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Anika Announces Regulatory Approval for MONOVISC® in India for the Treatment of Pain Associated with Osteoarthritis of All Synovial Joints

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 regulatory authorities in India granted approval to [MONOVISC®](#), its single injection viscosupplement for the treatment of pain associated with osteoarthritis of all human synovial joints. MONOVISC is commercially available in the United States, Canada and Europe, and Anika plans to expand into India, Australia, New Zealand and additional international markets over the next six to nine months.

"Expanding our global commercial footprint is one of our key strategic pillars of growth, and the approval of MONOVISC in India is a proof point for our ability to execute against the benchmarks we define each year," said Charles H. Sherwood, Ph.D., President and Chief Executive Officer of Anika Therapeutics. *"There is a growing demand for non-invasive, long-acting treatments for osteoarthritis in emerging countries such as India where knee replacement surgery is often the last option or not an option at all, due to limited medical resources outside major cities and high costs of surgery and postsurgical care. With its ability to safely relieve pain for up to six months with fewer office visits, lower treatment costs and no downtime after treatment, MONOVISC is poised to be well-received by physicians and patients in India."*

The global expansion of MONOVISC is the primary international orthobiologics revenue driver for Anika, and India represents a large and growing market opportunity. Anika has a multi-year, exclusive distribution agreement with Modi-Mundipharma Pvt. Ltd. ("MMP") to market MONOVISC in India. MMP is a leading multinational pharmaceutical company with a significant focus on pain management. Utilizing their large, dedicated sales force, MMP will be able to introduce MONOVISC to a broad range of physicians that treat a substantial number of patients suffering from the symptoms of osteoarthritis.

About MONOVISC

MONOVISC is Anika's next-generation HA-based therapy for treating osteoarthritis that features enhanced durability in a safe, easy-to-use, single injection regimen. MONOVISC is made from highly purified, non-animal, natural hyaluronan. Hyaluronan occurs naturally throughout the body, especially in articular cartilage, synovial fluid in joints and in the skin. For more information about MONOVISC, please visit Anika's website at www.anikatherapeutics.com.

About Anika Therapeutics, Inc.

[Anika Therapeutics, Inc.](#) (NASDAQ: ANIK) is a global, integrated orthopedic medicines company based in Bedford, Massachusetts. Anika is committed to improving the lives of patients with degenerative orthopedic diseases and traumatic conditions with clinically meaningful therapies along the continuum of care, from palliative pain management to regenerative cartilage repair. The Company has over two decades of global expertise developing, manufacturing, and commercializing more than 20 products based on its proprietary [hyaluronic acid \(HA\) technology](#). Anika's orthopedic medicine portfolio includes [ORTHOVISC®](#), [MONOVISC](#), and [CINGAL®](#), which alleviate pain and restore joint function by replenishing depleted HA, and [HYALOFAST®](#), a solid HA-based scaffold to aid cartilage repair and regeneration. For more information about Anika, please visit www.anikatherapeutics.com.

Forward-Looking Statements

The statements made in the second sentence of the first paragraph, second sentence of the second paragraph, and first sentence of the third 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 Company's international expansion plans, the market for the Company's products in emerging countries such as India, and the Company's Monovisc Product as a revenue driver for the Company. 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, but not limited to, (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, 510(k) applications, or new drug 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; and (x) 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. 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.

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