Anika Therapeutics announces positive results from CINGAL phase 3 trial for knee osteoarthritis

Published on July 10, 2015 at 9:19 AM

Anika Therapeutics, Inc., (NASDAQ: ANIK), a leader in products for tissue protection, healing, and repair based on hyaluronic acid (HA) technology, today reported positive results from the CINGAL® 13-02 study evaluating the safety of a repeat injection of Cingal for symptomatic relief of osteoarthritis (OA) of the knee. CINGAL combines the Company's proprietary cross-linked sodium hyaluronate (currently marketed as the single-injection viscosupplement MONOVISC®) with an FDA-approved steroid, triamcinolone hexacetonide. Earlier this year, Anika announced positive results from CINGAL 13-01, a randomized, double-blind, placebo-controlled Phase 3 study, which demonstrated the efficacy and safety of a single injection of CINGAL for treatment of pain caused by OA of the knee.

"CINGAL is poised to be the first injectable viscosupplement that combines the proven benefits of our proprietary hyaluronic acid formulation with a well-established steroid to effectively treat the symptoms associated with osteoarthritis of the knee," said Dr. Charles H. Sherwood, President and Chief Executive Officer of Anika Therapeutics. "The results of this follow-up study combined with our initial Phase 3 data suggest that CINGAL maintains a consistently strong safety profile in both an initial injection as well as a repeat injection."

The CINGAL 13-02 study enrolled 242 participants from the CINGAL 13-01 study who had received an initial injection of CINGAL, MONOVISC, or saline. In the follow-up CINGAL 13-02 study, the participants received an open-label injection of CINGAL and were monitored for adverse events (AEs). The retreatment study's key findings were:

- A low number of subjects (6.2%) experienced an adverse event (AE) related to the study injection. Observed AEs were typical of those associated with viscosupplements (arthralgia, injection site pain, swelling, and erythema), and over 95% were considered 'mild' or 'moderate' in severity. All AEs were transitory, resolving naturally without treatment.
- The AE rate associated with CINGAL was found to be consistent across both first-time and repeat injection studies. There were no statistically significant differences between the AE profile of participants in the CINGAL 13-01 study (single injection) and those in the CINGAL 13-02 study (repeat injection).

"Osteoarthritis is a chronic degenerative disease that requires ongoing management to address pain and preserve function of the joint in order to stave off knee replacement surgery," said Prof. Laszlo Hangody, MD, Ph.D., DSc., the global principal investigator of both CINGAL Phase 3 trials. "Our topline results suggest that CINGAL could be safely administered to patients requiring repeat injection, and enable physicians to have greater flexibility to meet the individual needs of each OA patient."

Source:
http://www.anikatherapeutics.com/