mSToPS Clinical Trial Demonstrates Zio by iRhythm Significantly Improves Health Outcomes for At-Risk Patient Populations

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Data published in PLOS One shows continuous monitoring leads to earlier diagnosis and prevents adverse cardiac events, furthering the case for cardiac screening

SAN FRANCISCO, Oct. 05, 2021 (GLOBE NEWSWIRE) -- iRhythm Technologies, Inc. (NASDAQ:IRTC), a leading digital healthcare solutions company focused on the advancement of cardiac care, announced the results of the mHealth Screening to Prevent Strokes (mSToPS) study were published today in *PLOS One*. This clinical research, led by researchers at the Scripps Research Translational Institute (SRTI), was previously presented at the American Heart Association in November of 2020. The mSToPS trial follows the results of the "SCREEN-AF" study , announced earlier in the year, which found that Zio by iRhythm led to a tenfold increase in the detection of AF versus patients receiving standard clinical care.

The three-year follow-up of this nationwide study intended to assess whether screening asymptomatic individuals for atrial fibrillation (AF) and other arrhythmias with Zio can improve clinical outcomes. The trial was designed to compare outcomes in a combined cohort of 1,718 individuals from eligible Aetna members aged 55 and over who underwent active monitoring and 3,371 matched observational controls. Patients who participated in active monitoring received Zio XT, a long-term continuous monitor, as part of their study enrollment and self-applied the monitor at home while receiving remote support from iRhythm.

Over the course of the study, active monitoring with Zio led to a statistically significant reduction in the combined primary endpoint of death, stroke, systemic emboli or myocardial infarction versus standard clinical care. While the investigators acknowledged that the prespecified endpoint could only be considered exploratory, the incidence rate of the prespecified combined primary endpoint for the outcomes listed above was 3.6 per 100 person-years among the actively monitored cohort and 4.5 per 100 person-years in the observational cohort. This data demonstrates that Zio is assisting clinicians in detecting AF in asymptomatic individuals and that this identification prevents more serious cardiac events after diagnosis.

"A significant portion of those with AF have no symptoms and aren't aware that they have it," said Steven Steinhubl, MD, Director of Digital Medicine at Scripps Research Translational Institute and principal investigator of the study. "Long-term, continuous monitoring is helping in the shift to more preventative and proactive treatment and care."

As reported in the primary findings in 2018, published in JAMA[1], individuals in the immediate monitoring group resulted in a nearly ninefold greater incidence of new AF identification relative to the control group. In total, after three years, AF was newly diagnosed in 11.4 percent of those actively monitored with Zio versus only 7.7 percent of the control group (a statistically significant 48 percent improvement).

Additionally, the researchers found a clinical event was common in the four weeks surrounding a clinical diagnosis of AF not detected by screening. Specifically, 6 percent experienced a stroke, 10.2 percent were newly diagnosed with heart failure, 9.2 percent had a myocardial infarction, and 1.5 percent systemic emboli. Cumulatively, 42.9 percent of participants were hospitalized in the four weeks surrounding diagnosis. However, for those diagnosed utilizing data provided by Zio, only one person experienced a negative clinical outcome in the period surrounding their diagnosis. People diagnosed with AF aided by Zio not only had a very low rate of clinical events around the time of diagnosis, but also throughout the three-year follow-up period. For individuals diagnosed with AF in which pharmacy data was available, 45.2 percent of the control group and 44 percent of the actively monitored group started an anticoagulant, helping to prevent more severe events from occurring.

"iRhythm's vision is to free people from the burden of heart disease," said Quentin Blackford, President and CEO of iRhythm. "The outcomes demonstrated in the study clearly show that screening for AF in at-risk populations can lead to positive patient health outcomes. iRhythm intends to lead the market in commercializing solutions that improve the detection and diagnosis of AF, as well as other significant arrhythmias."

Seventy thousand ischemic strokes – or strokes caused by a blockage in an artery that supplies blood to the brain – may be attributed to AF each year, and one-third of AF patients are asymptomatic at the time of diagnosis.[2] This data, coupled by the results of the study, demonstrates that there is an unmet need to screen for AF.

As a brand, iRhythm is committed to addressing that need in undiagnosed patient populations, including getting solutions to market that further support broader population health strategies. Powered by this peer-reviewed research, the company is dedicated to transforming the delivery of healthcare with the goal of proactive prevention, earlier diagnosis, and improved outcomes.

Clinical collaboration was supported through Scripps Research Translational Institute, Aetna, Healthagen, Janssen Research and Development and Johnson & Johnson.

Read the study manuscript here.

About the mSToPS Study

Researchers at the Scripps Research Translational Institute (SRTI) 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 eligible Aetna members who were identified through claims data to have risk factors for AF but had not been previously diagnosed. Individuals 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 CHA2DS2-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 iRhythm Technologies, Inc.
iRhythm is a leading digital healthcare 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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[1] Steinhubl SR, Waalen J, Edwards AM, et al. Effect of a Home-Based Wearable Continuous ECG Monitoring Patch on Detection of Undiagnosed Atrial Fibrillation: The mSToPS Randomized Clinical Trial. JAMA. 2018;320(2):146–155. doi:10.1001/jama.2018.8102

[2] Lin, H. et al. Newly Diagnosed Atrial Fibrillation and Acute Stroke: The Framingham Study. Stroke, 1995., AHA Guidelines for the Primary Prevention of Stroke, A Statement for Healthcare Professionals From the American Heart Association/American Stroke Association. Circulation, 2014.

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