Anika Investor Relations

Anika Therapeutics Announces Positive Results from Follow-up Study Evaluating Safety of a Repeat Injection of CINGAL for Treatment of Osteoarthritis of the Knee

BEDFORD, Mass.--(BUSINESS WIRE)-- 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. CharlesH. 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."

About Anika Therapeutics, Inc.

Headquartered in Bedford, Mass., Anika Therapeutics, Inc. develops, manufactures, and commercializes therapeutic products for tissue protection, healing, and repair. These products are based on hyaluronic acid (HA), a naturally occurring, biocompatible polymer found throughout the body. Anika's products range from orthopedic/joint health solutions led by ORTHOVISC and MONOVISC, treatments for osteoarthritis, to surgical aids in the anti-adhesion and ophthalmic fields. The Company also offers aesthetic dermal fillers for the correction of facial wrinkles. Anika's Italian subsidiary, Anika Therapeutics S.r.l., provides complementary HA products in the orthopedic/joint health and anti-adhesion fields, as well as therapeutics in areas such as advanced wound treatment and ear, nose, and throat care. Its regenerative technology advances Anika's vision to offer therapeutic products and medical solutions that go beyond pain relief to protect and restore damaged tissue.

The statements made in the first, second, and fourth paragraphs of this press release, which are not statements of historical fact, are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements include, but are not limited to, those relating to the safety and efficacy of CINGAL. These statements are based upon the current beliefs and expectations of the Company's management and are subject to significant risks, uncertainties, and other factors. The Company's actual results could differ materially from any anticipated future results, performance, or achievements described in the forward-looking statements as a result of a number of factors including (i) the Company's ability to successfully commence and/or complete clinical trials of its products on a timely basis or at all; (ii) the Company's ability to obtain pre-clinical or clinical data to support domestic and international pre-market approval applications or 510(k) applications, or to timely file and receive FDA or other regulatory approvals or clearances of its products, including for CINGAL; (iii) that such approvals will not be obtained in a timely manner or without the need for additional clinical trials, other testing or regulatory submissions, as applicable; (iv) the Company's research and product development efforts and their relative success, including whether we have any meaningful sales of any new products resulting from such efforts; (v) the cost effectiveness and efficiency of the Company's clinical studies, manufacturing operations and production planning; (vi) the strength of the economies in which the Company operate or will be operating, as well as the political stability of any of those geographic areas; (vii) future determinations by the Company to allocate resources to products and in directions not presently contemplated; (viii) the Company's ability to successfully commercialize its products, in the U.S. and abroad; (ix) the Company's ability to provide an adequate and timely supply of its products to its customers; (x) the Company's ability to continue to successfully manage Anika Therapeutics S.r.l.'s business; and (xi) the Company's ability to achieve its growth targets.

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