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HeartBeam Announces Positive Heart Attack Pilot Study Results at TCT 2026: Patient-Recorded 3D ECG Shown to Be as Accurate as Standard 12-Lead ECG

- *Device demonstrated higher specificity than standard 12-lead ECG (81.8% vs. 71.4%), with comparable sensitivity*
- *HeartBeam ECGs were interpreted more consistently across cardiologists than standard 12-lead ECGs*
- *100% of patients successfully recorded their own ECGs with HeartBeam device, supporting potential use outside traditional clinical settings*
- *Technology has received FDA Breakthrough Device Designation for heart attack assessment; results will inform U.S. pivotal study expected to begin Q1 2027*
- *First-of-its-kind, portable, cable-free ECG device designed for on-demand patient use at the first sign of heart attack symptoms at home*

SANTA CLARA, Calif.--(BUSINESS WIRE)-- HeartBeam, Inc. (NASDAQ: BEAT), a medical technology company focused on transforming the detection and monitoring of critical cardiac conditions, today announced positive results from its ALIGN-ACS pilot study evaluating the HeartBeam System for heart attack assessment. The results were presented in an oral presentation by Graham Nichol, MD, MPH, FRCP(C), of the University of Washington, at the Transcatheter Cardiovascular Therapeutics (TCT) 2026 conference in San Diego.

When a heart attack occurs, time to treatment is critical. Yet, many patients delay seeking emergency care after symptoms begin, often because they are unsure whether their symptoms require immediate medical attention. HeartBeam's goal is to help physicians assess a suspected heart attack remotely and accelerate access to emergency care, if warranted. The HeartBeam heart attack assessment technology has received the FDA Breakthrough Device Designation. It addresses the coronary artery disease market of 20 million people in the US, which is approximately four times larger than the arrhythmia market.

HeartBeam's portable, cable-free, credit-card-sized device enables patients to record their own ECG on-demand, wherever they are, including at home. Unlike conventional wearables, HeartBeam captures three-dimensional electrical information from the heart, giving physicians a more complete picture for comprehensive evaluation.

"Obtaining a clinically meaningful recording of the heart's electrical activity at the time of symptom onset could help physicians assess whether a patient may be experiencing a heart attack and reduce time to intervention," said Dr. Nichol. "In the ALIGN-ACS pilot study, patients were able to record their own ECGs with the HeartBeam device under clinical supervision. A cardiologist's review of that patient-recorded ECG could help patients at home decide whether to seek care. These early findings demonstrate the potential of this

technology to help shorten time to care for patients experiencing a heart attack."

The ALIGN-ACS pilot study enrolled 132 adults at the emergency departments of two major cardiology centers in Belgrade, Serbia, to evaluate the diagnostic accuracy of the HeartBeam System compared with a standard 12-lead ECG in assessing acute coronary syndrome (ACS), which includes myocardial infarction (MI, or heart attack). Eight cardiologists, blinded to each patient's diagnosis, independently interpreted both the HeartBeam and standard 12-lead ECG recordings. Their interpretations were compared with each patient's final diagnosis, as determined by an independent panel of three cardiologists who reviewed all available clinical information.

Key study findings:

- **Higher specificity, comparable sensitivity.** HeartBeam demonstrated higher specificity than standard 12-lead ECG (81.8% vs. 71.4%), with comparable sensitivity (60.2% vs. 63.0%), pointing to its potential as a rule-in diagnostic aid.
- **Comparable sensitivity in STEMI assessment.** For ST-elevation myocardial infarction (STEMI), the most time-sensitive form of heart attack, sensitivity was 82.9% for HeartBeam compared with 83.8% for standard 12-lead ECG.
- **More consistent interpretation.** Eight cardiologists interpreting the ECG readings agreed more often with the HeartBeam recordings than with standard 12-lead ECG recordings (Fleiss' kappa = 0.73 with HeartBeam vs. 0.54 with 12-lead ECG), supporting the consistency of interpretation across readers.
- **Patient ease of use.** 100% of patients successfully obtained their own HeartBeam recordings under clinical supervision and with no prior training, supporting the feasibility of a patient-recorded ECG and the potential for use outside traditional clinical settings.

"Today, patients with chest pain or other symptoms are largely limited to self-assessment of whether they are experiencing a heart attack or not, as there is no portable, on-demand device available to them," said Branislav Vajdic, Ph.D., Founder and President of HeartBeam. "The ALIGN-ACS pilot study results support our goal of providing accurate cardiac information to both patients and physicians remotely when symptoms occur, with the intent to help expedite the symptom-to-door time and reduce the lag between symptoms and care."

Results from the ALIGN-ACS pilot study are intended to inform the design of a U.S. pivotal study planned to commence in the first quarter of 2027. If successful, the study is intended to support a future FDA submission seeking to expand the HeartBeam System's indication beyond arrhythmia assessment to include heart attack assessment.

The HeartBeam System is not currently FDA-cleared for heart attack assessment, and this application remains investigational.

About HeartBeam, Inc.

HeartBeam, Inc. (NASDAQ: BEAT) is a medical technology company dedicated to transforming the detection and monitoring of critical cardiac conditions. The Company has developed the first-ever cable-free device capable of collecting ECG signals in 3D, from three non-coplanar directions, and synthesizing the signals into a 12-lead ECG. This platform technology is designed for portable devices that can be used wherever the patient is to

deliver actionable heart intelligence. Physicians will be able to identify cardiac health trends and acute conditions and direct patients to the appropriate care – all outside of a medical facility, thus redefining the future of cardiac health management. HeartBeam's 3D ECG technology received FDA clearance for arrhythmia assessment in December 2024, and the 12-Lead ECG synthesis software received FDA clearance for arrhythmia assessment in December 2025[1]. The technology is currently being studied for heart attack assessment and is considered investigational in that indication. The Company holds over 25 issued patents related to technology enablement. For additional information, visit HeartBeam.com.

Forward-Looking Statements

All statements in this release that are not based on historical fact are "forward-looking statements." While management has based any forward-looking statements included in this release on its current expectations, the information on which such expectations were based may change. Forward-looking statements involve inherent risks and uncertainties which could cause actual results to differ materially from those in the forward-looking statements, as a result of various factors including those risks and uncertainties described in the Risk Factors and in Management's Discussion and Analysis of Financial Condition and Results of Operations sections of our Forms 10-K, 10-Q and other reports filed with the SEC and available at www.sec.gov. We urge you to consider those risks and uncertainties in evaluating our forward-looking statements. We caution readers not to place undue reliance upon any such forward-looking statements, which speak only as of the date made. Except as otherwise required by the federal securities laws, we disclaim any obligation or undertaking to publicly release any updates or revisions to any forward-looking statement contained herein (or elsewhere) to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based.

[1]**Cleared Indications for Use**

The HeartBeam System with 12-Lead ECG synthesis software is FDA cleared for arrhythmia assessment only. The technology's use for heart attack assessment is investigational and not FDA cleared. For full details on the intended use of the HeartBeam technology, refer to the Company's Cleared Indications for Use and full instructions at https://www.heartbeam.com/indications.

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