Anika Investor Relations

# FDA Approves MONOVISC®, A New Single Injection Treatment for Treatment of Pain Due to Osteoarthritis of the Knee

BEDFORD, Mass.--(BUSINESS WIRE)-- Anika Therapeutics, Inc. (NASDAQ:ANIK) today announced it has received marketing approval for MONOVISC® from the U.S. Food and Drug Administration (FDA). MONOVISC is a single injection supplement to synovial fluid of the osteoarthritic joint, used to treat pain and improve joint mobility in patients suffering from osteoarthritis (OA) of the knee. MONOVISC is the first FDA approved single injection product with HA from a non-animal source. It is comprised of a sterile, clear, biocompatible, resorbable, viscoelastic fluid composed of partially cross-linked sodium hyaluronate (NaHA) in phosphate buffered saline.

MONOVISC will be marketed in the U.S. by DePuy Synthes, Mitek Sports Medicine (Mitek), a leading orthopedic sports medicine company. Under the license agreement with Mitek, Anika will receive a milestone payment of $5 million upon first commercial sale of MONOVISC in the market. The agreement also calls for potential additional payments contingent on achieving certain performance and sales threshold milestones, in addition to product transfer and royalty fees. Anika has marketed MONOVISC internationally since 2008. The product is currently sold in a variety of territories, including Canada, the U.K. and several countries in the Middle East, Europe and Asia.

"The U.S. market for viscosupplementation therapy is experiencing double digit growth annually. With FDA approval of MONOVISC, we can be better positioned with our single and multi-injection products to meet the varying needs of physicians and patients," said Charles H. Sherwood, Ph.D., President and Chief Executive Officer "We are moving forward rapidly with Mitek Sports Medicine to capitalize on the strengths of our viscosupplementation portfolio. Commercial introduction for MONOVISC in the U.S. is planned to take place in conjunction with the annual meeting of the American Academy of Orthopedic Surgeons to be held in New Orleans, March 11 to 15, 2014."

Product Summary

MONOVISC is indicated for the treatment of pain in OA of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and to simple analgesics (e.g. acetaminophen). It is a sterile, non-pyrogenic, viscoelastic solution of hyaluronan contained in a single-use syringe. MONOVISC consists of high molecular weight, ultra-pure natural hyaluronan, a complex sugar of the glycosaminoglycan family. The hyaluronan is derived from bacterial cells and is cross-linked with a proprietary cross-linker. MONOVISC was designed to deliver a comparable HA dose to Anika's three-injection viscosupplement, ORTHOVISC, in the convenience of a single 4 mL intra-articular injection.

Clinical Synopsis

The FDA approval of MONOVISC is based on safety and effectiveness data from a randomized, controlled, double-blind multi-center pivotal U.S. clinical study encompassing a total of 369 patients at 31 centers in the US and Canada suffering from OA of the knee. The objective of the study was to assess the safety and effectiveness of MONOVISC for the treatment of joint pain. Patients were randomized to either MONOVISC or control (saline injection) and were evaluated for improvement in pain as measured by the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) at follow-up assessments out to 26 weeks. The primary effectiveness analysis compared the proportion of MONOVISC patients achieving a greater improvement from baseline in WOMAC pain score versus control through 12 weeks. The safety analysis showed MONOVISC had an extremely low rate of adverse events. There were no serious adverse events associated with MONOVISC.

About Osteoarthritis of the Knee

Greater than 5% of the world's population is afflicted by osteoarthritis 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. Approximately 10 million Americans currently suffer from OA of the knee and that number is expected to increase.

OA of the knee is characterized by the breakdown of cartilage, the part of the joint that cushions the ends of bones, causing bones to rub against each other, resulting 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.

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

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®, a treatment for pain due to osteoarthritis of the knee; 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 orthopedic/joint health and anti-adhesion, as well as therapeutics in areas such as advanced wound treatment and ear, nose and throat care. Its regenerative tissue technology advances Anika's vision to offer therapeutic products that go beyond pain relief to protect and restore damaged tissue.

The statements made in 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 (i) the company and its partner's ability to commercialize Monovisc in the U.S., (ii) our ability to capitalize on the strengths of our viscosupplementation portfolio, (iii) our ongoing initiatives to improve performance across the business, (iv) our efforts and ability to strengthen and expand our international Orthobiologics distribution network, (v) the company's plans to continue to drive efficiencies in operations and manufacturing, (vi) the prospects for the company's product pipeline, including regenerative product development, (vii) bringing Cingal to market, and (viii) expectations for future growth and profitability improvement in the quarters ahead. 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, obtain pre-clinical or clinical data to support domestic and international pre-market approval applications or 510(k) application, or timely file and receive FDA or other regulatory approvals or clearances of its products, or 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; (ii) the company's research and product development efforts and their relative success, including whether the company has any meaningful sales of any new products resulting from such efforts; (iii) the cost effectiveness and efficiency of our clinical studies, manufacturing operations and production planning; (iv) 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; (v) future determinations by the company to allocate resources to products and in directions not presently contemplated; (vi) the company's ability to provide an adequate and timely supply of its products to its customers, (vii) our ability to successfully manage Anika S.r.l.'s business, and (viii) the company's ability to achieve its stated growth targets. Certain other factors that might cause the company's actual results to differ materially from those in the forward-looking statements include those set forth under the headings "Business," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the company's Annual Report on Form 10-K for the year ended December 31, 2012, as well as those described in the company's other press releases and SEC filings.

Anika Therapeutics, Inc.
Charles Sherwood, Ph.D., CEO, 781-457-9000
or
Sylvia Cheung, CFO, 781-457-9000

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