

ASX Release**Oventus receives US FDA clearance for O2Vent® Optima oral device****Key points:**

- **Oventus receives US FDA clearance for O2Vent® Optima oral device**
- **Clearance enables Oventus to commence sales of the device in the US market and officially launch recently announced material agreements with three US sleep groups**
- **FDA clearance follows the launch of the O2Vent® Optima in Australia and Canada earlier this year**
- **With key regulatory clearances in place, Oventus expects to secure further agreements across its key target markets in the US, Canada and Australia over the next 12-24 months, with a view to significant scaling through to the end of CY2019 and CY2020; negotiations ongoing with multiple groups**
- **Oventus is strongly positioned to scale sales substantially following its recent Placement and Entitlement Offer which raised a total of A\$9.3m**

Brisbane, Australia 2 September 2019: Oventus Medical Ltd or the Company (ASX: OVN) is pleased to announce that it has received regulatory clearance from the US Food and Drug Administration (FDA) for its O2Vent® Optima oral device.

O2Vent® Optima is the newest product in the O2Vent® oral device range within Oventus' Sleep Treatment Platform. It is a customised 3D-printed nylon oral appliance that offers the comfort and simplicity of a mandibular advancement device, but with a separate airway that adds further stability to the upper airway for Obstructive Sleep Apnoea (OSA) patients throughout the night.

CEO of Oventus, Dr Chris Hart commented, "We are thrilled to have received FDA clearance, which enables us to sell the O2Vent® Optima in the US – a core market for Oventus alongside Canada and Australia. We look forward to officially launching our material agreements within US sleep channels and working with our customers across their various treatment sites to deliver Optima devices to patients. With key regulatory clearances now in place and a robust cash balance following our recent capital raising, we are in a strong position to scale sales substantially across our key markets."

The FDA clearance follows the announcement in July that Oventus had signed its first material contract with an American sleep medicine group to adopt the Company's O2Vent® treatment platform for the treatment of obstructive sleep apnoea (OSA) across 8 clinical treatment sites and multiple US states, with a minimum monthly quota of 20 O2Vent® devices to be delivered to patients, per site. In August, Oventus announced further material agreements with two

US sleep provider groups. The companies will adopt Oventus' O2Vent® Sleep Treatment Platform and 'lab in lab' business model across a total of 10 facilities. Under the agreements, Oventus is the exclusive supplier of dental sleep services for the treatment of OSA and a minimum monthly quota of 20 O2Vent® devices will be delivered to patients per site. Combined with the 7 sites announced in Canada, the Company now has 25 sites under contract with the 'lab in lab' program across North America.

Early adoption of the Oventus Sleep Treatment Platform is being driven by growing clinical evidence demonstrating to clinicians that the O2Vent® technology can deliver greatly improved treatment outcomes compared to current commercially available oral appliances. The 'lab in lab' model delivers fast outcomes for patients within a framework that is commercially attractive for sleep therapy providers and dentists, a key driver of adoption.

Today's announcement follows the news earlier this year, that the O2Vent® Optima had been launched in the Australian and Canadian markets. Given the growing pipeline and a robust cash balance following the recent Placement and Entitlement Offer which raised a combined A\$9.3m,

Oventus is strongly positioned to significantly scale sales and expects to announce further agreements across its key markets over the next 12-24 months.

—ENDS—

For further information, please visit our website at www.o2vent.com or contact the individuals outlined below.

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About Oventus – see more at www.o2vent.com

Oventus is a Brisbane based medical device company that is commercialising a unique treatment platform for sleep apnoea and snoring. The Company has a collaborative Sleep Physician/ Dental strategy that streamlines patients' access to treatment. The Oventus lab model incorporates digital technology via intra oral scanning to achieve operational efficiencies, accuracy and ultimately patient outcomes.

Unlike other oral appliances or CPAP interfaces, Oventus O2Vent® devices manage the entire upper airway via a unique and patented built-in airway. O2Vent® devices allow for airflow to the back of the mouth while maintaining an oral seal and stable jaw position, bypassing multiple obstructions from the nose, soft palate and tongue. The devices reduce airway collapsibility and manage mouth breathing while keeping the airway stable.

O2Vent® devices are particularly designed for the many people that have nasal obstruction. They allow nasal breathing when the nose is unobstructed, but when obstruction is present, breathing is supplemented via the airways in the appliance.

The ExVent™, which is available in Australia and Canada, but yet to receive FDA regulatory clearance for the US market, is a valve accessory that fits into the open airway of the O2Vent® Optima device, to augment traditional oral appliance therapy by stabilising the airway. The ExVent™ valve contains air vents that open fully on inhalation for unobstructed airflow. The valve closes on exhalation, directing the air through the vents, creating the mild resistance or airway support required to keep the airway stable (known as PEEP, positive end expiratory pressure).

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 treatment³. The O2Vent® Optima and ExVent™ provide a discreet and comfortable alternative to CPAP for the treatment of OSA.

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.