

ASX Release

Oventus Medical Clinical Trial Update – O₂Vent indicated as an alternative to CPAP or as a strapless CPAP interface

Key Points:

- **First detailed physiological pilot study into the effect of the O₂Vent T**
 - **On pharyngeal pressure swings, which cause the airway to collapse in Obstructive Sleep Apnoea**
 - **And as a CPAP interface**
- **Encouraging data in a small sample size (n=4) supports the benefit of the airway in reducing pressure swings, collapsibility and CPAP pressure requirements**
- **Indicates the use of the O₂Vent T as a CPAP alternative either as a standalone appliance, or in combination with CPAP using it as a strapless CPAP interface**
- **Trial will progress to the next stage to confirm initial findings in a larger cohort**

Brisbane 24th January, 2017: Oventus Medical (ASX.OVN) is pleased to provide a clinical update, following the completion of its latest pilot study.

Oventus has developed a clinical trial program collaborating with some of Australia's leading research organisations to gather evidence evaluating the O₂Vent™ T and its unique patented airway. This follows the completion of the first clinical trial in 2016 which delivered positive results for people with obstructive sleep apnoea (OSA), including those with nasal obstruction¹, believed to be due to the presence of the airway.

The latest pilot study showed that O₂Vent T when used as a standalone device, reduces the number of respiratory events from an average AHI² of 37 to AHI of 8 (~78%), reduces pressure swings at the back of the mouth to similar levels as CPAP³, and was effective in the presence of high nasal resistance (nasal obstruction).

In addition, when the external airway of O₂Vent T was used as a CPAP interface, pressure requirements were reduced (~ 66%) to 2.3 cmH₂O (CPAPs typically operate at 5-20cmH₂O) and the appliance provided a stable airway at low pressure without the need for a mask. The design of the CPAP connection enabled simultaneous nasal CPAP delivery, while patients continued to breathe through the device airway. This is beneficial for the large percentage of mouth breathing patients that cannot tolerate CPAP.

Dr Chris Hart, Oventus Clinical Director said: "This study using the O₂Vent T showed benefits both when used as a standalone device, or as the interface to a CPAP machine. The results show that when there is a switch to breathing through the O₂Vent device airway, negative pressure swings were reduced, thus reducing the likelihood of airway collapse which causes obstructive sleep apnoea."

“We look forward to gathering more clinical evidence to validate the O₂Vent T as a viable alternative to CPAP and the further development of a strapless low pressure CPAP system for patients with very severe sleep apnoea.”

¹ *Oventus Clinical Trial Report. Data on file.*

² *The apnea-hypopnea index(AHI) is an index used to assess the severity of sleep apnoea based on the total number of complete cessations (apnoea) and partial obstructions (hypopnoea) of breathing occurring per hour of sleep*

³ *Continuous Positive Airway Pressure (CPAP) machines apply air pressure on a continuous basis to keep the airways continuously open in people who cannot breathe spontaneously on their own such as in obstructive sleep apnoea*

-ENDS-

For more information please contact:

Dr Mel Bridges, Chairman: M: 0413 051 600 (+61413051600)

Kyahn Williamson, WE Buchan: P: 03 8866 1214 or kwilliamson@buchanwe.com.au

About Oventus

Oventus is a Brisbane based medical device company that is commercialising a suite of oral appliances for the treatment of sleep apnoea and snoring. Unlike other oral appliances, the Oventus devices have a unique and patented airway within the device that delivers air to the back of the mouth bypassing multiple obstructions from the nose, soft palate and tongue. They are particularly designed for the many people that have nasal obstructions and consequently tend to mainly breathe through their mouth. While it may seem counterintuitive, the device actually prevents oral breathing. The O₂Vent is designed to allow nasal breathing when the nose is unobstructed, but when obstruction is present, breathing is supplemented via the airways in the appliance.

A clinical study completed earlier this year showed the company's first generation product the O₂Vent Mono™ is successful in treating OSA and that snoring was either eliminated or significantly reduced in 100 per cent of patients. The positive results included those people who had nasal obstructions and mainly breathed through their mouths, including when they were asleep. It also improves oxygen levels for patients.

According to a report published by the Sleep Health Foundation Australia, an estimated 1.5 million Australians suffer with sleep disorders and more than half of these suffer with obstructive sleep apnoea.¹

Continuous positive airway pressure (CPAP) is the most definitive medical therapy for obstructive sleep apnoea, OSA, however many patients have difficulty tolerating CPAP². Oral appliances have emerged as an alternative to CPAP for obstructive sleep apnoea treatment.³

¹ *Deloitte Access Economics. Reawakening Australia: the economic cost of sleep disorders in Australia, 2010. Canberra, Australia.*

² *Beecroft, et al. Oral continuous positive airway pressure for sleep apnea; effectiveness, patient preference, and adherence. Chest 124:2200–2208, 2003*

³ *Sutherland et al. Oral appliance treatment for obstructive sleep apnea: An updated Journal of Clinical Sleep Medicine. February 2014.*