A Clinic Study: Retrospective Data Review on Safety of Signature Cord

PURPOSE

Signature Biologics manages adverse event data collection for all of its distributed products. This procedure is in line with the company's Quality Management System and the good market vigilance exercised by the company. Because this data is collected reactively, Signature Biologics partnered with a clinic in Dallas to explore data gathered by the clinic proactively on patients who have received Signature Cord. Presented here are both the proactive and reactive data on the product.

CLINIC OVERVIEW

Clinic X is a regenerative orthopedics clinic located in Dallas, Texas. All treatment plans are recommended by board-certified orthopedic surgeons and pain management specialists. Treatment with Signature Cord can be either in lieu of or in conjunction with surgical intervention. The most common treatment sites are spine, knee, hips, and shoulders, but Signature Cord is also used in the ankle, foot, wrist, hand, and elbow.

CLINIC'S PATIENT FOLLOW UP

Clinic X follows a rigorous adverse event reporting protocol to monitor the safety of their patients. The clinic treats patients with Signature Cord on a Friday and follows up with all patients via telephone on the following Monday to administer a post-treatment questionnaire which includes adverse events. As of May 2020, Clinic X has administered 196 Signature Cord injections. There have been no reported adverse events at the time of injection, follow-up, or any time thereafter. A minority of patients experienced minor pain at the injection site, an expected possible side effect, which usually resolved without intervention within 24 hours.

CLINIC STUDY RESULTS

The dataset from Clinic X demonstrates no reportable adverse events at time of administration, during routine follow up, or post procedure contact. The proactive adverse event data from Clinic X is consistent with the larger dataset of Signature Biologics (see below).

About Signature Biologics and Signature Cord

Signature Biologics is a biotech company and tissue bank based in Dallas, TX. Signature Biologics' mission is to use its innovative techniques to manufacture human placental derived products to significantly improve and support the natural healing process of the body. We strive to provide best in class products that better the quality of life of patients.

Signature Cord

Signature Cord is a tissue product manufactured from the umbilical cord. It is regulated as a 361 product meaning it is minimally manipulated; is for homologous use only; is not combined with any other products, cells, or tissues; and it does not have a systemic effect or dependent on metabolic activity as its primary function. The umbilical cord is obtained from a full-term healthy cesarean delivery by a Tissue Recovery Organization that is registered with the FDA and follows current Good Tissue Practices. Signature Cord is a tissue product and is therefore measured by weight (75 mg per mL). It is delivered via injection and typically as a single injection.

Signature Cord has been injected at least 9,169 times as of December 2019 as a cushioning agent. These have primarily been single injections of 75 mg of tissue in a 1.0 mL suspension. No serious or reportable adverse events have been reported to date. One patient reported a headache and nausea 48 hours post injection which resolved without intervention.