Anika Investor Relations

Anika Therapeutics Receives Health Canada Approval for MONOVISC™

BEDFORD, Mass. --(BUSINESS WIRE)--Aug. 20, 2009-- 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 received Health Canada approval for MONOVISC™, its single injection viscosupplement approved for the treatment of osteoarthritis of the knee. Anika expects to launch MONOVISC this month through its long-term ORTHOVISC® distribution partner in Canada , Rivex Pharma Inc. , the specialty drug distribution division of Aurora, Ontario -based Helix BioPharma Corp. (TSX: HBP). MONOVISC has been broadly available in the European Union since the second quarter of 2008.

“We are very pleased to be the exclusive distributor of MONOVISC in the Canadian market and will begin aggressively marketing it immediately,” said Bill Chick, VP Product Distribution for Helix BioPharma Corp. “We believe that both patients and physicians stand to benefit from MONOVISC’s unique features: patients will welcome fewer office visits and lower treatment costs, while physicians will appreciate the simplicity of the single-injection regimen.”

“Health Canada approval marks an important next step as we continue to expand the geographic reach of our novel osteoarthritis treatment therapy and establish MONOVISC as the premier single-injection product on the market worldwide,” said Charles H. Sherwood, Ph.D., Anika’s President and Chief Executive Officer. “We are successfully moving forward on our goal of achieving FDA approval for MONOVISC in the U.S. The initial PMA modules have been submitted to the FDA and are currently under review. We expect to submit the final module containing the clinical study data prior to year-end 2009. We are confident that MONOVISC will be as well received in North America as it has been in Europe.”

The Company previously announced that it has completed the clinical segment of the U.S. pivotal trial for MONOVISC, and is now focused on completing the retreatment study for MONOVISC, which is designed to demonstrate the safety and benefit of repeat injections.

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 www.monovisc.com.

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 include ORTHOVISC®, a treatment for osteoarthritis of the knee available internationally and marketed in the U.S. by DePuy Mitek; HYVISC®, a treatment for equine osteoarthritis marketed in the U.S. by Boehringer Ingelheim Vetmedica, Inc.; a family of aesthetic dermatology products for facial wrinkles and scar remediation marketed in the U.S. by Coapt Systems, Inc.; AMVISC®, AMVISC® Plus, STAARVISC™-II and Shellgel™ injectable viscoelastic HA products for ophthalmic surgery; INCERT®, an HA-based anti-adhesive for surgical applications; ORTHOVISC®mini a treatment for osteoarthritis targeting small joints and available in Europe; MONOVISC™ a single-injection osteoarthritis product based on Anika’s proprietary cross-linking technology and available in Europe, Turkey, and Canada; and next generation products for joint health and aesthetic dermatology based on the Company’s proprietary, chemically modified HA.

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 and Section 21E of the Securities Exchange Act of 1934, including, without limitation, statements that may be identified by words such as

"expectations," "remains," "focus," "expected," "prospective," "expanding," "building," "continue," "progress," “plan,” "efforts," "hope," "believe," "objectives," "opportunities," "will," "seek," “expect” and other expressions which are predictions of or indicate future events and trends and which do not constitute historical matters identify forward-looking statements. These statements also include) the company’s expectations concerning its MONOVISC product, including the U.S. clinical trials and the filing of a PMA, and its expectations to reap significant financial rewards for moving the product through the pipeline. 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 clinical data to support a pre-market approval application or timely file and receive FDA or other regulatory approvals of its products, or that such approvals will not be obtained in a timely manner or without the need for additional clinical trials; (ii) 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 (iii) the company’s ability to launch MONOVISC in Canada and the U.S., if at all. Any delay in receiving any regulatory approvals may adversely affect the company's competitive position. Even if regulatory approvals are obtained, there is a risk that meaningful sales of the products may not be achieved. 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, 2008 and on Form 10-Q for the period ended June 30, 2009, as well as those described in the company's other press releases and SEC filings.

Source: Anika Therapeutics, Inc.

Anika Therapeutics, Inc.
Charles H. Sherwood, Ph.D., 781-457-9000
CEO
or
Kevin W. Quinlan, 781-457-9000
CFO
