Anika Investor Relations

Tactoset® Injectable Bone Substitute Now FDA Cleared for Hardware Augmentation

510(k) clearance expands the capability of Tactoset for augmenting suture anchor fixation

BEDFORD, Mass., Sept. 14, 2021 (GLOBE NEWSWIRE) -- Anika Therapeutics, Inc. (NASDAQ: ANIK), a global joint preservation company focused on early intervention orthopedics, today announced that it has received an additional 510(k) clearance by the FDA for Tactoset® Injectable Bone Substitute. This new indication expands the use of Tactoset to include augmentation of hardware and the support of bone fragments during surgical procedures. This expands Tactoset's addressable market to include augmentation of suture anchor fixation in addition to treatment of skeletal system defects such as insufficiency fractures.

"Poor quality bone and suture anchor pullout is a real problem for patients in our industry, and surgeons can now use Tactoset to augment their suture anchor fixation and reinforce it from inside the bone. We've taken our proprietary HA-enhanced Tactoset and opened an untapped market in the area of augmentation of hardware including soft tissue suture anchors," says Ben Joseph, Vice President of US Commercial and Global Brand Management at Anika. "Tactoset is a key growth driver within our current regenerative solutions portfolio, and this augmentation clearance highlights the transformation of Anika as a joint preservation and restoration company. We have big plans for Tactoset in the market and expect to have additional indications coming in the future."

Tactoset is a calcium phosphate based, biocompatible bone graft substitute that incorporates Anika's core hyaluronic acid (HA) technology. The HA component of Tactoset makes the product highly flowable, easily injectable and able to interdigitate trabecular bone architecture with overall improved handling characteristics compared to competitive products. Once injected, Tactoset hardens and mimics the properties of normal trabecular bone initially and remodels into healthy bone over time.

Since its launch in Q4 of 2019, Tactoset has been used for the treatment of bone voids, insufficiency fractures, and other skeletal defects, often performed in an outpatient surgical setting. With this expanded indication, surgeons can now use Tactoset in situations where augmenting hardware and/or bone fragments due to insufficient bone quality may be beneficial to their patients. Tactoset has been shown to increase the pull-out strength of a screw-in suture anchor two-fold1 in an osteoporotic bone model when augmented with the cured Tactoset compared to a suture anchor alone.

Dr. Misty Suri, MD from Ochsner Health in New Orleans said, "I am pleased to see the expanded indications for Tactoset cleared for use to augment hardware and bone fragments during surgical procedures. Bone quality is a critical factor when placing load bearing anchors, and the area in which hardware is normally placed is often weaker due to inferior bone quality or insufficiency fractures. Fundamentally, shoulders, knees and other joints that require surgery are often associated with either osteoporotic bone and/or lower quality bone, which significantly increases the potential for pain, hardware failure, and inferior patient outcomes. With this expanded Tactoset indication, we are now able to address the concern for microfractures and bone quality while creating a strong foundation to augment the use of suture anchors and other hardware. This gives surgeons more confidence in repairs such as rotator cuff, shoulder instability, and knee reconstructive surgeries."

Anika expects to begin actively marketing the expanded indication for Tactoset for hardware augmentation in October 2021.

1. Preclinical data on file. Results may not correlate to clinical performance.

Forward-Looking Statements
This press release may contain 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, concerning the Company's expectations, anticipations, intentions, beliefs or strategies regarding the future which are not statements of historical fact, including the last sentence of the second paragraph and the sixth paragraph.

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.

About Anika
Anika Therapeutics, Inc. (NASDAQ: ANIK), is a global joint preservation company that creates and delivers meaningful advancements in early intervention orthopedic care. We partner with physicians to understand what they need most to treat their patients and we develop minimally invasive products that restore active living for people around the world. We are committed to leading in high opportunity spaces within orthopedics, including osteoarthritis pain management, regenerative solutions, soft tissue repair and bone preserving joint technologies. For more information, please visit www.anika.com.

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