Kestra Announces Publication of ACE-PAS, the Largest Prospective Real-World Wearable Defibrillator Study, in the Journal of Cardiovascular Electrophysiology

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KIRKLAND, Wash., Nov. 16, 2026 (GLOBE NEWSWIRE) -- Kestra Medical Technologies, Ltd. (Nasdaq: KMTS), a leading wearable medical device and digital healthcare company, today announced publication of primary results from the ASSURE® WCD Clinical Evaluation Post-Approval Study (ACE-PAS) in the *Journal of Cardiovascular Electrophysiology*. The largest prospective real-world study of wearable cardioverter defibrillators (WCD) to date, ACE-PAS enrolled 21,612 patients across 35 U.S. states and met both primary safety and effectiveness endpoints. The study demonstrated 100% all-shock conversion success and sustained daily wear, while documenting ventricular arrhythmias early and continuously over subsequent months. The findings strengthen the clinical case for the ASSURE system across WCD indications and underscore the importance of protecting patients throughout periods of elevated arrhythmic risk.

“Advances in medical therapy have improved cardiac recovery after a myocardial infarction or a new heart failure diagnosis, but the recovery period can leave patients vulnerable to life-threatening ventricular arrhythmias,” said Jeanne E. Poole, MD, Professor of Medicine at the University of Washington and Principal Investigator. “ACE-PAS confirmed the early risk of ventricular tachycardia and ventricular fibrillation (VT/VF) and demonstrates why WCD protection matters: it provides an opportunity to prevent sudden cardiac death while giving patients time to recover.”

The publication provides a full report of findings first presented as late-breaking science at the American Heart Association Scientific Sessions 2025, along with additional analyses of arrhythmic risk. Key findings include:

- **100% all-shock conversion**
  - ASSURE WCD successfully converted all 303 analyzable VT/VF shock events with one or more shocks**,** meeting the primary effectiveness endpoint.
- **Primary safety endpoint achieved**
  - The inappropriate-shock rate was 0.0065 per patient-month, outperforming the prespecified safety performance goal.
- **94% of patients experienced no false-positive shock alarms**
  - The low alarm burden supports a better patient experience and helps enable the sustained wear needed for continuous protection.
- **23.1 hours of median daily wear—even beyond 90 days**
  - Patients wore ASSURE for a median of 23.1 hours per day.
  - 30% continued use beyond 90 days while maintaining the same median daily wear time, highlighting ASSURE’s practicality in real-world, long-term care.
- **VT/VF risk persisted beyond the first month**
  - 2.6% of patients experienced at least one shocked or unshocked VT/VF event. While 55% of episodes occurred during the first month, events continued in subsequent months—reinforcing the need for protection throughout the prescription period.
- **Meaningful arrhythmic risk extended across major etiologies**
  - Among patients with LVEF ≤35% who met primary-prevention criteria for sudden cardiac death, the estimated risk of experiencing VT/VF within 90 days was 3.2% following myocardial infarction, 2.8% in ischemic cardiomyopathy and 2.5% in nonischemic cardiomyopathy.

“Publication of the ACE-PAS results marks an important milestone in advancing the evidence base for wearable defibrillator therapy and monitoring,” said Brian Webster, President and CEO of Kestra Medical Technologies. “Real-world evidence at this scale reinforces confidence in the ASSURE system and strengthens the clinical foundation for protecting patients during recovery. We will continue to build on these insights to give providers more ways to protect at risk patients.”

Drawing on ACE-PAS data, Kestra introduced an enhanced detection algorithm in April 2026 for the ASSURE WCD that further reduces the already low false-positive alarm burden while maintaining VT/VF detection sensitivity. With the enhanced algorithm,

the inappropriate shock rate is projected to decrease by nearly 70%, from 0.0065 to 0.0020 per patient-month.[1, 2]

The peer-reviewed publication, “Real-World Performance of a Novel Wearable Cardioverter-Defibrillator System: Primary Results From a National Prospective Post-Approval Registry Study (ACE-PAS),” is available at http://doi.org/10.1111/jce.70556

About ACE-PAS
The ASSURE WCD Clinical Evaluation Post-Approval Study (ACE-PAS) was an FDA-mandated, prospective, single-arm post-approval registry evaluating the safety and effectiveness of the ASSURE Wearable Cardioverter Defibrillator in routine clinical use. Funded by Kestra, the study included 21,612 patients fitted between November 2021 and July 2025. Primary endpoints were all-shock VT/VF conversion success and inappropriate-shock incidence, evaluated against prespecified performance goals.

About Kestra
Kestra Medical Technologies, Ltd. is a leading wearable medical device and digital healthcare company focused on transforming patient outcomes in cardiovascular disease using monitoring and therapeutic intervention technologies that are intuitive, intelligent, and connected. For more information, please visit www.kestramedical.com.

Forward-Looking Statements
This press release contains forward-looking statements that involve risks and uncertainties. Actual results may differ materially from those expressed or implied by these statements. For a discussion of factors that could cause actual results to differ, see Kestra's filings with the U.S. Securities and Exchange Commission. Kestra undertakes no obligation to update any forward-looking statements except as required by law.

1. Finch D, et al. *Research Square*. April 22, 2026. Preprint.
2. Poole JE, et al. *Circulatio*n. 2025;152:e526–e605.

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