Anika Investor Relations

Anika Therapeutics Announces Regulatory Submissions with U.S. FDA and European Regulatory Authorities for Cingal®

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 that it has filed regulatory submissions in both the United States and Europe seeking the approval of Cingal, the Company's novel HA plus steroid single-injection treatment for osteoarthritis of the knee. Anika submitted its application for CE Mark approval to commercialize Cingal in the European Union and also filed its premarket approval application (PMA) with the U.S. Food and Drug Administration to allow for marketing and distribution in the United States.

"After meeting all of the primary and secondary endpoints from our multinational Phase III Cingal clinical trial in a clinically and statistically meaningful fashion, we filed the CE Mark application as planned at the end of 2014 and submitted the PMA a few days ago, ahead of schedule," said Anika President and CEO Dr. Charles H. Sherwood. "The filing of these submissions is a milestone achievement for Anika and, after approvals, positions us extremely well in the market from a competitive standpoint. In addition to the United States and Europe, we plan to commercialize Cingal in other key markets in the world. We look forward to patients benefiting from Cingal, which provides the convenience and efficacy of our current single-injection treatment, Monovisc®, with the added early symptom relief benefits of a commonly used steroid."

The Cingal Phase III trial was a 26-week, randomized, double-blind, three-arm, placebo-controlled study designed to evaluate the efficacy and safety of a single injection of Cingal in approximately 368 patients experiencing joint pain from osteoarthritis of the knee who had not responded to conservative treatment. Patients were randomized to receive a Cingal treatment, a placebo treatment or a treatment of Anika's Monovisc product. After the initial treatment, patients were assessed for 26 weeks at clinical sites in Europe and Canada. The primary clinical effectiveness endpoint data measured the change in the patients' knee pain over the course of the trial from their baseline level according to the WOMAC Pain Score.

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 of the knee; 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 orthopedic/joint health and anti-adhesion, 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, those relating to the results of our Cingal clinical trials, regulatory filings, and our expectations for regulatory approvals and Cingal's global commercialization strategy. 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, 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, 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) the Company's research and product development efforts and their relative success, including whether the Company has 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 the Company operates or will be operating, as well as the political stability of any of those geographic areas; (v) future determinations by the Company to allocate resources to products and in directions not presently contemplated; (vi) the Company's ability to successfully complete its commercialization plans for its products in the U.S. and internationally; (vii) the Company's ability to provide an adequate and timely supply of its products to its customers; (viii) our ability to continue to successfully manage Anika Therapeutics S.r.l.'s business; and (ix) the Company's ability to achieve its growth targets. Certain other factors that might cause the Company's 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 the Company's Annual Report on Form 10-K for the year ended December 31, 2013, as well as those described in the Company's other press releases and SEC filings.

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