

*ASX Release*

## **Clinical update on advancing O<sub>2</sub>Vent's PAP connection**

### **Key Points:**

- **Significant clinical progress has made on the Oventus proprietary hybrid therapy which combines an O<sub>2</sub>Vent appliance with a Positive Airway Pressure (PAP) connection.**
- **Following promising results from the pilot study (announced in January 2017), the process to optimise the connector has been completed and the first patient has been recruited into that arm of the expanded trial.**
- **The abstract for the initial pilot study has been accepted for Sleep 2017 in Boston in the first week of June, 2017.**
- **The 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 PAP<sup>1</sup> therapy**

**Brisbane, Australia 1<sup>st</sup> May 2017:** Sleep disorder device manufacturer and developer Oventus Medical Ltd. (ASX: OVN) is pleased to announce significant clinical progress made with the Oventus O<sub>2</sub>Vent oral appliance with a Positive Airway (PAP) connection.

This represents another step in the development and validation of the ever-expanding range of sleep apnoea solutions where Oventus Airway Technology can be deployed as a new treatment option or to enhance existing treatment options as part of the Oventus Sleep Apnoea Treatment Platform.

This hybrid system is designed to address two key issues: the clinical effectiveness of oral appliances for moderate to severe sleep apnoeics and the non-compliance of PAP patients to therapy ie. the amount of time patients use PAP once it is delivered. The system is designed to bridge the gap between current oral appliances, delivered by dentists, and PAP therapy, which is typically delivered by sleep clinicians or specialist sleep centres.

The results of the initial pilot study announced earlier this year showed the benefit of the O<sub>2</sub>Vent proprietary airway in reducing pressure swings and collapsibility – the cause of obstructive sleep apnoea. It also showed the reduced pressure requirements when used in combination with PAP, and as a maskless interface with PAP.

The abstract for this initial pilot study has now been accepted for Sleep 2017, the premier world forum for the presentation and discussion of latest developments in clinical sleep medicine, to be held in Boston in the first week of June 2017.

Following the completion of the pilot study, the PAP connector system has completed the optimisation of the design process and is being used in the expanded PAP connection study (hybrid therapy). The trial is now underway following the recruitment of the first patient in

that arm of the study. This is the first study as part of the CRC-P – a \$2.95 million grant from the Australian government of which Oventus is the lead participant.

Dr Chris Hart, Oventus Medical founder and Clinical Director said “The pilot study using the O<sub>2</sub>Vent T showed benefits both when used as a standalone device, or as the interface to a PAP machine. This gave us confidence to move forward with advancing the current design of the PAP connector system and initiating the expanded trial.

“The 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 PAP therapy.”

It is anticipated that the trial will be completed towards the end of 2017, however the actual US FDA 510k submission for the initial combination system with nasal PAP, is planned to be lodged by the end of June 2017.

Footnotes:

1. Positive airway pressure therapy (PAP) uses a machine to help a person who has obstructive sleep apnea (OSA) breathe more easily during sleep.

**-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 O<sub>2</sub>Vent 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>. Oral appliances have emerged as an alternative to CPAP for obstructive sleep apnoea treatment.<sup>3</sup>

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

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