

# BETTER SLEEP, BETTER HEALTH and a BETTER LIFE

ASX release

### **Oventus Clinical Evidence Update**

### **Key Points:**

- Further to the 1<sup>st</sup> May clinical update focussed on the Oventus O<sub>2</sub>Vent used in combination with Continuous Positive Airway Pressure (CPAP) machine, significant progress has been made in executing Oventus' clinical trials strategy to advance validation of the benefit of the Oventus proprietary airway
- Peer reviewed article on the O<sub>2</sub>Vent Mono has been accepted for publication by the Journal of Dental Sleep Medicine (JDSM)
- Brisbane clinical trial assessing the value of mandibular advancement with the Oventus Airway now fully recruited
- Perth clinical trial examining the physiologic effect of Oventus Airway technology is now underway
- Clinical evidence is building to support the use of Oventus Airway Technology in both stand-alone oral appliance therapy and maskless low pressure CPAP therapy
- Building body of clinical evidence, in addition to the CRC-P CPAP connection trial, will be used to further engage with the sleep clinician channel critical for the acceptance of oral appliances by sleep specialists and critical for the many patients that are non-compliant with current CPAP therapy

Brisbane, Australia; 3<sup>rd</sup> May 2017: Sleep disorder device manufacturer and developer Oventus Medical Ltd. (ASX: OVN) is pleased to announce significant progress has been made regarding the clinical validation of the Oventus O<sub>2</sub>Vent oral appliances and, in particular, validation of the benefit of the Oventus proprietary airway.

A paper outlining the results of the pilot clinical trial, has recently been accepted as a peer reviewed article in the Journal of Dental Sleep Medicine (JDSM). This trial, on the Oventus O<sub>2</sub>Vent Monoblock appliances, showed that the O<sub>2</sub>Vent Mono is effective not only in the mild to moderate range of sleep apnoea but also in the moderate to severe range of sleep apnoea and was effective in reducing time under 90% O<sub>2</sub> saturation for moderate to severe sufferers as well. 100% of patients involved in the trial experienced a significant improvement in snoring, and in 82% snoring was eliminated completely. The study highlighted that the O<sub>2</sub>Vent Mono can treat self-reported nasal obstructers as effectively as those with no nasal obstruction – a current unmet market need.

The clinical trial in Brisbane, which is designed to assess the value of mandibular advancement alone versus mandibular advancement with the addition of the proprietary



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Oventus Airway Technology, has been fully recruited. The trial is anticipated to be completed in the coming quarter.

An additional trial at Sir Charles Gairdner Hospital in Perth is now underway. This trial is focusing on specific pressure and flow measurements in the patient's airway at various levels of advancement.

Dr Chris Hart, Oventus Medical founder and Clinical Director said: "It is a significant achievement for our original clinical trial to be published in a peer reviewed journal. The subsequent trials have been designed to prove that the Oventus Airway Technology is specifically the reason our initial clinical results were so promising and facilitates a change in the paradigm of care for patients with OSA.

"The additional clinical evidence will be used to further engage with the sleep clinician channel – critical for the acceptance of oral appliances by sleep specialists and critical for the many patients that are non-compliant with current CPAP therapy."

It is anticipated that both trials will be completed over the coming six months.

### -ENDS-

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#### **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.

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.<sup>1</sup>

Continuous positive airway pressure (CPAP) is the most definitive medical therapy for obstructive sleep apnoea, OSA, however many patients have difficulty tolerating CPAP<sup>2</sup>.



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Oral appliances have emerged as an alternative to CPAP for obstructive sleep apnoea treatment.<sup>3</sup>

<sup>&</sup>lt;sup>1</sup> Deloitte Access Economics. Reawakening Australia: the economic cost of sleep disorders in Australia, 2010. Canberra, Australia.

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

<sup>&</sup>lt;sup>3</sup> Sutherland et al. Oral appliance treatment for obstructive sleep apnea: An updated Journal of Clinical Sleep Medicine. February 2014.