

Media release

Oventus announces recruitment of first patient in new clinical trial

Key Points:

- **First patient with obstructive sleep apnoea (OSA) recruited in clinical trial of titratable appliance - O₂Vent™ T**
- **Trial to produce additional comfort, safety and efficacy data of O₂Vent™ T**
- **Also aims to determine comfort and efficacy of airway in an oral appliance**
- **Trial to enrol 40 patients and anticipated to be completed in the first quarter of 2017 calendar year**

Brisbane, Australia 26th July 2016: Sleep disorder device manufacturer and developer Oventus Medical Ltd. (ASX: OVN) is pleased to announce the recruitment of the first patient with obstructive sleep apnoea (OSA) in its latest clinical trial.

The trial is designed to produce data around the comfort, safety and efficacy of the O₂Vent™ T, as well as the comfort and efficacy of the inclusion of an airway into an oral appliance.

The airway is designed to deliver air to the back of the mouth, bypassing obstructions from the nose, soft palate and tongue. The airway makes Oventus' devices unique from other mandibular advancement products on the market.

Oventus founder and Clinical Director Dr Chris Hart said: "Our first clinical trial using the O₂Vent™ Mono showed the benefit of the inclusion of the airway, especially for OSA patients with nasal obstructions. This trial uses our 2nd generation device, the O₂Vent™ T, which allows the patient to adjust their lower jaw position under dentist supervision.

"The trial will provide more qualitative and quantitative data on the benefits of the inclusion of the airway for people with and without nasal obstructions. This trial is the first of numerous clinical trials planned over the coming year. The additional clinical evidence will help us to implement our world-wide market rollout plans," Dr Hart said.

The trial will involve 40 patients and be carried out in Brisbane, Queensland.

The O₂Vent™ T is registered with the Australian Therapeutic Goods Administration while a 510k application for the device has been lodged with the US Food and Drug Administration.

-ENDS-

For more information please contact:

Dr Mel Bridges, Chairman: M: 0413 051 600 (+61413051600)

Gavin Lower, WE Buchan: P: 03 8866 1215 or M: 0414 796 726

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.¹

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