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Adaptive Servo-ventilation (ASV) Therapy Suggests Positive Cardiovascular Outcomes for People with Sleep-Disordered Breathing and Heart Failure With Preserved Ejection Fraction In Phase II Study

Top-line results from ResMed-sponsored CAT-HF study announced at 2016 annual Heart Failure Congress

FLORENCE, Italy, May 22, 2016 /PRNewswire/-- ResMed (NYSE: RMD) today announced primary results from a multicenter, randomized controlled Phase II trial known as CAT-HF presented at the European Society of Cardiology's 2016 Annual Heart Failure Congress. CAT-HF assessed whether the treatment of moderate to severe sleep-disordered breathing (obstructive or central sleep apnea) with adaptive servo-ventilation (ASV) therapy could improve cardiovascular outcomes in patients who were hospitalized for a sudden worsening of their heart failure symptoms (acute decompensated heart failure) over six months.

The results of the trial were presented as a late-breaking presentation by Christopher M. O'Connor, M.D., the principal investigator of the study and Chief Executive Officer and Executive Director of the Inova Heart and Vascular Institute.

Cardiovascular outcomes were defined in the trial by a Global Rank Score primary endpoint that included survival free from cardiovascular hospitalization and improvement in functional capacity as measured by the six-minute walk distance.

The overall study results were neutral (based on a hazard ratio [HR] = 1.07, 95 percent confidence interval [95% CI] = (0.75, 1.51), p-value = 0.717). However, a pre-specified subgroup analysis showed a statistically significant improvement in the primary endpoint for people with heart failure with preserved ejection fraction who have sleep-disordered breathing (based on a HR = 0.38, 95% CI = (0.15, 0.98), p-value = 0.045).

"These results are important because they are the first to show that addressing sleep-disordered breathing with ASV therapy may improve cardiovascular outcomes for people with preserved ejection fraction heart failure," said ResMed Chief Medical Officer, Glenn Richards, M.D. "We look forward to fully analyzing the results to better understand the role of addressing sleep-disordered breathing in patients with heart failure to determine who

would be appropriate candidates for ASV therapy."

Chronic heart failure occurs when the heart does not pump enough blood to meet the needs of the body. When the heart contracts normally but does not relax sufficiently to fill the chamber with enough blood, it is classified as heart failure with preserved ejection fraction. If the heart cannot contract to pump enough blood, it is heart failure with reduced ejection fraction. Approximately half of people with chronic heart failure have heart failure with preserved ejection fraction.

CAT-HF is the second randomized controlled ResMed-sponsored study examining the role of treating sleep-disordered breathing in people with heart failure. Last year, results were published from a Phase IV study known as SERVE-HF that showed ASV therapy should not be used for patients with predominant central sleep apnea and symptomatic chronic heart failure with reduced ejection fraction.

CAT-HF was designed to address a different scientific question of whether cardiovascular outcomes could be improved with ASV therapy after hospitalization for sudden worsening symptoms for people with both preserved and reduced heart failure who also have either obstructive or central sleep apnea.

"There are no level of evidence 1A guideline recommended therapies specific for heart failure with preserved ejection fraction, which accounts for half of all people living with chronic heart failure," O'Connor said. "These results from CAT-HF suggest we need to study the role of whether addressing sleep-disordered breathing can help people who have heart failure with preserved ejection fraction."

ResMed is researching how addressing sleep-disordered breathing may help people with cardiovascular diseases, from hypertension and coronary artery disease, to heart failure, atrial fibrillation, and stroke.

About Sleep-disordered Breathing

Sleep-disordered breathing encompasses a spectrum of breathing problems during sleep. The two most common types of sleep apnea, a condition that results in repetitive pauses in breathing during sleep, are obstructive sleep apnea and central sleep apnea.

Obstructive sleep apnea is a sleep disorder in which the throat muscles relax, block the airways and stop the flow of breath during sleep. Central sleep apnea is a sleep disorder in which the brain does not transmit the "breathe" signal to the muscles that control breathing during sleep. In either situation, the lack of oxygen causes the person to wake up to catch their breath and start breathing again, interrupting continuous sleep. This may occur multiple times in an hour.

Sleep-disordered breathing is found more commonly in patients with heart failure than it is in the general population, and people with heart failure often report poor sleep as a symptom.

About CAT-HF

CAT-HF is a randomized controlled trial that evaluated whether adding adaptive servo-ventilation (ASV) to optimized medical therapy could improve cardiovascular outcomes at six months for people with acute decompensated heart failure (HF) patients compared to optimized medical therapy alone. Patients were enrolled with a prior or new diagnosis of

heart failure after admission to the hospital with sudden worsening of heart failure symptoms.

The primary endpoint was cardiovascular outcomes measured as a Global Rank Score of six-minute walk distance, hospitalizations due to cardiovascular issues and death. The study also assessed changes in functional parameters, arrhythmias, biomarkers, quality of life (QoL), and sleep and breathing.

About ResMed

ResMed (NYSE:RMD) changes lives with award-winning medical devices and cutting-edge cloud-based software applications that better diagnose, treat and manage sleep apnea, chronic obstructive pulmonary disease (COPD) and other chronic diseases. ResMed is a global leader in connected care, with more than 1 million patients remotely monitored every day. Our 5,000-strong team is committed to creating the world's best tech-driven medical device company – improving quality of life, reducing the impact of chronic disease, and saving healthcare costs in more than 100 countries.

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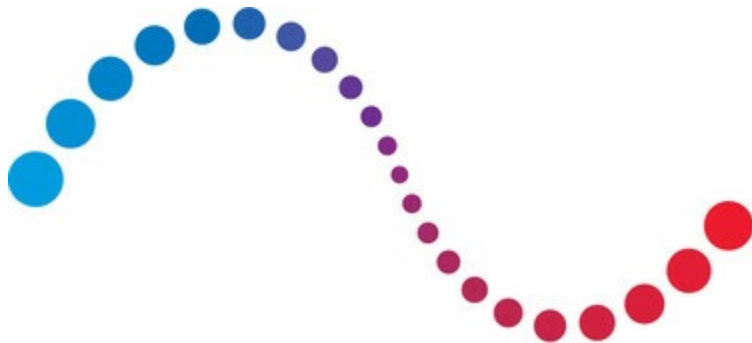
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