



Anika Therapeutics Files Investigational Device Exemption to Initiate Phase III Study to Expand Indication of MONOVISC® to Treat Pain Caused by Osteoarthritis of the Hip

Study to be Sponsored by Company's Exclusive U.S. Distributor and Commercial Partner, DePuy Synthes Mitek Sports Medicine

BEDFORD, Mass.--(BUSINESS WIRE)-- [Anika Therapeutics, Inc.](#), (NASDAQ: ANIK), a leader in products for tissue protection, healing, and repair based on hyaluronic acid (HA) technology today announced that it has submitted an Investigational Device Exemption (IDE) with the U.S. Food & Drug Administration (FDA) to conduct a Phase III clinical trial to support the expanded use of MONOVISC for the treatment of pain caused by osteoarthritis (OA) of the hip. MONOVISC, a single injection viscosupplement comprised of non-animal sourced hyaluronic acid, is currently approved by the FDA for the treatment of pain caused by osteoarthritis of the knee. The study will be sponsored by DePuy Synthes Mitek Sports Medicine*, a leading orthopedic sports medicine company, and Anika's commercial partner and exclusive distributor of MONOVISC in the U.S.

Osteoarthritis is a chronic condition characterized by the degeneration of cartilage and underlying bone within a joint, which eventually leads to pain and joint stiffness. OA affects approximately 27 million Americans, and one in four adults will develop symptoms of hip OA by age 85. There is currently no cure for OA.

The IDE seeks approval for a prospective, double-blind, randomized, placebo-controlled, superiority study designed to demonstrate the efficacy of MONOVISC by measuring change in WOMAC1 A1 pain scores over a 26-week period following initial treatment. The study plans to enroll approximately 560 subjects across 20 investigational sites in the U.S., beginning in 2015.

"The submission of this IDE represents an important step towards extending the benefits of MONOVISC to patients living with the chronic pain associated with hip osteoarthritis, for whom non-surgical treatment options are currently limited," said Dr. Charles H. Sherwood, President and Chief Executive Officer, Anika Therapeutics. "We believe the expanded indication will further enhance the clinical and commercial value of MONOVISC, and strengthen our position in the viscosupplementation market as a leading provider of innovative and effective therapies."

About Anika Therapeutics, Inc.

Headquartered in Bedford, Mass., [Anika Therapeutics, Inc.](#) develops, manufactures, and commercializes therapeutic products for tissue protection, healing, and repair. These products are based on [hyaluronic acid \(HA\)](#), a naturally occurring, biocompatible polymer found throughout the body. Anika's products range from orthopedic/joint health solutions led by [Orthovisc](#) and [Monovisc](#), treatments for osteoarthritis, to surgical aids in the [anti-adhesion](#) and [ophthalmic](#) fields. The Company also offers [aesthetic dermal fillers](#) for the correction of facial wrinkles. Anika's Italian subsidiary, Anika Therapeutics S.r.l., provides complementary HA products in the orthopedic/joint health and anti-adhesion fields, as well as therapeutics in areas such as advanced wound treatment and ear, nose, and throat care. Its regenerative technology advances Anika's vision to offer therapeutic products and medical solutions that go beyond pain relief to protect and restore damaged tissue.

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 commercialization of MONOVISC for an indication to treat pain caused by osteoarthritis of the hip, including the Company's expectations regarding the data to be obtained in the Phase III pivotal trial, the timing of the Phase III pivotal trial, and the enhancement of the clinical and commercial value of the Company's MONOVISC

product. 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 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, including for expanded indications of the Company's MONOVISC product; (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.

* DePuy Synthes Mitek Sports Medicine is a division of DePuy Orthopaedics, Inc.

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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