

**ASX Release**

**Positive Oventus clinical data to be presented at  
ERS International Congress**

**Key points:**

- Positive Oventus clinical data from the “NeuRA study” to be presented this week at the largest meeting of respiratory professionals in the world – the European Respiratory Society conference
- Professor Danny Eckert, Principal Research Scientist with NeuRA to discuss NeuRA trial data during his *“The physiological phenotypes of OSA- the PALM scale approach”* presentation which forms part of a session, entitled *“Sleep apnoea: is it time for new therapies?”*
- Benjamin Tong of NeuRA to present two abstracts in a poster session titled, *“Alternative treatment options to positive airway pressure (PAP)”*
- The presentation data has been generated as part of Oventus’ ongoing Australian Federal Government-funded “NeuRA study” and highlights:
  - The ability of Oventus Airway Technology to treat patients with nasal obstruction with Oventus’ O<sub>2</sub>Vent as a stand alone oral appliance and
  - That through Oventus’ sleep treatment platform, patients requiring CPAP can be treated at lower pressures and without the need for a full face mask

Brisbane, Australia 17th September 2018: Oventus Medical Ltd (ASX: OVN) is pleased to announce that positive clinical data on Oventus’ sleep treatment platform will be presented by Professor Danny Eckert and Benjamin Tong of Neuroscience Research Australia (NeuRA) at the European Respiratory Society (ERS) Congress in Paris, France between 15-19 September 2018. The presentations summarise data released by Oventus in May 2018 from two arms of the Company’s ongoing “NeuRA study”.

The ERS International Congress is the largest meeting of respiratory professionals in the world, with over 22,000 delegates in regular attendance. This year's meeting will specifically highlight the importance of environment in respiratory health and focus on the need to personalise respiratory medicine.

**Session details**

|                                 |                                                                                                                      |
|---------------------------------|----------------------------------------------------------------------------------------------------------------------|
| <b>Session 1: date and time</b> | Monday 17 September at 8:30 am CET                                                                                   |
| <b>Presenter</b>                | Professor Danny Eckert of Neuroscience Research Australia (NeuRA), principal investigator on the NeuRA Study         |
| <b>Session name</b>             | Sleep apnoea: is it time for new therapies?                                                                          |
| <b>Presentation title</b>       | The physiological phenotypes of OSA- the PALM scale approach                                                         |
|                                 |                                                                                                                      |
| <b>Session 2: date and time</b> | Tuesday 18 September at 12:50 pm CET                                                                                 |
| <b>Presenter</b>                | Benjamin Tong of Neuroscience Research Australia (NeuRA)                                                             |
| <b>Poster session</b>           | Alternative treatment options to positive airway pressure (PAP)                                                      |
| <b>Abstract 1 title</b>         | Postural effects on nasal resistance in obstructive sleep apnoea (OSA) and efficacy of a novel oral appliance        |
| <b>Abstract 2 title</b>         | Combined CPAP and oral appliance (OA) therapy reduces CPAP requirements and pharyngeal pressure (Pepi) swings in OSA |

Earlier this year the Company released data from the NeuRA study which showed that its range of products could treat 78% of patients without the need for CPAP and 100% of patients using the CPAP connect product which is in development.

The two abstracts being presented at the congress further explore the personalised nature of Oventus' sleep medicine.

Oventus CEO, Dr Chris Hart commented, "We are thrilled that the compelling data from our NeuRA trial on Oventus' treatment platform will be showcased in such a prominent setting at the ERS Congress this week.

"The data demonstrates Oventus' ability to improve treatment outcomes compared to existing therapies and deliver a more personalised treatment outcome to patients, depending upon the severity of their disease, using our range of treatment options."

The first abstract examines the effect of posture on nasal resistance, showing that nasal resistance increases not only when patients lay down on their back but also when they lay on their side. Oventus' ability to treat patients with increased nasal resistance may indicate the use of our O<sub>2</sub>Vent oral appliance therapy in patients with posture dependent obstructive sleep apnoea, in effect extending the indications for the technology.

"We are pleased to be able to contribute evidence to the respiratory community that will help clinicians to better personalise treatment for patients based on the level of nasal obstruction and their sleep posture," Dr Hart said. "Importantly, this data also reaffirms that the Oventus O<sub>2</sub>Vent device can successfully treat patients with nasal obstruction."

The second dataset provides evidence that by combining the Oventus O<sub>2</sub>Vent oral appliance with a mask-free CPAP connection, severe obstructive sleep apnoea patients can be treated at lower pressures and without the need for a full face mask.

"We are working on bringing this device to market and believe it will be an effective therapeutic option for patients who cannot tolerate CPAP due to high pressures, and for those who do not respond to oral appliance therapy alone," Dr Hart said.

The ERS 2018 Congress abstracts are comprised of data that has been collected under a three year, Australian Federal Government-funded CRC-P grant titled: "Targeted therapy for sleep apnoea: A novel personalised approach" of which Oventus and NeuRA are key participants.

Copies of the abstracts are attached with this announcement and will also be published in the European Respiratory Journal's congress abstract book.

Further information on Oventus O<sub>2</sub>Vent appliances 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 Australian Federal Government-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 Australian Federal Government-funded Cooperative Research Centres Programme (CRC-P) project, entitled, "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 nasal CPAP. 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 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, 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.

Authors: Benjamin Tong, Carolin Tran, Andrea Ricciardiello, Michelle Donegan, Nicholas Murray, Alan Chiang, Jason Amatoury and Danny Eckert

### **Postural effects on nasal resistance in obstructive sleep apnoea (OSA) and efficacy of a novel oral appliance**

Oral appliance (OA) therapy is a common second-line therapy for OSA and has higher compliance than CPAP albeit with varying efficacy. High nasal resistance (NR) is associated with OA treatment failure. However, the effects of posture and mandibular advancement on nasal resistance in OSA are unknown. A novel OA (Oventus O<sub>2</sub>VentT) with an oral airway has been shown to reduce pharyngeal pressure swings during sleep. The aims of this study were to determine the: 1) role of body posture and mandibular advancement on NR in OSA and 2) efficacy of a new OA device including in OSA patients with high NR.

20 people with OSA have been studied to date (14 males, aged 29-78 years, BMI 22-38 kg/m<sup>2</sup>, AHI 5-82 events/h). Participants were instrumented with a nasal mask, pneumotachograph, and a choanal pressure catheter (Pcho) for gold standard NR quantification. Awake NR (Pcho/flow@200mL/s) was measured during 5mins of quiet breathing in 3 randomised postures: seated, supine and lateral (with and without OA). Standard split night polysomnography was then conducted with and without OA (order randomised).

Awake NR increased from seated, to supine, to lateral posture (median IQR= 1.9[1.2,4.8], 3.0[1.8,4.5], 4.0[1.9,7.2] cmH<sub>2</sub>O/L/s respectively, p=0.002). Mandibular advancement did not change NR in all postures (2.5[1.2,6.3], 3.4[1.6,5.3], 3.8[2.7,7.4] cmH<sub>2</sub>O/L/s, p=0.606). The AHI reduced by ~40% (29 vs. 18 events/h, p<0.05) with OA therapy. People with high NR (>3 cmH<sub>2</sub>O/L/s) had a comparable reduction in AHI (28 vs. 16 events/h).

Nasal resistance changes with posture in people with OSA. The novel oral appliance reduces OSA severity in people with OSA including in those with high nasal resistance.

Support: This study was funded by a Cooperative Research Centre Project Grant, a collaboration between the Australian Government, Academia and Industry (Industry partner: Oventus Medical).

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### **Combined CPAP and oral appliance (OA) therapy reduces CPAP requirements and pharyngeal pressure (Pepi) swings in OSA**

CPAP is efficacious for OSA. However, it is poorly tolerated, particularly in oronasal mask users who often require high pressures. Adherence to OA therapy is higher but efficacy varies. Combination therapy in incomplete OA responders is a potential option. However, this has been minimally studied. A novel OA device (Oventus O<sub>2</sub>VentT) with built-in oral airway to allow oral airflow reduces Pepi swings in people with OSA. Our aims were to use this device to compare changes in Pepi swings and therapeutic CPAP requirements when CPAP is combined with OA therapy in incomplete OA responders.

To date, data from 4 of 7 incomplete responders to OA therapy (residual AHI>10 events/h) have been analysed (3 males, aged 43-60y, BMI 22-38kg/m<sup>2</sup>, residual AHI 14-23events/h). Participants were instrumented with a nasal mask, pneumotachograph, epiglottic pressure catheter and standard PSG equipment. CPAP titrations were conducted in NREM supine sleep during (order randomised): 1) OA only, 2) CPAP only, 3) CPAP + OA airway open, and 4) CPAP + OA airway closed.

OSA was eliminated at  $6.1 \pm 1.2$  and  $6.5 \pm 1.0$  cmH<sub>2</sub>O when CPAP was used with OA (open) and OA (closed), respectively. These pressures were ~25-30% less than CPAP alone ( $8.5 \pm 0.7$  cmH<sub>2</sub>O). Combination of CPAP + OA (open) and OA (closed) reduced Pepi swings by >75% ( $-3.2 \pm 1.2$  and  $-3.6 \pm 1.6$  cmH<sub>2</sub>O respectively) compared to OA therapy alone ( $-10.0 \pm 4.9$  cmH<sub>2</sub>O).

Combined CPAP and OA therapy reduces CPAP requirements. CPAP remained efficacious while oral airway breathing continued. This may be a therapeutic option for patients who cannot tolerate CPAP due to high pressures including oronasal mask users and those who do not respond to OA therapy alone.

Support: This study was funded by a Cooperative Research Centre Project Grant, a collaboration between the Australian Government, Academia and Industry (Industry partner: Oventus Medical).