Anika Reports Topline Results from U.S. Pivotal FastTRACK Phase III Study for Hyalofast® Cartilage Repair Scaffold and Provides Program Update

Hyalofast consistently demonstrated improvements over microfracture, but missed on statistical significance of the pre-specified co-primary endpoints of percent change in KOOS Pain and IKDC function

Hyalofast showed statistically significant improvements over microfracture in pre-defined secondary endpoints and other measures that align with prior FDA approvals for cartilage repair products

Hyalofast has been used to treat over 35,000 patients in more than 35 countries outside the U.S since 2009; data from independent studies performed outside the U.S. will be filed with FDA submission

Based on the totality of the data, Anika plans to file the final PMA module in H2 2025

Bedford, Mass., July 30, 2025 – Anika Therapeutics, Inc. (Nasdaq: ANIK), a global leader in osteoarthritis pain management and regenerative solutions, today announced topline results from its U.S. pivotal clinical trial of Hyalofast, a resorbable, hyaluronic acid scaffold used in conjunction with autologous bone marrow aspirate concentrate (BMAC) for cartilage repair. Enrollment for this trial was completed in 2023 and the results announced today follow the recently completed, evaluator-blinded two-year follow-up period post-treatment.

The FastTRACK study, started in 2015, is a prospective, randomized, active treatment-controlled evaluator-blinded multicenter study to establish superiority of Hyalofast with autologous BMAC in the treatment of articular knee cartilage defect lesions in comparison to a microfracture control (an active comparator). Superiority between the groups was to be determined with two pre-specified co-primary endpoints: percent change from baseline to two years in both Knee injury and Osteoarthritis Outcomes Score (KOOS) pain and International Knee Documentation Committee (IKDC) Subjective Knee Evaluation Score (a measure of function).

While Hyalofast demonstrated consistent improvements in treated patients across all measures of pain and function relative to microfracture, the study did not meet its pre-specified co-primary endpoints. The study was likely impacted by both a higher subject dropout rate in the microfracture arm and missed visits during COVID. This resulted in missing data, which reduced the evaluable sample size and complicated the statistical analysis. Hyalofast exhibited a comparable safety profile when compared to microfracture following the initial effects of the differences in surgical procedure, supporting a favorable benefit-risk profile for Hyalofast.

Based on the totality of the clinical data the company has collected on Hyalofast, Anika plans to file the final PMA module by the end of the year. Hyalofast showed statistically significant improvements in key pre-defined secondary endpoints including KOOS Sports and Recreation Function, and Quality of Life. In addition, Hyalofast demonstrated statistically significant improvement in Total KOOS, a composite pain and function measure. These additional measures have supported prior FDA approvals for cartilage repair products. Hyalofast has been used outside the U.S. to successfully treat more than 35,000 patients since its launch in 2009 and is currently available in more than 35 countries. Hyalofast has demonstrated a favorable safety and effectiveness profile from this real-world clinical experience across multiple independent studies performed outside the U.S. including positive 15-year outcomes published last year.

“While we are disappointed that the co-primary endpoints were not achieved under the original statistical framework, we are encouraged by the consistency and robustness of our results on pain and function measures including achieving significance on measures used for prior FDA cartilage repair approvals and the published global evidence supporting the safety and effectiveness of Hyalofast. We believe the totality of evidence presented in this study and the data from outside the U.S. demonstrates the true clinical value of Hyalofast, a single stage procedure, for patients

who suffer from cartilage lesions in the knee," said Cheryl Blanchard, President and CEO of Anika Therapeutics.

Anika plans to file the third and final PMA module in the second half of 2025 and seek approval from the FDA. The third module will include ongoing additional post-hoc analyses including consideration of additional endpoints previously accepted by the FDA for cartilage repair product approvals. Anika expects that the FDA will consider these additional post-hoc analyses and the additional data from outside the U.S. as part of its review of the PMA submission under its Breakthrough Device Designation, but whether these analyses are sufficient to support approval will be a review issue.

About Hyalofast

Hyalofast is Anika's single-stage, off-the-shelf, resorbable, hyaluronic acid scaffold for cartilage repair. It supports the regeneration of hyaline-like cartilage and is currently marketed in over 35 countries outside the US, with multiple clinical trials demonstrating its safety and effectiveness. Hyalofast has been designated as a breakthrough device by the FDA, allowing prioritized interaction and review.

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 clinical effectiveness of Hyalofast, the timing of the planned submission of a third PMA module for Hyalofast, the timing of FDA's review of the PMA submission and the likelihood of approval. 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 timely complete regulatory submissions, including the third PMA module for Hyalofast, (ii) the FDA's ability to timely review any such submission, and (iii) that the FDA may not approve the Hyalofast PMA because of the failure to achieve the pre-defined primary endpoints or because the FDA may determine that achievement of secondary endpoints and/or post hoc data analyses are not sufficient to support approval. 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 the global leader in the design, development, manufacturing, and commercialization of hyaluronic acid innovations. In partnership with clinicians, our sole focus is dedicated to delivering and advancing osteoarthritis pain management and orthopedic regenerative solutions. At our core is a passion to deliver a differentiated portfolio that improves patient outcomes around the world. Anika's global operations are headquartered outside of Boston, Massachusetts. For more information about Anika, please visit www.anika.com.
