Anika Investor Relations

Anika Announces Publication of Phase III Data Demonstrating the Efficacy and Safety of CINGAL® for the Treatment of Knee Pain Associated with Osteoarthritis

Positive Data Provides Further Rationale for Strong and Growing Physician Demand for CINGAL following Commercial Launches in Europe and Canada

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 the publication of Phase III data demonstrating the efficacy and safety of CINGAL®, its novel HA-corticosteroid combination viscosupplement for the treatment of symptoms associated with osteoarthritis ("OA") of the knee. The data, published in this month's issue of the peer-reviewed journal Cartilage, demonstrated that CINGAL provided superior immediate and short term pain relief after injection as compared to HA alone, and superior relief from OA-related pain, stiffness and function through 26 weeks as compared to saline. These Phase III study results were part of the comprehensive clinical data package that formed the basis for CINGAL's CE Mark and Health Canada approval in 2016.

"We are excited to share published, peer-reviewed Phase III data that validates the efficacy, safety and clinical significance of our novel viscosupplement, CINGAL," said Charles H. Sherwood, Ph.D., President and Chief Executive Officer of Anika Therapeutics. "CINGAL fulfills a tremendous unmet clinical need for a low-volume corticosteroid and hyaluronic acid combination viscosupplement that has an established track record of safety and efficacy, and provides immediate and long-term relief from knee OA symptoms for 6 months and potentially beyond."

CINGAL is the first and only viscosupplement that combines triamcinolone hexacetonide, a well-established, FDA-approved steroid that may be utilized to treat inflammation, with Anika's proprietary cross-linked, non-animal-derived hyaluronic acid, which is the active "cushioning" ingredient in the global market-leading viscosupplements, ORTHOVISC® and MONOVISC®. Viscosupplements are injected by a licensed medical professional into synovial joints to replenish the natural cushioning within joints that depletes with age and degenerative orthopedic diseases, causing pain.

The multicenter, double-blind, saline-controlled clinical trial evaluated 368 patients with knee osteoarthritis who were randomized for treatment with a single injection of CINGAL (n=149), MONOVISC (n=150) or saline (n=69). Changes in pain, stiffness and physical function were assessed using a variety of validated measurement tools including the Western Ontario and McMaster Universities Arthritis Index (WOMAC)1.

Below are the key findings:

- CINGAL reduced WOMAC Pain by 70% at 12 weeks and 72% at 26 weeks as compared to saline - more improvement than that reported in previous viscosupplement studies.2, 3, 4, 5
- CINGAL demonstrated rapid pain relief following administration (a 59% improvement in WOMAC Pain at 1 week and 68% at 3 weeks) - unmatched by prior trials of triamcinolone hexacetonide alone.6, 7
- CINGAL met all primary and secondary endpoints relative to saline in the ITT analysis.
- CINGAL demonstrated significant improvement with respect to most secondary endpoints for pain and function at most time points through 26 weeks.
- At 1 and 3 weeks, CINGAL was significantly better than MONOVISC for most endpoints.
- CINGAL and MONOVISC provided similar benefits from 6 weeks through 26 weeks.
- CINGAL was shown to be safe, and was associated with a low incidence of adverse events (n=6) that resolved over time. There were no serious adverse events considered to be related to CINGAL.

"Steroid injections and hyaluronic acid-based viscosupplements are two forms of effective non-surgical

interventions to manage knee osteoarthritis," said Prof. Laszlo Hangody, MD, Ph.D., DSc., the study's lead author, Clinical Professor at the Debrecen Medical School and Senior Consultant in the Orthopaedic Department at Uzsoki Hospital, Budapest, Hungary. "By combining a proven viscosupplement, MONOVISC, with an established steroid in a single injection, CINGAL gives patients a safe, convenient and highly effective treatment option for immediate and sustained relief from the debilitating symptoms of knee OA."

CINGAL is commercially available in certain countries of the European Union (E.U.), and Canada, and is under regulatory review in the United States. Anika recently completed site initiation in the E.U. to begin enrolling patients in a supplemental Phase III study requested by the U.S. Food and Drug Administration. Anika anticipates FDA approval of CINGAL after it completes the study in 2018.

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 third sentence of the final 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 expectations regarding the Company's supplemental Phase III study for CINGAL and FDA approval of CINGAL. 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.

1Western 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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