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ResMed Provides Update on Phase III SERVE-HF Study of Adaptive Servo-Ventilation (ASV) Therapy In Central Sleep Apnea and Chronic Heart Failure

Study Did Not Meet Primary Endpoint

Safety Signal of Increased Cardiovascular Mortality Found For ASV Therapy In People With Predominant Central Sleep Apnea and Symptomatic Chronic Heart Failure

Results and Safety Signal Observed Only In This Specific Study Population

SAN DIEGO, May 13, 2015 /PRNewswire/ -- ResMed (NYSE: RMD) today announced that SERVE-HF, a multinational, multicenter, randomized controlled Phase III trial did not meet its primary endpoint. SERVE-HF was designed to assess whether the treatment of moderate to severe predominant central sleep apnea with Adaptive Servo-Ventilation (ASV) therapy could reduce mortality and morbidity in patients with symptomatic chronic heart failure in addition to optimized medical care.

The study did not show a statistically significant difference between patients randomized to ASV therapy and those in the control group in the primary endpoint of time to all-cause mortality or unplanned hospitalization for worsening heart failure (based on a hazard ratio [HR] = 1.136, 95 percent confidence interval [95% CI] = (0.974, 1.325), p-value = 0.104). The results from SERVE-HF are preliminary and will be submitted for future publication after further analysis.

A preliminary analysis of the data identified a statistically significant 2.5 percent absolute increased risk of cardiovascular mortality for those patients in the trial who received ASV therapy per year compared to those in the control group. In the study, the cardiovascular mortality rate in the ASV group was 10 percent per year compared to 7.5 percent per year in the control group. There were no issues associated with the performance of the ASV therapy device in the trial.

"Patient safety is our first and foremost priority. We have alerted and are working with appropriate global regulatory authorities about the safety signal observed in this study," said Glenn Richards, M.D., ResMed Chief Medical Officer. "The safety signal in SERVE-HF was observed only with the use of ASV therapy in people who have predominant central sleep apnea and symptomatic chronic heart failure with reduced ejection fraction. We are further analyzing the data to understand why this unexpected result was observed in this trial."

ResMed is working with global regulatory authorities to proactively revise the labels and instructions for use for ResMed ASV devices to include a contraindication for people with symptomatic chronic heart failure (with left ventricular ejection fraction, LVEF, less than or equal to 45 percent). The company is also proactively informing healthcare providers, physicians, and patients of the cardiovascular safety signal observed in SERVE-HF.

The safety signal observed in SERVE-HF was observed only with ASV therapy in patients with moderate to severe predominant central sleep apnea and symptomatic chronic heart failure with reduced ejection fraction. The study did not include people with central sleep apnea in the absence of heart failure. It is also important to note that SERVE-HF did not include any patients with predominant obstructive sleep apnea, and did not include any other treatment modality such as continuous positive airway pressure (CPAP) or auto-adjusting positive airway pressure (APAP).

"SERVE-HF did not meet its primary endpoint, however this study provides valuable, practice-changing guidance on how to best care for people with chronic heart failure," said Prof. Martin Cowie, M.D., the co-principal investigator of the study and Professor of Cardiology at Imperial College, London. "SERVE-HF was a well-designed and executed study and because of it we now know that ASV therapy should not be used to treat central sleep apnea in people with symptomatic chronic heart failure with reduced ejection fraction."

Healthcare providers and patients who have questions or would like more information are encouraged to call 1-800-478-9010 and visit www.SERVE-HFFAQs.com

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 (OSA) 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 some cases, people with central sleep apnea also exhibit an abnormal breathing pattern known as Cheyne-Stokes respiration. With Cheyne-Stokes respiration, there is a period of shallow breathing followed by deep breathing, with intermittent central apnea, in which the breath is stopped for more than 10 seconds during each apnea.

In both obstructive and central sleep apnea, the lack of oxygen causes the person to wake up and start breathing again, interrupting continuous sleep. In central sleep apnea, this occurs more than five times per hour of sleep.

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 SERVE-HF

SERVE-HF is a multinational, multicenter, randomized controlled Phase III study that was designed to assess whether treatment of moderate to severe predominant central sleep apnea with ASV therapy in addition to optimized medical care could reduce mortality and morbidity in patients with symptomatic chronic heart failure.

About ResMed

The global team at ResMed (NYSE:RMD) is united in their commitment to changing lives with every breath. With more than 4,000 employees and a presence in over 100 countries, the company has been pioneering new and innovative devices and treatments for sleep-disordered breathing, chronic obstructive pulmonary disease, and other key chronic diseases for more than 25 years. ResMed's world-leading products and innovative solutions improve the quality of life for millions of patients worldwide, reduce the impact of chronic disease, and save healthcare costs. For more information about ResMed and its businesses, visit www.resmed.com or follow @resmed on Twitter.

Safe harbor statement

Statements contained in this release that are not historical facts are "forward-looking" statements as contemplated by the Private Securities Litigation Reform Act of 1995. These forward-looking statements — including statements regarding subsequent analyses of existing data and new data received from past, ongoing and future studies, the nature and scope of the impact that study results may have on the current or future markets for ResMed ASV devices, and the nature and timing of regulatory and other legal action — are subject to risks and uncertainties, which could cause actual results to materially differ from those projected or implied in the forward-looking statements. Additional risks and uncertainties are discussed in ResMed's periodic reports on file with the U.S. Securities & Exchange Commission. ResMed does not undertake to update its forward-looking statements.

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