



## SERVE-HF

*Treatment of Sleep-Disordered Breathing by  
Adaptive Servo-Ventilation in HF patients*

### KEY FACTS

- Sponsored by ResMed, SERVE-HF is, to date, the largest randomised controlled study in the field of sleep-disordered breathing related to chronic heart failure to investigate if treatment of predominantly central sleep apnea (CSA) improves survival and the hospitalisation rate of patients with stable heart failure.
- The study is being conducted across 80 centres throughout Europe and Australia.
- Results from SERVE-HF are expected in 2016.
- Findings of the study may have significant therapeutic implications by conclusively answering the question: what are the benefits of treating CSA in heart failure patients with PaceWave™ Adaptive Servo-Ventilation (ASV) therapy?
- The study seeks to assess impact of PaceWave™ ASV therapy on mortality, hospitalisation rate, cardiac function, biomarkers and quality of life.
- A health economics analysis will also be performed to assess the cost/benefits ratio of PaceWave™ ASV therapy in heart failure.

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- In 2013 SERVE-HF finished recruitment, with its 1,325<sup>th</sup> patient enrolled.

### Rationale for SERVE-HF

- There are an estimated 14 million patients suffering from heart failure in Europe, which is likely to rise as life expectancy increases.<sup>1,2</sup>
- Among multiple heart failure co-morbidities, sleep-disordered breathing (SDB) is the most common. However it remains the least recognised by cardiologists.<sup>3</sup>
- Central sleep apnea with Cheyne–Stokes respiration (CSA-CSR) is a common type of central sleep-disordered breathing in patients with heart failure, occurring in 30-50 percent of them.<sup>4,5</sup>
- Studies have shown that central SDB is associated with increased mortality, cardiac hospital readmissions and lower quality of life in heart failure patients.<sup>6</sup>

- Effective treatment of central SDB can improve cardiac function and survival in these patients.<sup>7,8</sup> However, to date, no large-scale randomised trial has been conducted to conclusively demonstrate the precise benefits of longer-term therapy on multiple outcomes.
- SERVE-HF is seeking to show the extent of benefit of PaceWave™ ASV therapy on patients with heart failure and central sleep-disordered breathing as well as the cost/benefit ratio of the therapy.

### **SERVE-HF study design**<sup>9</sup>

- The design of the SERVE-HF trial was developed in collaboration with a Steering Committee of highly experienced experts in the field of both heart failure and sleep medicine.
- Co-principal investigators of SERVE-HF are:
  - Prof. Martin Cowie, National Heart and Lung Institute (NHLI), Brompton Campus, London, UK
  - Prof. Helmut Teschler, Department of Respiratory Medicine, Ruhrlandklinik, Essen, Germany
- The first patient was randomised in 2008 and the study is likely to complete in Q4 2015.
- Patients will be followed up for an average of ~54 months (minimum 24 months – maximum 84 months).

### **Primary endpoints include time to:**

- All-cause death
- Unplanned hospitalisation for worsening chronic heart failure

### **Secondary endpoints include:**

- Changes in general and disease-specific quality of life and in heart failure symptoms
- Change in six minute walk distance
- Changes in cardiac function
- Changes in cognitive function
- Changes in biomarkers

### **Outcomes**<sup>9</sup>

- SERVE-HF is an important randomised controlled trial that will assess, for the first time, whether treating SDB with PaceWave™ ASV can reduce morbidity and mortality in patients with heart failure.
- The findings may have important implications for individualised therapeutic strategies targeted at reducing the morbidity, mortality and economic burden of heart failure.
- Results may also offer the opportunity to review current practices in the diagnosis and treatment of SDB in heart failure.

### References

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