTRIDE – Zimmer- Double-Blind, Randomized, Saline-Controlled Study of a Single, Intra- Articular Injection of Autologous Protein Solution in Patients with Knee Osteoarthritis**

### **Inclusion:**

- 1- Male or female  $\geq 21$  and  $\leq 80$  years old at time of screening
- 2- A Standing radiograph of the knee showing a Kellgren grade 2 to 4 Osteoarthritis
- 3- A WOMAC pain scale total  $\geq 9$  and  $\leq 19$
- 4- Has undergone at least one prior conservative OA treatment

### **Exclusion:**

- 1- Symptomatic OA in the non-study knee; the WOMAC pain sub-scale must be  $\leq 5$
- 2- Clinically symptomatic patellofemoral chondromalacia or diagnosis of isolated patellofemoral OA
- 3- Untreated symptomatic injury of the index knee characterized by mechanical issue such as locking or catching