News Release

Aventyn® Remote-HF-1 Mobile Heart Failure Clinical Study Sponsored at International Heart Centers

Evaluate Heart Failure Patients with "Vitalbeat", a Specially Designed Patient Adherence and Monitoring Software on Standard Mobile Devices

Highlights

- *Measuring resiliency and reliability of standard mobile technology for transmitting and retrieval of daily patient vital signs and symptoms as per discharge guideline. Measuring quality of life score of heart failure patients on a qualitative scale*
- *In collaboration with BMS Hospital Trust in India; AT&T Healthcare, University of California and Zephyr Technology in the USA.*
- *Medical applications and mobile health listed as one of the Top 10 Innovations for 2012**

mhealth Summit, Washington DC and Carlsbad, California – December 04, 2011 – Aventyn Inc., an innovative provider of remote patient monitoring and chronic disease management solutions, announced the Remote-HF clinical study objective and highlights at the 2011 mHealth Summit. The summit is organized by the Foundation for the National Institutes of Health in partnership with mHIMSS, the mHealth Alliance and the National Institutes of Health.

Background

Heart failure is a common cardiovascular problem which is increasing in both prevalence and incidence globally and is associated with substantial morbidity and mortality. Management of heart failure patients is complex and has become a priority world over. Effective methods to keep heart failure patients out of the hospital are essential, both in the interests of the patient's health, as well as to reduce the burden on the health care system[1].

The Cleveland Clinic estimates between 500,000 and 900,000 new cases of heart failure are diagnosed each year in United States Medicare patients leading to 200,000 deaths and 1 million hospitalizations annually. Re-admissions for care of heart failure patients occur at a rate of over 27% after the first 30 days of discharge with more than half of that percentage re-admitted over the course of the next 180 days to 12 months with overall costs for re-admissions estimated at $20 billion[*]. These costs are possible to avoid with patient-centric mobile health monitoring solutions like Vitalbeat for heart failure and chronic disease management.

Study Methodology

Phase 1 of the Remote-HF trial is a planned feasibility study. Mobile devices enable patients and clinicians in the study stay connected and informed using the Vitalbeat remote patient monitoring and

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[1] Hunt SA, Abraham WT, Chin MH, Feldman AM, Francis GS, Ganiats TG, Jessup M, Konstam MA, Mancini DM, Michl K, Oates JA, Rahko PS, Silver MA, Stevenson LW, Yancy CW, Antman EM, Smith SC Jr, Adams CD, Anderson JL, Faxon DP, Fuster V, Halperin JL, Hiratzka LF, Jacobs AK, Nishimura R, Ornato JP, Page RL, Riegel B; ACC/AHA 2005 Guideline Update for the Diagnosis and Management of Chronic Heart Failure in the Adult: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Update the 2001 Guidelines for the Evaluation and Management of Heart Failure): developed in collaboration with the American College of Chest Physicians and the International Society for Heart and Lung Transplantation: endorsed by the Heart Rhythm Society. American College of Cardiology; American Heart Association Task Force on Practice Guidelines; American College of Chest Physicians; International Society for Heart and Lung Transplantation; Heart Rhythm Society. Circulation. 2005 Sep 20;112(12):e154-235

[*] Cleveland Clinic Top 10 Innovations: 2012, #4 Medical Apps for Mobile Devices and 2011, #6 Telehealth Monitoring for Individuals with Heart Failure/Implanted Wireless Cardiac Device for Monitoring Heart Failure

chronic disease management system. This personalized patient software solution is being tested for remotely monitoring heart failure patients and securely sharing patient vital sign information with clinicians to care for patients recruited in the study. The software has been developed to provide easy navigation and use, with provision for standard data capture of parameters used in heart failure monitoring. The patient-entered data and vital signs captured from medically certified devices and bio-sensors are instantaneously available on the software monitored at the physician's end. Phase 1 of the study features English and Swedish versions of Vitalbeat, provisioned as required by the respective regional heart centers.

A total of 65 patients have been recruited from five centers across three continents. For these patients each center has been provided with mobile smartphone devices activated by a local mobile service provider. Additionally, clinicians and study coordinators were equipped with tablet computers for monitoring secure patient data, providing mobility and immediate access of information. Automated blood pressure (BP) monitoring apparatus, weight scales and Bioharness wearable monitors were used by the patient to send vital sign data along with diet and medication adherence and activity levels to the monitoring clinician.

"The phase 1 primary objective is to evaluate the specially designed patient adherence and monitoring software Vitalbeat on standard mobile devices in terms of its reliability, seamless data transmission and early data availability to the physician to improve patient physician interaction," said core principal investigator, Dr. Satish Govind, MD, PhD. "Phase 2 in 2012 is planned as an interventional trial with a significantly large patient enrollment, more sophisticated vital sign sensor devices, pharmacotherapy and improving medication adherence, and secure cloud data sharing for managing long term preventive and wellness programs."

"We are additionally assessing patient response to use of mobile device monitoring, patient self-monitoring skills and physician response to transmitted patient data using smartphone, tablet devices and wearable Holter monitors," said core principal investigator, Dr. Marcus Stahlberg, MD, Ph.D. "This is a unique opportunity to practically observe the pattern of use of mobile device monitoring across representative and geographically diverse populations in a multicenter, multinational setting."

Since there are very few clinically registered studies of heart failure patients who have been monitored with standard mobile devices[2], the investigators seek to formulate a practical solution using the very affordable mode of wireless communication. The attraction of mobile technology is that it is already generally available in established and developing markets and can be implemented with minimal additional cost to the patient (using the patient's own mobile device) or the care provider. User friendly software, instantaneous access to clinical information on a continuous basis, and quick response to alerts could translate into reducing morbidity/mortality and reducing the burden on many fronts. This international multi-center study is also uniquely positioned to assess different health systems and infrastructures across nations on three continents for the very first time. Moreover, it is the first study aiming at testing the feasibility of mobile device monitoring in a representative sample of at-risk patients. Existing methods for home monitoring (paper based, telephone based or web based methods) to improve management of heart failure has limitations and alternative use of mobile based remote monitoring

[2] Scherr D, Kastner P, Kollmann A, Hallas A, Auer J, Krappinger H, Schuchlenz H, Stark G, Grander W, Jakl G, Schreier G, Fruhwald FM; MOBITEL Investigators. Effect of home-based telemonitoring using mobile phone technology on the outcome of heart failure patients after an episode of acute decompensation: randomized controlled trial. J Med Internet Res. 2009;11(3):e34.

techniques could be a superior, practical and convenient option to better manage the at-risk heart failure patient with improved quality of life.

The study core principal investigators are Satish C Govind, MD, PH.D, Vivus-BMJ Heart Center, Bangalore, India and Marcus Stahlberg, MD, PhD, Karolinska University Hospital, Stockholm, Sweden. International multi-center principal investigators are Nicole M. Orr, MD, St Francis Hospital, Roslyn, New York, USA, Justine S. Lachmann, MD, Winthrop-University Hospital NY, USA, and Bagirath R, MD, Narayana Hrudayalaya Heart Hospital, Bangalore. The study centers are Vivus-BMJ Heart Centre, Bangalore and Narayana Hrudayalaya, Bangalore in India. Karolinska University Hospital at Solna, Stockholm, Sweden and Saint Francis Hospital, Roslyn, New York and Winthrop-University Hospital, Mineola, New York in the USA.

Serving as advisors to the study are Frieder Braunschweig, MD, PhD, FESC Karolinska University Hospital, Lars Ake Brodin, MD, PhD, Royal Institute of Technology, Stockholm, Sweden, Aasha S Gopal, MD, FACC, St Francis Hospital, NY, USA, Samir K Saha, MD, PhD, Regional Hospital, Sundsvall, Sweden, Ramesh S S, MD, FACC, Vivus-BMJ Heart Centre, Bangalore, India and Partho P Sengupta, MD, University of California, Irvine, USA.

The trial is registered in the United States FDA clinical trials registration site under NCT01430936. The two phase trial is sponsored by Aventyn, Inc., in collaboration with BMS Hospital Trust in India, AT&T Healthcare, University of California and Zephyr Technology in the USA. The phase 2 protocol is structured as a two-year study conducted in collaboration with pharma and life science companies, wearable sensor-based medical device companies and global cloud, mobile service providers.

About Aventyn Inc.

Aventyn Inc. is an early stage health technology company delivering innovative, standards based secure core to cloud Connected Clinical Information Processing solutions. Our CLIP®Care EMR solutions with CareLock™ health information security and integrated wireless bio-sensor capability enable continuity of care anytime, anywhere and anyplace. Vitalbeat–Integrated Chronic Disease Management™ patient personalized solutions are tailored for home and remote monitoring. We offer bundled and per patient per month subscription solutions with strategic provider and payer partners. Aventyn UK Ltd., and Aventyn Pvt. Ltd., India are wholly owned subsidiaries of Aventyn Inc., USA.

CONTACT: Aventyn Inc.
Puja Chandler
Email: puja@aventyn.com
Phone: +1.858.232.2698

INVESTOR RELATIONS:
Magnus Gunnarsson
Email: magnus@aventyn.com
Phone: +1.858.344.6172

SOURCE: Aventyn Inc.