



## Anika Therapeutics Wins CE Mark Approval for Cingal® for the Treatment of Pain Associated with Osteoarthritis of the Knee

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 that it received CE Mark approval for CINGAL® as a medical device to treat pain associated with osteoarthritis of the knee. CINGAL is the first and only commercially-available combination viscosupplement, formulated with the Company's proprietary cross-linked sodium hyaluronate (currently marketed as the single-injection viscosupplement MONOVISC®) and triamcinolone hexacetonide, a well-established, FDA-approved steroid to treat inflammation. CINGAL is Anika's third-generation viscosupplement, following the company's ORTHOVISC® and MONOVISC® products, to treat pain associated with osteoarthritis of the knee.

"The European approval of CINGAL marks an important milestone for Anika as it advances our global expansion strategy, provides a platform for us to demonstrate our commercialization capabilities, and most importantly, reinforces the product's tremendous clinical value to people struggling with the debilitating symptoms of osteoarthritis," said Charles H. Sherwood, Ph.D., President and Chief Executive Officer. "We look forward to working with our distribution partners to commence our European launch in the coming months, while remaining steadfast in our commitment to collaborate with the FDA to bring this important treatment to the millions of Americans coping with chronic knee pain."

Anika recently announced plans to strengthen its global commercialization capabilities, and the company will support key aspects of the European launch, which will be executed through a network of existing and new commercial partnerships. The Company previously achieved approval of CINGAL in Canada, and is currently working with its distribution partner to finalize the commercial launch of the product in the second quarter of 2016. Anika also continues to vigorously pursue regulatory approval of the product in the U.S.

"The availability of CINGAL is welcome news for millions of Europeans living with osteoarthritis-related knee pain due to a lack of effective, long-lasting, non-surgical treatment options," said Prof. Laszlo Hangody, MD, Ph.D., DSc., Clinical Professor at the Semmelweis Medical School Budapest, former President of the Hungarian Orthopedic Society, and global principal investigator for the CINGAL Phase III program. "CINGAL combines two proven, approved therapies for pain and inflammation into a single injection treatment that has been shown to provide immediate pain relief that lasts for 6 months, reduce stiffness, and improve function. For knee pain sufferers, the availability of CINGAL not only translates to postponing an invasive and costly knee replacement surgery, but also to enabling these individuals to resume their normal lifestyle prior to the onset of chronic pain."

CINGAL is administered via injection into the knee by a licensed physician. In clinical studies, CINGAL demonstrated superiority over placebo for the change in WOMAC Pain Score<sup>1</sup> over baseline levels through 12 weeks after treatment in the Intent to Treat (ITT) population (-40.2 mm vs. -31.0 mm, p=0.0099), and sustained these benefits 26 weeks after the initial injection (-42.4 mm, p=0.01). In addition to pain relief, CINGAL was associated with significant improvements in stiffness and physical function through 26 weeks (p=0.01 and p=0.02, respectively) compared to placebo.

### 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 and third 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 company's commercialization capabilities in various markets, the commercial launch timelines for CINGAL in both Europe and Canada, and the regulatory status of CINGAL in the U.S. 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; (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 operates 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. Additional factors and risks are described in the Company's periodic reports filed with the Securities and Exchange Commission, and they are available on the SEC's website at [www.sec.gov](http://www.sec.gov). Forward-looking statements are made based on information available to the Company on the date of this press release, and the Company assumes no obligation to update the information contained in this press release.

1 The Western Ontario and McMaster Universities Arthritis Index (WOMAC) is a widely used, proprietary set of standardized questionnaires used by health professionals to evaluate the condition of patients with osteoarthritis of the knee and hip, including pain, stiffness, and physical functioning of the joints

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For Investor Inquiries:

Anika Therapeutics, Inc.

Sylvia Cheung, 781-457-9000

Chief Financial Officer

or

For Media Inquiries:

Pure Communications

Susan Heins, 864-286-9597

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