Anika Therapeutics Reports on Cingal® 13-01 Study Clinical Trial Top Line Data and Announces the Completion of Cingal 13-02 Study's Patient Enrollment

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 announced the completion of enrollment in the Cingal 13-02 study, an open-label, follow-on study to the Cingal 13-01 study, to evaluate the safety of a repeat injection of cross-linked sodium hyaluronate combined with triamcinolone hexacetonide (Cingal) intended to provide symptomatic relief of osteoarthritis (OA) of the knee. A total of 242 subjects, all of whom participated in the Cingal 13-01 study, were enrolled and re-treated with an additional Cingal injection. Study results will be available mid-year, and they will be used to support labeling for repeat injections with Cingal.

Cingal combines the cross-linked hyaluronic acid formulation of Monovisc®, approved to provide long-term relief of the symptoms of OA, with an FDA-approved steroid to provide additional short-term pain relief. In the pivotal Cingal 13-01 study, 368 subjects were enrolled in a multicenter, randomized, double blind, saline-controlled study with an active comparator arm (Monovisc). The Cingal 13-01 study was conducted to investigate the safety and efficacy of Cingal in treating pain in patients with OA. The study results demonstrated that Cingal is statistically and clinically superior to saline with the data meeting the primary and all secondary endpoints. Adverse event rates were very low, evidencing the safety of the product.

In the Cingal 13-01 study, Cingal met the primary endpoint by demonstrating superiority over saline for the change in WOMAC Pain Score over baseline levels through 12 weeks after treatment in the Intent to Treat (ITT) population (-40.2 mm vs. -31.0 mm, p=0.0099). The benefits proved long lasting as Cingal delivered a 72% improvement (-42.4 mm, p &#60 0.01) in WOMAC Pain Score relative to baseline at 26 weeks after injection.

Cingal also met all secondary endpoints relative to saline in the ITT analysis. Over 92.0% of Cingal subjects met the definition of OMERACT- OARSI Responders through 26 Weeks (p=0.01 vs. saline). Global Assessments (Patient and Evaluator) show the strong clinical benefit of Cingal through 26 weeks, with improvements over saline of 10.6 mm and 9.1 mm respectively (p &#60 0.01). In addition to pain relief, endpoints measuring stiffness and physical function through 26 weeks support the superiority of Cingal compared with saline (p=0.01 and p=0.02, respectively).

These study results were included in pre-marketing applications submitted in theUnited States and European Union, and they demonstrate that Anika's single injection HA viscosupplementation product, Monovisc, provides long-term pain relief and that the addition of the steroid provides a short-term, statistically-significant improvement in pain reduction during the first three weeks following treatment.

"The pivotal study results unequivocally demonstrate the strong clinical benefit of Cingal," said Global Principal Investigator Prof. Laszlo Hangody, MD, Ph.D., DSc. "Patients receiving Cingal experienced significant symptom relief from the first week that continued and even strengthened throughout six months. I look forward to having the strong clinical benefits of Cingal commercially available."

Cingal is Anika Therapeutics' third-generation viscosupplementation product, and it adds to Anika's strong product portfolio for the treatment of joint pain associated with OA. Anika already has a market leadership position in the United States and internationally with its multi-injection product, Orthovisc®, and its single-injection product, Monovisc.

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 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, the timing, result, and availability of clinical data for the Cingal 13-02 study, our statements regarding the effectiveness of Cingal, and the commercial timeline and impact of the product. These statements are based upon the current beliefs and expectations of our management and are subject to significant risks, uncertainties, and other factors. The actual results could differ materially from any anticipated future results, performance, or achievements described in these or other forward-looking statements made by us as a result of a number of factors including (i) our ability to successfully commence and/or complete clinical trials of our products, including Cingal 13-02, on a timely basis or at all, obtain pre-clinical or clinical data to support domestic and international pre-market approval applications or 510(k) applications, or timely file and receive FDA or other regulatory approvals or clearances of its products, including Cingal, or 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; (ii) our research and product development efforts and their relative success, including whether we have any meaningful sales of any new products resulting from such efforts; (iii) the cost effectiveness and efficiency of our clinical studies, including the associated regulatory approval applications, our manufacturing operations and our production planning; (iv) the strength of the economies in which we operates or will be operating, as well as the political stability of any of those geographic areas; (v) future determinations by us to allocate resources to products and in directions not presently contemplated; (vi) our ability to successfully complete our commercialization plans for its products in the U.S. and internationally; (vii) our ability to provide an adequate and timely supply of our products to its customers; (viii) our ability to continue to successfully manage Anika Therapeutics S.r.l.'s business and product lines; and (ix) our ability to achieve our growth targets. Certain other factors that might cause our actual results to differ materially from those in the forward-looking statements include those set forth under the headings "Business," "Risk Factors," and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2014, as well as those described in our other press releases and SEC filings.

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Source: Anika Therapeutics, Inc.

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