Anika Investor Relations

# Anika Continues to Expand Addressable Market for Tactoset® Injectable Bone Substitute with Additional 510(k) Clearance from FDA

**Tactoset cleared by the FDA to be combined with autologous bone marrow aspirate, a core element for regenerative healing**
**Anika reaches agreement to distribute the Marrow Cellution™ Bone Marrow Aspiration Needle in the U.S. and commences launch**
**Launches enhanced Tactoset cannulas, which improve targeting and ease of use in a variety of foot and ankle procedures**

**BEDFORD, Mass., April 3, 2023** – 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 from FDA for Tactoset Injectable Bone Substitute. This new indication expands the use of Tactoset to be combined with autologous bone marrow aspirate ("BMA"). BMA is a rich source of various cellular and molecular components which have demonstrated positive effects on tissue regeneration in musculoskeletal injuries. This increases Tactoset's commercial reach by combining BMA with Tactoset for the treatment of bone defects such as osteoporotic bone, cysts, and insufficiency fractures.

Tactoset is an injectable, settable, calcium phosphate-based 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 into trabecular bone architecture with improved handling characteristics compared to competitive products. Once injected, Tactoset hardens and mimics the properties of normal trabecular bone initially before remodeling into healthy bone over time.

"Combining Tactoset with BMA gives surgeons the ability to better address the needs of patients where healing is a concern, such as areas of the body with poor vascularity," said Anil Ranawat, MD, Chief, Hip and Knee Division of Sports Medicine Institute, Hospital for Special Surgery, New York, NY. "Mesenchymal stem cells (MSCs) found within marrow play a role in bone defect repair by differentiating to become bone-forming osteoblasts and aiding in the remodeling processes."

As Anika continues to focus on early intervention orthopedics with regenerative solutions, offering a novel product with a BMA solution is a foundational component of a regenerative platform and a key catalyst for leveraging a patient's own biology. To that end, Anika has signed an agreement to distribute the Marrow Cellution Bone Marrow Aspiration Needle in the U.S. This system utilizes a patented technology that combines aspiration and cannula motion to maximize cell recovery, while eliminating the need to remove materials from the sterile field for centrifuge processing. This drives efficiencies and mitigates risk to the patient compared to competitive systems. Finally, Anika also recently launched enhanced Tactoset delivery cannulas, which improve ease of use and simplify the targeting and delivery of the material, especially in foot and ankle procedures.

"Tactoset, a regenerative solutions product, continues to be a key growth driver within our joint preservation and restoration portfolio, as it is uniquely positioned to address unmet needs in patients with insufficiency fractures and poor-quality bone including cysts where augmenting hardware, such as suture anchors, gives surgeons additional confidence in their repair constructs," said Cheryl R. Blanchard, PhD, President and CEO, Anika Therapeutics. "This new FDA clearance for mixing Tactoset with BMA provides a product with improved regenerative capacity and showcases Anika's commitment to developing unique solutions that are meaningful to our customers and their patients. It also further reinforces our confidence that we can increase Tactoset's addressable market to well beyond $100 million by creating a new market for hardware augmentation. The BMA clearance, together with the release of enhanced cannulas and our distribution of the Marrow Cellution Bone Marrow Aspiration Needle announced today, highlight our continued investment in differentiated products that expand and reinforce our regenerative solutions portfolio and enhance growth and profitability for our shareholders."

With the continued expansion of Tactoset, Anika is extending its strong track record of innovation and execution through the development of numerous new indications which have been recognized with an award for innovative products. In late 2021, Tactoset achieved approval for use in hardware augmentation, such as soft tissue anchors, an additional indication for which it received the Accelerating the Cutting Edge (ACE) Award from the American Orthopaedic Society for Sports Medicine (AOSSM). These new product launches further expand the indications and support of this innovative product.

**About Anika**
Anika Therapeutics, Inc. (NASDAQ: ANIK), is a global joint preservation company that creates and delivers meaningful advancements in early intervention orthopedic care. Leveraging our core expertise in hyaluronic acid and implant solutions, we partner with clinicians to provide minimally invasive products that restore active living for people around the world. Our focus is on high opportunity spaces within orthopedics, including Osteoarthritis Pain Management, Regenerative Solutions, Sports Medicine and Arthrosurface Joint Solutions, and our products are efficiently delivered in key sites of care, including ambulatory surgery centers. Anika's global operations are headquartered outside of Boston, Massachusetts. For more information about Anika, please visit www.anika.com.



**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. 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.*

**For Investor Inquiries:**
Anika Therapeutics, Inc.
Mark Namaroff, 781-457-9287
Vice President, Investor Relations, ESG and Corporate Communications
investorrelations@anika.com

**For Media Inquiries:**
Greenough
Christine Williamson, 617-922-1289
Senior Vice President
cwilliamson@greenough.biz

---

https://ir.anika.com/2023-04-03-Anika-Continues-to-Expand-Addressable-Market-for-Tactoset-R-Injectable-Bone-Substitute-with-Additional-510-k-Clearance-from-FDA