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HeartBeam Initiates Pilot Study of First On-Demand 12-Lead ECG Patch to Detect Ischemia Outside the Clinic

- *Ambulatory patch device designed to aid in detecting ischemia and complex arrhythmias*
- *Targets a \$2 billion market with established reimbursement; ischemia detection has potential to disrupt the patch market which is currently limited to atrial fibrillation detection*

SANTA CLARA, Calif.--(BUSINESS WIRE)-- [HeartBeam, Inc.](#) (NASDAQ: BEAT), a medical technology company focused on transforming cardiac care by providing powerful cardiac insights, announced the initiation of a pilot study evaluating its novel on-demand 12-lead ECG patch in patients with suspected coronary artery disease. The study is being conducted at two leading hospitals in Belgrade, Serbia. The initiation of the pilot study represents a significant step in the development of the HeartBeam patch which has the potential to disrupt the long-term continuous monitor and mobile cardiac telemetry (MCT) markets.

Patch-based ambulatory cardiac monitoring represents an approximately \$2 billion market with established reimbursement pathways. Today's ambulatory patch ECG monitors are limited to one to three leads and are primarily designed to assess heart rhythms, not ischemia. As a result, patients experiencing intermittent chest pain or cardiac symptoms outside the clinic often cannot obtain a clinical-grade ECG at the moment symptoms occur.

The HeartBeam on-demand patch, which is currently investigational and not yet FDA cleared, is designed to extend this capability beyond medical facilities. The patch device follows HeartBeam's credit card-sized device as the second form factor and leverages the same patented 3D ECG technology that captures the heart's electrical signals from 3 non-coplanar dimensions. The HeartBeam patch continuously records a single-lead ECG and enables patients to initiate a full synthesized 12-lead ECG recording on demand by placing two fingers on the device. This approach is intended to provide clinicians with high-quality cardiac insights when symptoms occur outside of traditional care settings.

To see how the HeartBeam patch works, [watch this demo video](#).

The pilot study will enroll approximately 50 patients with a high risk of coronary artery disease whose resting ECGs show no evidence of ischemia. Each participant will undergo exercise stress testing, a standard diagnostic procedure used to identify ischemic changes. Immediately following exercise, patients will activate the HeartBeam patch to generate a synthesized 12-lead ECG, which will be compared directly with a standard 12-lead ECG recorded at the same time. The results will help inform the Company's broader regulatory strategy for the HeartBeam patch.

"Ischemia detection has not been possible on patch-based ambulatory monitors, and they do

not provide clinical-grade insights over an extended period of time. The HeartBeam patch is designed to change that," said Robert Eno, Chief Executive Officer of HeartBeam. "A device capable of generating an on-demand 12-lead ECG at the moment symptoms occur — wherever the patient may be — could fundamentally expand the role of ambulatory cardiac monitoring beyond rhythm assessment alone. Entering a \$2 billion market with established reimbursement is compelling on its own. Adding ischemia detection as a capability makes the opportunity significantly larger."

This study also supports the 12-lead ECG patch as one of HeartBeam's core growth initiatives, along with the limited launch for arrhythmia assessment, future indication expansion for heart attack detection and advancement of its AI program. Together, the initiatives reflect a broader strategy to extend clinical-grade cardiac evaluation beyond traditional care settings.

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 2025¹. The Company holds over 20 issued patents related to technology enablement. For additional information, visit [HeartBeam.com](https://www.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.

¹Cleared Indications for Use

The HeartBeam System with 12-Lead ECG synthesis software is FDA cleared for arrhythmia

assessment. Refer to the Company's Cleared Indications for Use at <https://www.heartbeam.com/indications> for details on the intended use of its technology.

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