Anika Therapeutics Files IDE Application with U.S. FDA for Hyalofast®

CE Marked Cartilage Regeneration Product Has Demonstrated Positive Outcomes Internationally

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 an Investigational Device Exemption (IDE) with the U.S. Food and Drug Administration to conduct a pivotal Phase III clinical trial for Hyalofast, a biodegradable, 3D, HA-based scaffold with autologous bone marrow aspirate concentrate (BMAC). European clinical data demonstrated that patients who utilized Hyalofast with BMAC in a one-step arthroscopic procedure were able to naturally regenerate hyaline-like cartilage with a minimally invasive and cost-effective procedure. Hyalofast is CE Marked in Europe for the entrapment of mesenchymal stem cells in connection with the treatment of chondral and osteochondral lesions, and it is commercially available in Europe and certain other international markets.

The Hyalofast pivotal trial, "FastTRACK," will compare Hyalofast's treatment of articular knee cartilage defect lesions to that of a control microfracture treatment. FastTRACK is a prospective, randomized, active treatment-controlled, evaluator-blinded, and multi-center study. Anika expects to enroll 200 patients at up to 30 sites inthe United States and Europe beginning in the fourth quarter of 2015.

"We are excited to progress Hyalofast toward commercialization in the United States," said Dr.Charles H. Sherwood, Anika's President and CEO. "We have seen very positive clinical outcomes from Hyalofast in the treatment of knees and ankles internationally, which bodes well as we advance the product in the clinic domestically. As the only HA-based scaffold for regeneration, Hyalofast has distinct advantages over other products constructed of different biomaterials or synthetics. We look forward to commencing our Phase III pivotal trial later this year."

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 theanti-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 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 commercialization of Hyalofast, including the Company's expectations regarding the data to be obtained in the Phase III pivotal trial, the timing of the Phase III pivotal trial, and the commercial and clinical advantages of the product. 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 these or other forward-looking statements made by the Company 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, including Hyalofast, on a timely basis or at all, 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, 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, 2014, as well as those described in the Company's other press releases and SEC filings.

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or
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Source: Anika Therapeutics, Inc.
