NEWS RELEASE

SERVE-HF; the World's Largest Study of Sleep-Disordered Breathing in Heart Failure Completes Recruitment

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Results, expected in 2016, set to demonstrate the impact of effective treatment of central sleep apnea on morbidity and mortality in a heart failure population

AMSTERDAM, Sept. 3, 2013 /PRNewswire/ -- ResMed (NYSE: RMD), a pioneer and global leader in sleep and respiratory medicine, announced today at the European Society of Cardiology Congress 2013, that SERVE-HF has completed enrollment.1 SERVE-HF is an international, randomized study of 1,325 participants investigating if the treatment of central sleep-disordered breathing (central sleep apnea) improves survival and outcomes of patients with stable heart failure.

(Logo: http://photos.prnewswire.com/prnh/20100203/RESMEDLOGO)

Approximately 14 million people in Europe are living with heart failure2 and central sleep-disordered breathing is known to be a highly prevalent comorbidity in these patients. With an estimated 30-50 percent of heart failure patients potentially at risk,3,4,5 the results from SERVE-HF may have important consequences for the future management of these patients.

"Completing recruitment of SERVE-HF has been an important milestone in this landmark trial," said co-principal investigator, Professor Martin Cowie of the Royal Brompton Hospital in London. "We owe much to the commitment and dedication of SERVE-HF investigators and to a strong collaboration between sleep specialists and cardiologists."
We now look forward to results in 2016 and to a fuller understanding of just how important the treatment of central sleep-disordered breathing is in heart failure patients."

SERVE-HF will, for the first time, provide conclusive evidence of the health impact of effectively treating heart failure patients who have central sleep-disordered breathing. The trial, which began in 2008, is sponsored by ResMed. Designed as an event-driven study, its completion is anticipated by mid-2015 and results are expected to be available in the first half of 2016.

Central sleep-disordered breathing (central sleep apnea)

Studies have demonstrated that patients with an abnormal waxing and waning breathing pattern, called central sleep apnea with Cheyne–Stokes respiration (CSA-CSR), have a poorer quality of life and increased mortality.6,7,8 Between 30-50 percent of patients with heart failure may suffer from central sleep-disordered breathing,3,4,5 meaning that this condition likely applies to millions of patients across Europe living with stable heart failure. However, studies so far have indicated that treatment of CSA-CSR with PaceWave™ Adaptive Servo-Ventilation (ASV) during sleep normalizes breathing, controls sleep-disordered breathing, improves cardiac function7 and may lead to increased survival and better quality of life.8,9,10

About SERVE-HF

SERVE-HF is being conducted across more than 80 sites in Germany, France, the UK, Norway, Sweden, Denmark, Finland, Australia, Switzerland, the Netherlands and the Czech Republic.

The primary goal of the study is to determine whether managing CSA-CSR with ResMed's PaceWave™ proprietary Minute Ventilation ASV technology (found in its AutoSet CS™ and VPAP™ Adapt devices) increases survival rates and decreases the burden of hospitalizations in this patient population. ASV is an intelligent method of non-invasive ventilation that continuously monitors and stabilizes the breathing patterns of individuals with sleep-disordered breathing throughout the night.

"The aim of SERVE-HF is to not only assess survival rates, but also to see if Adaptive Servo-Ventilation improves quality of life, sleep and physiologic changes associated with heart failure," said Professor Cowie. "Additionally, a health economic analysis will be performed to evaluate the potential economic benefits of therapy."

"Given the prevalence of central sleep apnea in heart failure patients, particularly men, its treatment could be crucial to improving heart failure outcomes in the future," added co-principal investigator, Professor Helmut Teschler, medical director at the Department of Pneumology, Ruhrland Clinic, Essen, Germany.

Although there are established links between sleep-disordered breathing and heart failure,9 the diagnosis, treatment and management of sleep-disordered breathing remains in the domain of sleep or respiratory medicine.
with a limited involvement of cardiologists to date. The goal of the study is to achieve greater cardiologist involvement in managing sleep-disordered breathing in heart failure patients.

Additional study information, updates and news can be obtained at the dedicated SERVE-HF study website www.servehf.com.

NOTES TO EDITORS

Sleep-disordered breathing in heart failure: A European Working Group
Monday, Sept. 2, 2013 sees the inaugural meeting of a new European Working Group, specifically focused on identifying unmet needs and improving outcomes in heart failure patients with sleep-disordered breathing. Including a host of experienced professionals in the fields of cardiology and sleep disorders, the Working Group will spend the next two years supporting ResMed in improving education and awareness of optimal care in these patients.

About ResMed
ResMed is a leading developer, manufacturer and distributor of medical equipment for treating, diagnosing and managing sleep-disordered breathing and other respiratory disorders. We are dedicated to developing innovative products to improve the lives of those who suffer from these conditions and to increasing awareness among patients and healthcare professionals of the potentially serious health consequences of untreated sleep-disordered breathing. For more information on ResMed, visit www.resmed.com.

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References
2 Data on heart failure in Europe is sketchy. One common estimate is ‘14 million Europeans.’ J Am Coll Cardiol 2009;53:1960-64, which would be ~3.3% of the population of the EU27 over 14. A comparison of population-based heart failure prevalence in Framingham, Ma (NHLBI, 2006 Chart Book on Cardiovascular and Lung Diseases, Table 5-42) and in the Dutch city of Rotterdam (see European Heart Journal 1999 Mar;20(6):447-55) which suggests roughly comparable rates of heart failure prevalence (~3.5%).

SOURCE ResMed Inc.