Zio by iRhythm Detects Previously Undiagnosed Atrial Fibrillation and Helps to Prevent Hospitalizations, Stroke, and Death as a Result

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- *Three-Year Study Results Presented at 2020 American Heart Association Scientific Sessions*
- *Zio Supports Better Healthcare Utilization Rates and Patient Outcomes With Ambulatory Cardiac Monitoring*

SAN FRANCISCO, Nov. 16, 2020 (GLOBE NEWSWIRE) -- iRhythm Technologies, Inc. (NASDAQ:IRTC), a leading digital health care solutions company focused on the advancement of cardiac care, today announced the three-year clinical outcomes of the mHealth Screening to Prevent Strokes (mSToPS) study.

The study evaluated the detection of silent, or previously undiagnosed, atrial fibrillation (AF) in moderate-risk individuals using the FDA-cleared Zio by iRhythm ambulatory monitoring patch. This study is the first siteless, nationwide study of its kind and was led by researchers at the Scripps Research Translational Institute, in partnership with collaborators, Aetna and Janssen Pharmaceuticals.

The study aimed to determine if participant-generated data available through a wearable ECG patch could improve the identification of AF relative to routine care and to determine if screening for AF by wearing Zio could improve clinical outcomes at three years after the initiation of screening. mSToPS evaluated the time to this first serious cardiac event, including stroke, systemic embolism, myocardial infarction, or death, via claims and Aetna membership data.

At the end of three years after the initial onset of monitoring:

- AF was newly diagnosed in 11.4% of those actively monitored with Zio versus only 7.7% of the control group (a statistically significant 48% improvement).
- The trial found the incidence rate of a cardiac event (stroke, myocardial infarction, systemic embolism, or death) was 8.4 per 100 person-years in people diagnosed with AF who underwent active monitoring, compared to the control group incidence rate of 13.8 per 100 person-years (a statistically significant improvement). This data demonstrates Zio's detection of AF in moderate-risk patients supported the prevention of serious cardiac events after diagnosis.
- Active monitoring with Zio also led to fewer hospitalizations for bleeding, the primary safety endpoint for the study (incidence rate of 0.32 per 100 person-years versus 0.71 per 100 person-years).
- Active monitoring also led to fewer total hospitalizations (12.9 versus 18.9 per 100 person-years).

Ultimately, the mSToPS study found that active screening for AF, as part of a prospective, pragmatic, direct-to-participant and nationwide study, was associated with a significant improvement in clinical outcomes and safety at three years relative to routine care. Through research like mSToPS, Zio has been demonstrated to help clinicians detect AF earlier, especially in instances when routine care may not.

The lifetime risk of developing AF is nearly 40%[1] for adults over age 55, the monitored demographic in this study. For many individuals, AF is undiagnosed until the time of stroke[2] or another serious cardiac event. The American Heart Association published estimates that the annual costs of stroke will nearly double[3] by 2030. Early detection of AF lowers the overall rates of cardiac incidents and hospitalizations, and the detection of silent or undiagnosed AF can greatly reduce the cost of healthcare resource utilization and improve patient care.

"Through clinical validation with studies like mSToPS, iRhythm demonstrates the importance of shifting to preventative and more proactive care to catch undiagnosed atrial fibrillation and improve the lives of millions of people," said Kevin King, CEO of iRhythm. "Zio also helps decrease costs associated with increased healthcare utilization and more significant, potentially life-threatening clinical events. At iRhythm, we are helping to create a new standard of patient care."

"The three-year results support the clinical value of early screening and targeted detection in moderate-risk populations," said Steven Steinhubl, MD, Director of Digital Medicine at Scripps Research Translational Institute and principal investigator of the study. "The study validates continued research into how to best monitor high-risk populations and confirms the value in discovering ways we can detect previously undiagnosed AF. It underscores the value of detecting AF as soon as possible to produce better patient outcomes."

These results were presented at the American Heart Association's 2020 virtual Scientific Sessions on November 16 at 9:21 a.m. CT by Dr. Steven Steinhubl of the Scripps Research Translational Institute.

About Atrial Fibrillation
Atrial fibrillation (AF or AFib) is a quivering or irregular heartbeat, also known as an arrhythmia, which can lead to blood clots, stroke, heart failure, and other heart-related complications. Normally, your heart contracts and relaxes to a regular beat. In AF, the upper chambers of the heart (the atria) beat irregularly instead of beating effectively to move blood into the ventricles.

iRhythm estimates more than 10 million Americans are at high risk for AF. With the aging of the U.S. population, this number is expected to increase. AF is associated with a five-fold increase[4] in the risk of stroke, with these strokes tending to be more severe and are associated with higher mortality. However, approximately one-third[5] of those who have AF are not aware that they have it.

For the approximately 20% to 50%[6] of individuals who experience a stroke due to AF, the occurrence of AF was not diagnosed until the time of their

stroke or shortly afterward. Asymptomatic or undiagnosed AF is referred to as being “silent” and there are certain risk factors like high blood pressure, diabetes, and asthma that increase an individual’s likelihood of developing it.

About the mHealth Screening to Prevent Strokes (mSToPS) Study
Researchers at the Scripps Translational Science Institute conducted the study in partnership with collaborators, Aetna and Janssen Pharmaceuticals. The innovative study design demonstrated that the digital solution enabled by Zio effectively monitored a large and geographically dispersed population of patients who had risk factors for AF.

The study involved 5,214 eligible Aetna members who were identified through claims data to have risk factors for AF but had not been previously diagnosed. 1,738 individuals were enrolled via a web-based platform to undergo either immediate or delayed active ECG monitoring at home for up to four weeks with a Zio XT patch monitor (two-week monitoring periods spaced four months apart). Each monitored participant was matched with two non-monitored participants with a similar CHA_2DS_2-VASc, a standardized stroke-risk assessment score, to act as controls. The study looked at the time to first diagnosis of AF and its clinical consequences for the active monitoring cohort as well as the cohort undergoing usual care.

About Dr. Steven Steinhubl, MD
Dr. Steven Steinhubl is Director of Digital Medicine at Scripps Research Translational Institute and a cardiologist at Alaska Native Tribal Health Consortium. He received his undergraduate training in Chemical Engineering at Purdue University in Indiana, graduate training in Physiology at Georgetown University in Washington, DC, and his medical degree at St. Louis University in Missouri. Dr. Steinhubl’s internal medicine residency training was completed at David Grant Medical Center at Travis Air Force Base, California. Following residency, he was a staff internist at Elmendorf Air Force Base Hospital in Anchorage, Alaska. His cardiology and interventional cardiology fellowships were at the Cleveland Clinic Foundation where he was also chief cardiology fellow. Prior to joining the Translational Institute, Dr. Steinhubl was Director of Cardiovascular Wellness and the Medical Director for Employee Wellness for the Geisinger Healthcare System. He was also the Cardiology Fellowship Director, a clinician-scientist, and a staff cardiologist there. Dr. Steinhubl has been active in clinical research for almost 20 years and has been the principal investigator of dozens of national and international trials and has published over 270 peer-reviewed manuscripts.

About iRhythm Technologies, Inc.
iRhythm is a leading digital health care company redefining the way cardiac arrhythmias are clinically diagnosed. The company combines wearable biosensor devices worn for up to 14 days and cloud-based data analytics with powerful proprietary algorithms that distill data from millions of heartbeats into clinically actionable information. The company believes improvements in arrhythmia detection and characterization have the potential to change the clinical management of patients.

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