



# Anika Therapeutics Announces Health Canada Approval of CINGAL® for the Treatment of Pain Associated with Osteoarthritis of the Knee

## **Achieves First Approval for Innovative Therapy Combining Hyaluronic Acid Technology with FDA-Approved Steroid**

BEDFORD, Mass.--(BUSINESS WIRE)-- Anika Therapeutics, Inc., (NASDAQ: ANIK), a global, integrated orthopedics medicines company specializing in therapeutics based on its proprietary hyaluronic acid ("HA") technology, today announced Health Canada approval of CINGAL® as a medical device to treat pain associated with osteoarthritis (OA) of the knee. CINGAL is the first and only approved combination viscosupplement formulated with the Company's proprietary cross-linked sodium hyaluronate (currently marketed as the single-injection viscosupplement MONOVISC®) and triamcinolone hexacetonide, an FDA-approved steroid to treat inflammation.

"We are very pleased to announce the first regulatory approval for our breakthrough, next generation viscosupplement, CINGAL," said Charles H. Sherwood, Ph.D., President and Chief Executive Officer. "In its pivotal clinical study, CINGAL has demonstrated an ability to provide immediate and long-lasting pain relief for those affected by osteoarthritis of the knee. The availability of CINGAL allows us to extend the proven benefits of MONOVISC to a broader range of patients across the spectrum of osteoarthritis management. We look forward to advancing CINGAL through regulatory channels globally and improving the lives of millions of people worldwide struggling with the debilitating symptoms of osteoarthritis."

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.

### About Osteoarthritis of the Knee

Greater than 5% of the world's population is afflicted by OA of the knee, making it the most common joint disease. Most commonly affecting middle-aged and older people, OA can range from very mild to very severe. Risk factors include being overweight, joint injury, muscle weakness, having other forms of arthritis, and heredity.

OA of the knee is characterized by the breakdown of cartilage, the part of the joint that cushions the ends of bones, which causes bones to rub against each other, and results in pain and loss of movement. Degradation changes in the synovial fluid contained in the joint may also play a role in OA. Synovial fluid, which mostly consists of hyaluronan, lubricates the joint and is needed to facilitate movement of the joint.

Standard treatment modalities that seek to relieve pain, improve mobility and increase range of motion include analgesics, nonsteroidal anti-inflammatory drug (NSAIDs), viscosupplementation, and intra-articular steroids. Should these approaches become insufficient or fail, some patients may become surgical candidates. Viscosupplementation represents an effective, safe, convenient, and non-surgical therapeutic alternative or adjunct to physical therapy, medication or surgery.

### About Anika Therapeutics, Inc.

Anika Therapeutics, Inc. (NASDAQ: ANIK) is a global, integrated orthopedic 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 paragraph 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 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 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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