

ASX Release

New data shows Oventus Airway Technology with newly developed PEEP valves enable over 75% of patients to be treated effectively without CPAP

Key points:

- Oventus' newly developed "ExVent" PEEP valve technology trialled in conjunction with Oventus' O₂Vent™ oral appliance as part of the ongoing NeuRA Sydney clinical study
- ExVent moderates breathing exhalation and was shown to further reduce sleep events in failed CPAP users and difficult to treat obstructive sleep apnoea patients, when used in combination with Oventus' O₂Vent™ oral device
- Addition of Oventus' ExVent PEEP valve technology resulted in a statistically and clinically significant improvement in sleep apnoea severity (number of obstructive sleep events) from baseline of 49% ($p < 0.01$)
- 54% (7 of 13 patients) achieved a 50% reduction in apnoea-hypopnea index (AHI) to below 10 sleep events per hour from baseline when using Oventus O₂Vent™ with ExVent valve technology added, recognising those patients' OSA as having been successfully treated
- It is estimated that with the "ExVent" PEEP valve add-on accessories, over 75% of patients with all treatment severities may be able to be treated with O₂Vent™ plus newly developed ExVent valve technology without the need for CPAP
- The Oventus patented "ExVent" valves fit into, or onto, the "duckbill" of O₂Vent™ devices and allow easy inhalation for the patient while increasing pressure on exhalation. It is this additional pressure – expired positive air pressure (EPAP) – which helps keep the patient's airway open
- This data further enhances Oventus' key objective of providing compelling treatment options for all OSA patients, including those that would normally be treated with CPAP
- The first of these add on accessories is due to come to market in 4Q CY2018

Brisbane, Australia 29th May 2018: Oventus Medical Ltd (ASX: OVN) is pleased to announce positive interim data being presented today in a lecture at Macquarie University on a group of hard-to-treat obstructive sleep apnoea (OSA) patients, who were studied in a sub-group as part of the ongoing "NeuRA Sydney study".

Researchers studied 13 patients who had failed previous treatment with oral appliances and / or CPAP. This group of patients was treated using "Oventus Airway Technology" with the O₂Vent™ oral appliance in combination with Oventus' ExVent oral EPAP valve with or without the addition of a nasal EPAP valve (in late stage development).

Addition of Oventus' ExVent PEEP valve technology resulted in a statistically and clinically significant improvement in sleep apnoea severity (number of obstructive sleep events) from baseline of 49% ($p < 0.01$) 7 of 13 patients that had failed previous treatment with oral appliances and/or CPAP were treated successfully with a 50% reduction in the number of obstructive events, moving their apnoea-

hypopnea index (AHI) score to below 10 obstructive events per hour, without the need for continuous positive airway pressure (CPAP) intervention.

Previous studies have shown that our O₂Vent™ devices alone, can successfully treat at least 53% of patients. With “ExVent” PEEP valve technology added in, this treatment success has increased significantly, estimated to be over 75%. This extension of Oventus’ “Sleep Treatment Platform” represents a major clinical benefit to the many patients, up to 80% of OSA sufferers, that are currently out of care due to limitations with existing treatment options.

Oventus’ Founder and Clinical Director, Dr Chris Hart said, “Previous results from Oventus-led clinical trials have shown that the existing O₂Vent™ device successfully treats at least 53% of patients. If we combine our trial results, we can see that across our whole Oventus Sleep Treatment Platform of O₂Vent™ devices and add on accessories, 78% of patients across the full spectrum from mild to severe OSA, may able to be treated using our devices without the need for CPAP.

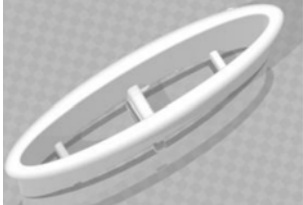


Since we know that there are such problems with patients adhering to CPAP, we’ve been driven to offer an alternative, and these results point to the fact that our technology really can be game-changing for the treatment of sleep apnoea. We plan to build upon these results with further clinical studies.”

NeuRA study leads to expanded Sleep Treatment Platform for the treatment of more OSA patients

Today’s study findings are from the Federal government funded CRC-P project titled: “Targeted therapy for sleep apnoea: A novel personalised approach” of which Oventus and NeuRA are key participants.

These results have been released in follow up to Oventus’ announcement on 22 May 2018 that through the OVEN-003 Brisbane clinical trial, the “Oventus Airway Technology” had been found to increase the number of patients that respond to traditional mouthguards (jaw advancement therapy / mandibular advancement splints) by 40%. While that finding was significant and increases the reach of oral appliance therapy as a stand-alone treatment, today’s results show a dramatic improvement on this, rising to over 75% with addition of the newly developed “ExVent” valves.

About the Oventus ExVent PEEP valve and O₂Vent™ Connect – CPAP interface add on accessories

	Oventus ExVent Oral Peek End Expiratory Pressure (PEEP) valve Launch 4QCY18	Oventus ExVent oral/nasal Peek End Expiratory (PEEP)valve Late Stage Development	Oventus O ₂ Vent™ Connect – CPAP interface Late Stage Development
Appliance innovations are further increasing efficacy of O ₂ Vent™			

As part of the CRC-P project entitled *Targeted therapy for sleep apnoea: A novel personalised approach*, Oventus has been developing the O₂Vent™ – CPAP Connect interface, an ultra-low pressure, mask-free continuous positive air pressure (CPAP) interface, which previous clinical trial work has shown may eliminate the need for full face masks and straps.

In the process of developing the Oventus O₂Vent™ Connect – CPAP interface, a peak end expiratory pressure (PEEP) valve was developed to manage exhalation through the device while delivering nasal CPAP (nCPAP). Today's results now show that using these valves in conjunction with "Oventus Airway Technology" (without CPAP) is generating results equivalent to CPAP in the majority of patients in the NeuRA valve trial that have failed to respond to, or adhere to, CPAP and oral appliance therapy. These add on accessories to the O₂Vent™ build out Oventus' Sleep Treatment Platform.

The ExVent PEEP valve is the white oval pictured above which sits inside the "duck bill" of the Oventus O₂Vent™ device. It directs "back pressure" into the throat, acting as a virtual mini CPAP within the device, without the need for additional, machine-pumped oxygen (CPAP).

The first of these valves, the "Oventus ExVent" is expected to be in market by 4Q CY18 in both Australia and North America.

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

—ENDS—

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About the NeuRA study and the \$2.95m AusIndustry-funded CRC-P project: Targeted therapy for sleep apnoea: A novel personalised approach

The NeuRA study is being conducted as part of the \$2.95m AusIndustry-funded Cooperative Research Centres Programme project, entitled project titled, "Targeted therapy for sleep apnoea: A novel personalised approach". The project aims to improve the efficacy, compliance and monitoring of sleep apnoea therapy using a tailored suite of treatments to suit the needs of the individual patient.

The range of therapies to be used, singularly or in combination, include oral appliances (with mandibular advancement and an airway) - with or without a positive airway pressure machine (with reduced pressure and air flow), supplemental oxygen delivery and/or a sleep consolidation aid.

Oventus Medical is the lead participant together with Medical Monitoring Solutions Pty Ltd, Neuroscience Research Australia (NeuRA), Western Sydney University (WSU) and the CSIRO.

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.*

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.*