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Avant Technologies and Ainnova Request Pre-Submission Meeting with US FDA for VisionAI Platform Technology

LAS VEGAS, April 29, 2025 /PRNewswire/ -- Avant Technologies, Inc. (OTCQB: AVAI) ("Avant" or the "Company"), and its JV partner, Ainnova Tech, Inc., (Ainnova), a leading healthcare technology company focused on revolutionizing early disease detection using artificial intelligence (AI), today announced that The Center for Devices and Radiological Health of the U.S. Food and Drug Administration (FDA) has received the company's submission package requesting a pre-submission meeting with the FDA for its VisionAI platform technology and is now under review.

Ainnova is requesting a pre-submission meeting with the FDA's review team to discuss any questions and/or concerns about its proposed formal submission, including seeking advice to finalize the protocol and obtain agency guidance for a clinical trial of its VisionAI platform in the early detection of diabetic retinopathy.Â A pre-submission meeting allows companies to clarify regulatory requirements, get feedback on their plans, and potentially avoid delays or issues during the formal review process.

The clinical studies will aim to support an FDA 510(k) submission to obtain clearance from the regulatory agency to market its technology in the U.S.

Ai-nova Acquisition Corp. (AAC), the company formed by the partnership between Avant and Ainnova to advance and commercialize Ainnova's technology portfolio, including its VisionAI platform and its versatile retinal cameras, has worldwide licensing rights for this portfolio.Â The licensing rights include the U.S., where the FDA regulates drug and medical device development, so the success of Ainnova's interactions with the FDA are paramount to marketing the technology portfolio in the United States.

Vinicio Vargas, Chief Executive Officer at Ainnova and a member of AAC's Board of Directors, said, "This milestone reflects our two-tiered strategy, rapid deployment in low-regulation markets where VisionAI operates as a screening tool, and simultaneous progress toward FDA clearance for the U.S. market.Â Entering the U.S. will unlock significant commercial potential, and early engagement with regulators ensures we do so with speed, credibility, and a validated product."

For medical device applicants like Ainnova, the FDA's pre-submission program is useful to determine a clear regulatory pathway for the successful launch of the device, including the number of patients and the number of clinics that will be needed to generate the necessary clinical data for the FDA to make an informed decision on Ainnova's VisionAI platform.Â For Avant, the pre-submission meeting will help define a precise budget for the strategic partnership's entire FDA process.

About Ainnova Tech, Inc.

Ainnova is a Nevada-based healthtech startup with headquarters in San Jose, Costa Rica, and

Houston, Texas. Founded by an experienced and innovative team that is dedicated to leveraging artificial intelligence for early disease detection. Recognized with multiple global awards and renowned partnerships with hospitals and medical device companies, we proudly introduce VisionAI â€“ our cutting-edge platform designed to prevent blindness and detect the early onset of diabetes. Explore how Ainnova is revolutionizing healthcare through advanced technology and proactive solutions.

About Avant Technologies, Inc.Â

Avant Technologies, Inc. is an emerging technology company developing solutions in artificial intelligence in healthcare.Â With a focus on pushing the boundaries of what is possible in AI and machine learning, Avant serves a diverse range of industries, driving progress and efficiency through state-of-the-art technology.

More information about Avant can be found at https://avanttechnologies.comÂ

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Forward-Looking Statements

Certain statements contained in this press release may constitute "forward-looking statements."Â Forward-looking statements provide current expectations of future events based on certain assumptions and include any statement that does not directly relate to any historical or current fact.Â Actual results may differ materially from those indicated by such forward-looking statements because of various important factors as disclosed in our filings with the Securities and Exchange Commission located at their website (https://www.sec.gov).Â In addition to these factors, actual future performance, outcomes, and results may differ materially because of more general factors including (without limitation) general industry and market conditions and growth rates, economic conditions, governmental and public policy changes, the Company's ability to raise capital on acceptable terms, if at all, the Company's successful development of its products and the integration into its existing products and the commercial acceptance of the Company's products.Â The forward-looking statements included in this press release represent the Company's views as of the date of this press release and these views could change.Â However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so.Â These forward-looking statements should not be relied upon as representing the Company's views as of any date after the date of the press release.

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