

Avertix Data Presented at TCT 2023 Shows 150% Increase in Medication Adjustments of Antiarrhythmics for High-Risk Heart Attack Survivors

Patients with Guardian™ System alarms active experienced a substantial increase in new prescriptions or medication adjustments related to rate and rhythm abnormalities, with 29.0% of Alarms ON patients receiving changes compared to 13.2% of Alarms OFF patients

Study demonstrates impact on medication adjustments for management of abnormal heart rates and rhythms

EATONTOWN, N.J., October 24, 2023 – Avertix Medical, Inc. (“Avertix” or the “Company”), creator of the world’s first and only real-time heart attack detection and patient alerting system designed to improve long-term management and outcomes of recurrent events in high-risk patients who have survived one or more heart attacks, announced The Guardian System™ data was presented today at the Transcatheter Cardiovascular Therapeutics (TCT) conference in San Francisco. The study found an increase of more than 150% in new administration or titration of medications related to rate and rhythm abnormalities in patients whose Guardian™ alarms were activated compared to patients whose alarms were off.

The Guardian System, the first and only FDA-approved implantable heart attack detection and warning system, also alerts patients in real-time of abnormal heart rates and rhythms and provides a recent history of intracardiac recordings. The study included data from the first 12-months of each subject and was presented by Andrew J. Kaplan, M.D., FACC, FHRS, an electrophysiologist and Director of Electrophysiology at Phoenix Heart, Vein and Vascular.

“This data has provided us with valuable insights into addressing the care needs of high-risk Acute Coronary Syndrome (ACS) patients,” said Dr. Kaplan. “Our findings demonstrate that the use of the Guardian System, with its continuous intracardiac monitoring and patient-alerting capabilities, offers physicians a powerful tool to proactively manage cardiac events, enabling appropriate medication management as part of providing responsive, long-term care.”

Dr. C. Michael Gibson, the lead author of this ALERTS trial study, is a pioneering figure in cardiology research, known for inventing crucial measures of coronary blood flow. As CEO of the Baim Institute of Clinical Research at Harvard Medical School and founder of the PERFUSE academic research organization at Beth Israel Deaconess Medical Center, Dr. Gibson has led over 1,000 studies and authored thousands of manuscripts. He serves as Chief Medical Correspondent for the American College of Cardiology and has been an at-large member of the FDA's cardiorenal panel.

“With a career-long commitment to improving patient wellbeing and advancing cardiovascular research, The Guardian System is changing the paradigm for heart attack survivors,” said Dr. Gibson. “The wealth of real-time data and insights it offers empowers physicians to make tailored medication adjustments

responsive to changes in a patient’s cardiac health and reducing challenges faced by our high-risk ACS patients.”

Summary of ALERTS Medication Adjustments Associated with Implantation of a Cardiac Alerting Device: The ALERTS Trial

Acute Coronary Syndrome (ACS) patients are at a higher risk for recurrent ACS events and may also be prone to cardiac rate and rhythm disturbances which also contribute to increased risk. ALERTS (AngelMed for Early Recognition and Treatment of STEMI), was a prospective, multi-center, randomized trial of 907 subjects to evaluate the safety and efficacy of the Guardian System, an implantable cardiac monitor that alerts patients to rapidly progressive ST-segment deviation associated with coronary occlusion. In addition to endpoints assessing ACS events, the trial collected data on medication usage and adjustments.

Patients with active Guardian System alarms exhibited an increase in new medication prescriptions or adjustments, with 29.0% receiving changes compared to 13.2% of patients without active alarms ($p < 0.001$). No differences were observed concerning antiplatelets, anticoagulants, antihypertensives, or other non-cardiac medications. This observed medical management improvement within the active alarm group potentially contributed to the enhanced preservation of left ventricular ejection fraction (LVEF) in the ALERTS study. The correlation arises from the notion that poorly regulated atrial fibrillation rates and elevated rates in sinus rhythm may be associated with increased ischemia and decreased LV function. Improving medical management of rate and rhythm irregularities presents the prospect of better long-term outcomes and a reduction in downstream sequelae for ACS patients. The forthcoming post-market studies for the Guardian System will provide further evaluation of these findings.

About The Guardian™ System

The Guardian System is implanted subcutaneously by a cardiologist or electrophysiologist during a low-risk, outpatient surgical procedure. The Guardian System’s proprietary algorithm uses machine learning to establish a patient’s baseline, then continuously records the heart’s electrical activity, 24/7, detecting and alerting for shifts in the ST segment, indicative of heart attacks. The Guardian System provides a more effective diagnosis of a life-threatening event when compared to patient symptoms alone.

About Avertix Medical, Inc.

[Avertix](#) is a cutting-edge medical device company offering the first and only FDA-approved Class III implantable device that can detect silent and atypical symptomatic heart attacks in real-time. With a robust portfolio of U.S. patents pertaining to Acute Coronary Syndrome (ACS) events, Avertix is at the forefront of innovation in cardiovascular care and is committed to improving patient outcomes and saving lives through advanced medical technologies. For more information, visit [avertix.com](#).

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