

ASX Release

Trial Results Show Oventus Airway Technology Improves Patient Response to Jaw Advancement Therapy by 40%

Key points:

- OVEN-003 Brisbane clinical trial (patient group of 32 suffering from sleep apnoea) showed overall efficacy of 'Oventus Airway Technology' in a jaw advancement oral appliance to reduce the apnoea hypopnoea index (AHI) from 23.9 to 10.2 events per hour
- The number of patients that responded to treatment increased by 40% when Oventus' 'Airway Technology' was incorporated into oral appliance therapy for non-responders to traditional jaw advancement therapy
- This means that 40% more patients will respond to treatment using Oventus' Treatment Platform than if they were treated with other oral appliances that only act to move the jaw forward
- The main reason for this improvement in response rate was a 20% increase in efficacy for patients that failed to respond to treatment using jaw advancement alone
- These findings support the position that treatment incorporating Oventus' 'Airway Technology' improves clinical outcomes compared to traditional mandibular advancement therapy
- Results further showed Oventus' 'Airway Technology' is able to specifically improve clinical outcomes for patients who do not respond well to traditional jaw advancement therapy
- Study was based on a randomised control design comparing jaw advancement oral appliances with and without 'Oventus Airway Technology'.

Brisbane, Australia 22nd May 2018: Oventus Medical Ltd (ASX: OVN) is pleased to announce the results of the OVEN-003 clinical trial study being conducted in Brisbane by the company, a randomised controlled clinical trial examining the treatment outcomes of oral appliance therapy with and without 'Oventus Airway Technology'*.

A strong response was found across the group of 32 patients suffering from obstructive sleep apnoea (OSA) wearing a jaw (mandibular) advancement oral appliance incorporating 'Oventus Airway Technology', resulting in a statistically significant overall efficacy improvement of 57% based on patients' apnoea hypopnoea index (AHI) reducing from 23.9 to 10.2 events per hour ($p < 0.0001$).

The study found that the number of patients that responded to treatment increased by 40%, for non-responders to traditional jaw advancement therapy. A responder is defined as achieving a minimum 50% improvement in AHI.

Patients in the trial that did not respond well to jaw advancement alone (achieving less than 50% improvement in AHI), who then used the same device incorporating 'Oventus Airway Technology', achieved a statistically significant 20% improvement in AHI ($p=0.05$).

A large number of responding patients in the study were found to have nasal restriction. Further data analysis from the study at the patient subgroup level is ongoing.

Previous studies have shown increases in efficacy of between 30%¹ and 50%², reduced collapsibility similar to levels achieved by optimised CPAP and the ability to treat those with and without nasal obstruction and/or soft palate collapse equally as effectively^{1,3} where other devices may not be able to⁴. Additionally, when used as a CPAP interface, 'Oventus Airway Technology' has been shown to reduce pressure requirements by 67% and allow mouth breathing while simultaneously delivering nasal CPAP (nCPAP) eliminating the need for full face mask and the need for straps².

In recent presentations of 'Oventus Airway Technology' to stakeholders in the all-important US market, the feedback on 'Oventus Airway Technology' was overwhelmingly positive. Sleep physicians in particular understand the technology and the benefits it can deliver for many of their patients. These discussions, the clinical evidence and Oventus Treatment Platform technology, are a key part of the strategy to launch 'Oventus Airway Technology' as a new treatment modality within the sleep channel at the upcoming AADSM (dental sleep) and SLEEP 2018 conferences in Baltimore June 1-6, 2018.

Founder and Clinical Director Dr Chris Hart commented, "These results further consistently demonstrate treatment incorporating 'Oventus Airway Technology' is more efficacious than traditional mandibular advancement therapy alone.

We also now have further clinical evidence that our 'Airway Technology' is able to improve clinical outcomes for patients that have previously failed to respond to traditional oral appliance therapy.

Nasal obstruction is very common in obstructive sleep apnoea sufferers – it is an issue which impacts more than 50% of patients. The 'Airway Technology' embedded in our O₂Vent™ appliance range recognises that these patients will be unable to breathe through their noses, and therefore delivers air through the mouth to the back of the throat. It effectively operates like a second nose, helping mild to moderate OSA patients to sleep better without the need for conventional sleep apnoea treatments, like CPAP machines."

¹ Walsh J, Pantin C, Lim A, Maddison K, Baker V, Szollosi I, McArdle N, Hillman D, Eastwood P. The Effect of a Novel Oral Appliance Therapy on Obstructive Sleep Apnoea: Preliminary Results. Abstract Sleep Downunder Auckland 2017

² Amatoury J, Tong B, Nguyen C, Szollosi I, Eckert DJ THE ROLE OF A NOVEL ORAL APPLIANCE THERAPY DEVICE ON PHARYNGEAL PRESSURE SWINGS AND CPAP REQUIREMENTS DURING SLEEP IN OBSTRUCTIVE SLEEP APNEA: A PILOT STUDY. Abstract Supplement ADSM Boston 2017

³ Benjamin Tong, Jason Amatoury, Jayne Carberry and Danny Eckert. The effects of posture and mandibular advancement on nasal resistance and obstructive sleep apnea treatment outcome with a novel oral appliance therapy device. Neuroscience Research Australia (NeuRA) and the University of New South Wales, Sydney, Australia. Poster and Abstract World Sleep Prague 2017.

⁴ Prescinotto R1, Haddad FL2, Fukuchi I3, Gregório LC2, Cunali PA4, Tufik S2, Bittencourt LR. Impact of upper airway abnormalities on the success and adherence to mandibular advancement device treatment in patients with Obstructive Sleep Apnea Syndrome. Braz J Otorhinolaryngol. 2015



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* 'Oventus Airway Technology' is a 3D printed airway within an oral jaw advancement appliance that bypasses obstructions caused by the nose and soft palate, reduces collapsibility and stabilises the tongue base simultaneously.

About the Oventus O₂Vent airway technology

The Oventus O₂Vent is an oral appliance device which brings the lower jaw forward (a process commonly referred to as mandibular advancement) and incorporates an opening to the oral cavity to allow breathing through the device airway, bypassing obstructions of the nose soft palate, stabilising the tongue base tongue and reducing airway collapsibility during sleep.

Further information can be found on our website: <http://oventus.com.au/how-it-works/>.

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About Oventus

Oventus is a Brisbane based medical device company that is commercialising a unique treatment platform for the treatment of sleep apnoea and snoring. Unlike other oral appliances or CPAP interfaces, the Oventus devices have a unique and patented airway within the treatment platform that allows air to flow to the back of the mouth unobstructed while maintaining an oral seal and stable jaw position, bypassing multiple obstructions from the nose, soft palate and tongue, reducing airway collapsibility and managing mouth breathing while maintain a stable airway with or without nCPAP. 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, this technology actually manages mouth breathing by converting it to device breathing and normalising ventilation. 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.¹

Continuous positive airway pressure (CPAP) is the most definitive medical therapy for obstructive sleep apnoea, 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.*



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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.