Anika Investor Relations

Anika Completes Enrollment in Hyalofast® U.S. Pivotal Phase III Study Achieving Key Milestone

Hyalofast – a single-stage, off-the-shelf, resorbable, hyaluronic acid scaffold for cartilage repair is marketed in over 35 countries outside the U.S. where it has been clinically demonstrated to be safe and effective

Hyalofast has been designated as a breakthrough device by FDA, allowing prioritized interaction and review; Anika to begin filing modular PMA in 2024 with final module filing expected in 2025

Hyalofast positions Anika to lead and expand the over $350 million[1] U.S. knee cartilage repair market with significant benefits for all stakeholders in the healthcare system

BEDFORD, Mass., May 30, 2023 – Anika Therapeutics, Inc. (NASDAQ: ANIK), a global joint preservation company focused on early intervention orthopedics, today announced that it has completed enrollment of the pivotal Phase III clinical study for Hyalofast (Hyalofast 15-01) on its path to achieving FDA approval in the United States.

Hyalofast is a highly differentiated, single-stage, bone preserving, hyaluronic acid (HA) matrix and its approval would immediately position Anika as a leader in the regenerative knee cartilage repair market, which is growing at a 5-year CAGR of 11% and is expected to reach in excess of $350 million by 2025[1]. Unlike the current standard of care which requires two surgeries, removal of autologous cartilage, cell expansion, and subsequent cell reimplantation at the diseased site, or an alternative product that requires removing healthy bone to accommodate an implant, Hyalofast is implanted in just a single surgery following debridement of only the diseased tissue. In addition to reducing the burden on patients and the healthcare system, Hyalofast is stocked at the surgical facility and can simply be pulled off the shelf during surgery when a cartilage lesion is identified.

“This is an important milestone for Anika, bringing us one step closer to making Hyalofast available for patients in the United States,” said Anika’s President and CEO, Cheryl R. Blanchard, Ph.D. “The knee cartilage repair market in the U.S. is large and growing and is perfectly aligned with our strategic focus as we continue to introduce groundbreaking regenerative solutions that expand our Joint Preservation and Restoration portfolio. We believe that Hyalofast will drive significant market expansion and further accelerate our company’s growth in the coming years. We are pleased that FDA has granted Hyalofast Breakthrough Device Designation and has agreed to a modular PMA filing, both of which will facilitate an efficient review process.”

Hyalofast is already marketed in more than 35 countries outside the U.S. and is truly a game changing treatment for patients with pain and decreased function caused by cartilage lesions. The U.S. cartilage repair market has been constrained by the need for surgeons to perform, and patients to endure, a second surgical procedure in order to use the product on the market today. The off-the-shelf, bone-preserving design of Hyalofast allows surgeons to quickly repair lesions intraoperatively, without the need for a second costly, invasive surgery.

FDA has granted Anika Breakthrough Device Designation for the Hyalofast plus autologous bone marrow aspirate concentrate (BMAC) combination product. The Breakthrough Device Program is a voluntary program for certain medical devices that are aimed at providing more effective treatment of life-threatening or irreversibly debilitating diseases or conditions. It offers Anika the opportunity to engage with FDA on a prioritized basis to efficiently address topics as they arise during the premarket review phase, ultimately enabling patients’ faster access to new therapies.

The Company has also obtained agreement from FDA to file a modular PMA submission and expects to file the first module of the application in 2024. This allows Anika to file product and manufacturing information while continuing to collect and analyze clinical data, making the regulatory review process more efficient. The final module with clinical data is expected to be filed in 2025.

In the U.S., Hyalofast would join Tactoset® Injectable Bone Substitute in Anika’s regenerative portfolio, as well

as other products in the regenerative pipeline including the HA-based, arthroscopic patch system. Tactoset is an HA and calcium phosphate based, biocompatible bone graft substitute that is highly flowable, easily injectable, settable, and interdigitates into the trabecular bone architecture with improved handling characteristics compared to other competitive products. While widely used to treat insufficiency fractures, it is also indicated for use with the augmentation of hardware, such as suture anchors.

About Hyalofast

Hyalofast is a biodegradable, resorbable, non-woven scaffold composed of HYAFF® fibers. HYAFF is Anika's proprietary solid form of HA, composed of a benzyl ester of hyaluronic acid. It is intended as support for the entrapment of mesenchymal stem cells obtained from autologous bone marrow aspirate concentrate (BMAC) for the repair of chondral and osteochondral lesions. Hyalofast is implanted into a cartilage lesion with BMAC and fills the defect until it is eventually resorbed and replaced by new, hyaline like cartilage that integrates with the surrounding tissues. Hyalofast allows for the repair of both chondral and osteochondral lesions without removing healthy subchondral bone.

Outside the U.S., Hyalofast has been clinically demonstrated to be safe and effective in medium to long term follow up in the repair of ankle and knee chondral and osteochondral lesions. Over 40 Hyalofast clinical publications representing greater than 10 years of clinical data show that patients consistently report reduction in pain and improvement in function of the affected joint, thus enabling return to their active lifestyle with substantial pain relief and high satisfaction[2]. Hyalofast has also demonstrated a strong safety profile since being placed on the market outside the U.S. in 2009.

The Hyalofast Phase III 15-01 Study Design

The Hyalofast 15-01 study is a prospective, randomized, active treatment-controlled, evaluator-blinded multicenter study to establish the superiority of Hyalofast with autologous bone marrow aspirate concentrate (BMAC) in the treatment of articular knee cartilage defect lesions in comparison to microfracture as a control. The current enrolled study involves 200 subjects randomized 1:1 versus microfracture with co-primary endpoints being the % change in KOOS Pain Score from baseline to two years and % change in IKDC Subjective from baseline to two years. The study, which began in 2015, was significantly delayed due to the impact COVID had on new site initiation and elective surgical procedures. Hyalofast plus BMAC is a device-biologic combination product that will be subject to a premarket approval application (PMA) under the jurisdiction of FDA's Center for Biologics Evaluation and Research (CBER).

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, including statements about the planned premarket approval filing of Hyalofast with the FDA, the timing and potential for FDA approval of Hyalofast, the future commercialization of Hyalofast, the size of or ability for Anika to compete in the cartilage repair market, and the potential impact to the growth rate of Anika if and when Hyalofast is approved for sale in the U.S. market. 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.

[1] SmartTRAK and Anika estimates

[2] Gobbi A et al. Long-term Clinical Outcomes of One-Stage Cartilage Repair in the Knee with Hyaluronic Acid-Based Scaffold Embedded with Mesenchymal Stem Cells Sourced From Bone Marrow Aspirate Concentrate. Am J Sports Med. 2019 May 16; Additional data on file.

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