

Now Enrolling: Phase 3 CRPS Clinical Trial of an Oral Non-Opioid Investigational Medication

CREATE-1 (CRPS Treatment Evaluation 1 Study) is a Phase 3 multinational, multicenter, randomized, double-blind, placebo-controlled trial designed to evaluate the efficacy and safety of AXS-02 for the treatment of pain associated with CRPS. AXS-02 is an oral, non-opioid, investigational drug that has been granted Fast Track and Orphan Drug Designation by the U.S. FDA, and Orphan Medicinal Product Designation by the European Medicines Agency for the treatment of CRPS. AXS-02 is not approved by the FDA.

The study is enrolling patients at sites in the United States, Canada, the United Kingdom and Australia. Eligible patients must be at least 18 years of age with recently diagnosed CRPS type 1 related to a traumatic injury. Eligible patients will be randomized to receive either AXS-02 or placebo by mouth once weekly for six weeks. The primary efficacy measure is the change in patient-reported pain intensity at the end of Week 12. Secondary outcome measures include assessments of the change in the Brief Pain Inventory (BPI) score, Patient and Clinician Global Impression of Change (PGI-C and CGI-C, respectively) and other quality-of-life measures. More information about the CREATE-1 study is available at www.clinicaltrials.gov.

To learn about eligibility and to find a study site, patients can visit www.CRPSTrial.com.