Anika Investor Relations

Anika Therapeutics Announces Decision to Proceed with CINGAL® Premarket Review Through FDA's Center for Drug Evaluation and Research

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 that the U.S. Food & Drug Administration's (FDA) Office of Combination Products has assigned CINGAL® to the Center for Drug Evaluation and Research (CDER) as the lead center for premarket review.

CINGAL is the first combination viscosupplement formulated with Anika's proprietary cross-linked sodium hyaluronate (currently marketed as the single-injection viscosupplement MONOVISC®) and triamcinolone hexacetonide, an FDA-approved steroid to treat inflammation. Earlier this year, Anika announced positive results from its CINGAL 13-01 and 13-02 studies, demonstrating the efficacy and safety of a single injection of CINGAL for treatment of pain caused by osteoarthritis (OA) of the knee, as well as the safety of a repeat injection.

"While we strongly disagree with the FDA's decision, as our position of CINGAL's device-lead classification is supported by both regulations and scientific data, we intend to proceed expeditiously to move CINGAL through regulatory review," said Dr. Charles H. Sherwood, President and Chief Executive Officer of Anika Therapeutics. "We have already been in contact with CDER to start the NDA process, and are confident that the definitive results from two clinical studies provide the essential foundation for marketing approval of CINGAL."

CINGAL is Anika Therapeutics' third-generation viscosupplementation product, adding to the Company's strong product portfolio for the treatment of joint pain associated with OA. Anika already maintains a market leadership position in the United States and a growing presence internationally, with its multi-injection product, ORTHOVISC®, and its single-injection product, MONOVISC. CINGAL was approved in Canada as a medical device to treat pain associated with OA of the knee, and is under review in the E.U.

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 third 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 U.S. and global regulatory progress of CINGAL and the Company's leadership position in the viscosupplementation market. 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, including for CINGAL, 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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