Anika Therapeutics Reports Filing of Final PMA Module for Hyalofast® Cartilage Repair Scaffold and Data from U.S. Pivotal FastTRACK Phase III Study

BEDFORD, Mass., November 5, 2025 – Anika Therapeutics, Inc. (NASDAQ: ANIK), a global leader in joint preservation and regenerative solutions, announced that it filed the third and final module of its Premarket Approval application (PMA) for Hyalofast—its resorbable, hyaluronic acid-based scaffold used with autologous bone marrow aspirate concentrate (BMAC) for treating articular cartilage defects in the knee. The Company also reported results from its U.S. pivotal Phase III FastTRACK clinical trial evaluating Hyalofast.

On October 31, 2025, Anika submitted the third and final module of its Hyalofast PMA to the U.S. Food and Drug Administration (FDA). The PMA includes FastTRACK 24-month data and incorporates additional post-hoc analyses and real-world data.

“We are pleased to announce the filing of the PMA for Hyalofast and to provide the results of the pivotal FastTRACK Phase III study. We believe the comprehensive results of the FastTRACK study reinforce Hyalofast’s potential as a transformative, single-stage, off-the-shelf cartilage repair solution for patients in the U.S.,” said Cheryl Blanchard, President and CEO of Anika Therapeutics. “We are proud of the robust clinical data that we presented to the FDA and we look forward to working with the FDA on our goal of bringing Hyalofast to patients in the U.S.”

Key Findings from U.S. Pivotal Phase III FastTRACK Clinical Trial
Initiated in 2015, the FastTRACK study was a prospective, randomized, active treatment-controlled, evaluator-blinded, multicenter clinical trial designed to establish superiority of Hyalofast combined with BMAC in the treatment of articular knee cartilage defect lesions in comparison to microfracture, an active control arm that was considered the standard of care at the time. The study enrolled patients with symptomatic cartilage lesions and monitored outcomes for two years following treatment.

Primary Endpoints (24-month data):
As previously reported, the study did not meet its pre-specified co-primary endpoints under the original statistical framework. The two co-primary endpoints were the percent change in baseline at 24 months for Knee injury and Osteoarthritis Outcomes Score pain (KOOS Pain) and International Knee Documentation Committee Subjective Knee Evaluation Score (IKDC Function), a measure of function. The results are reported as the relative difference between the Hyalofast arm compared to the microfracture arm. At 24 months, KOOS Pain scores showed an 8.11% difference between the arms favoring microfracture (p=0.81), while IKDC Function scores showed a 4.84% difference favoring Hyalofast (p=0.34); neither result was statistically significant. These percent changes were influenced by high variability in baseline scores, particularly in the microfracture arm. To provide additional context, absolute changes from baseline were also analyzed on a post-hoc basis. For KOOS Pain, Hyalofast demonstrated an average improvement of 4.54 points over microfracture (p=0.15). Hyalofast demonstrated an improvement in IKDC score of 2.19 points over microfracture (p=0.28).

The number of subject dropouts for the microfracture arm was nearly double that of the Hyalofast arm, resulting in more missing data in the microfracture arm. The missing data was in part due to missed visits during COVID, as well as dissatisfaction with microfracture as a treatment. The original pre-specified endpoint analysis assumed data would be normally distributed and missing at random. Therefore, on a post-hoc basis, the company also prepared the results without imputation (observed data) using a non-parametric statistical t-test, which is used for data sets with skewed distributions. In that analysis, at the same 24-month timepoint, Hyalofast demonstrated a 23.37% improvement over microfracture in the KOOS Pain score (p=0.02) and showed superiority in KOOS Pain with an absolute difference of 4.54 points (p=0.02) over microfracture. Both of these results were statistically significant.

Key Secondary Endpoints Demonstrated Statistically Significant Improvements with Hyalofast:
Hyalofast demonstrated statistically significant improvements in key secondary endpoints. Compared to microfracture, Hyalofast showed a 12.19-point gain in KOOS Sports and Recreation scores (p=0.01) and a 9.52-point improvement in KOOS Quality of Life scores (p=0.03) over microfracture. Additionally, Hyalofast outperformed microfracture in Total KOOS—a composite measure of both pain and function—by 6.57 points (p=0.02). These results underscore the broader functional and quality-of-life benefits observed with Hyalofast. All other secondary endpoints showed consistent benefit of Hyalofast over microfracture, however, without statistical significance over the active control microfracture arm.

Post-Hoc Responder Analysis Demonstrated a Significantly Greater Proportion of Patients Treated with Hyalofast Achieved Clinically Meaningful Improvements of KOOS Pain
A responder analysis provides a picture of how many patients achieve clinically significant improvement. This approach is widely recognized by clinicians and regulators as a meaningful measure of treatment benefit. At 24 months, a significantly greater proportion of patients treated with Hyalofast achieved clinically meaningful improvements in KOOS Pain.

Compared to microfracture, Hyalofast demonstrated statistically significant advantages at higher improvement thresholds, with 87.4% of Hyalofast patients achieving at least a 10-point improvement versus 75.3% of microfracture patients (p=0.050). At a 15-point improvement, the gap widened in favor of Hyalofast to 83.5% vs. 60.8% (p=0.004). And, at an even higher threshold of 20 points improvement, 72.8% of Hyalofast patients responded, compared to 52.6% in the microfracture group (p=0.029).

These findings underscore the consistency and depth of pain relief achieved with Hyalofast, with statistically significant advantages over microfracture at higher improvement thresholds.

Clinical and Regulatory Implications
While the study did not meet its pre-specified co-primary endpoints under the original statistical framework, Anika attributes this outcome to several study dynamics, including COVID-related disruptions, a shift in the standard of care away from microfracture since study initiation, and higher dropout rates in the microfracture active control arm due to patient dissatisfaction with that treatment —which collectively impacted statistical power. Despite these challenges, the Company remains confident in the clinical value of Hyalofast. Hyalofast showed statistically significant improvements in key pre-defined secondary endpoints including KOOS Sports and Recreation, and Quality of Life. In addition, Hyalofast demonstrated statistically significant improvement in Total KOOS, a composite pain and function measure. These measures have supported prior FDA approvals for cartilage repair products. Additionally, Anika has real world experience with Hyalofast, having treated over 35,000 patients globally since 2009, with positive long-term (to 15 years) outcomes from international published studies, and has also received Breakthrough Device Designation from the FDA.

About Hyalofast®
Hyalofast is an off-the-shelf, single-stage scaffold designed to support regeneration of hyaline-like cartilage. It is currently marketed in over 35 countries and has demonstrated safety and efficacy in multiple clinical trials.

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 potential of Hyalofast, the timing of the FDA's review of regulatory submissions for Hyalofast and the outcome of such review. 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, or to timely file domestic and international pre-market approval applications, 510(k) applications, or new drug applications, including the PMA for Hyalofast; (iii) that the FDA or other regulatory bodies may not approve or clear the Company's applications, including 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; (iii) that

such approvals or clearances 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.*

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