



Anika Therapeutics, Inc. Announces First Patient Enrolled in FastTRACK Phase III HYALOFAST® Study

Cartilage Regeneration Therapy Builds Upon Company's Orthobiologics Experience, Representing Expansion into Field of Regenerative Medicine

BEDFORD, Mass.--(BUSINESS WIRE)-- Anika Therapeutics, Inc., (NASDAQ: ANIK), a global, integrated orthopedics medicines company specializing in therapeutics based on its proprietary hyaluronic acid technology, today announced the enrollment of the first patient in its pivotal HYALOFAST® FastTRACK Phase III clinical study.

The HYALOFAST FastTRACK study is a prospective, randomized, active treatment-controlled, evaluator-blinded multicenter study to establish the superiority of a hyaluronan-based scaffold (HYALOFAST®) with autologous bone marrow aspirate concentrate (BMAC) in the treatment of articular knee cartilage defect lesions. The study will enroll approximately 200 patients at up to 30 sites in the U.S. and Europe.

HYALOFAST is a biodegradable scaffold that is used to enable cartilage regeneration in patients suffering from cartilage defects. European clinical data demonstrates that patients treated with HYALOFAST plus autologous BMAC in a one-step, minimally invasive arthroscopic procedure were able to successfully regenerate hyaline-like cartilage. HYALOFAST is CE Marked in Europe and is available commercially in 18 countries with more than 6,000 uses to date.

"HYALOFAST is an exciting, emerging product in our pipeline, representing Anika's expansion into the rapidly evolving field of regenerative medicine in the orthopedics space," said Dr. Charles H. Sherwood, President and Chief Executive Officer of Anika Therapeutics. "We have seen very positive clinical outcomes in the treatment of knees and ankles internationally using HYALOFAST. We believe the FastTRACK study will give us the pivotal clinical data to support a marketing application for an indication for the repair of cartilage defects of the knee in the U.S."

"I congratulate the FastTRACK investigators for beginning enrollment in this trial," said Dr. Alberto Gobbi, Global Principal Investigator. "We know from prior research that the HYALOFAST scaffold supports the adhesion, migration and proliferation of mesenchymal stem cells, and their differentiation into chondrocytes. We look forward to demonstrating the unique advantages of HYALOFAST in a randomized clinical trial."

About Anika Therapeutics, Inc.

Anika Therapeutics, Inc. (NASDAQ: ANIK) is a global, integrated orthopedics medicines company based in Bedford, Mass. Anika is committed to improving the lives of patients with degenerative orthopedic diseases and traumatic conditions by providing clinically meaningful therapeutic pain management solutions along the continuum of care, from palliative care to regenerative medicine. The Company has over two decades of expertise developing, manufacturing and commercializing more than 20 products, in markets across the globe, based on its proprietary hyaluronic acid (HA) technology. Anika's orthopedic medicine portfolio is comprised of marketed (ORTHOVISC® and MONOVISC®) and pipeline (CINGAL® and HYALOFAST® in the U.S.) products to alleviate pain and restore joint function by replenishing depleted HA and aiding cartilage repair and regeneration. For more information about Anika, please visit <http://www.anikatherapeutics.com>.

Forward-Looking Statements

The statements made in the second, third, fourth, and fifth 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 progress, size, and success of the clinical study of HYALOFAST and the clinical benefits associated with the use of HYALOFAST. 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, including for HYALOFAST or for expanded indications of the Company's MONOVISC product, 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; (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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Anika Therapeutics, Inc.
Christopher Ranjitkar, 781-457-9000
IR & Corporate Communications Manager

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