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ASX Release

U.S. Medicare reimbursement approval granted for O₂Vent Optima

Key highlights:

- Notification received that O₂Vent Optima is reimbursable for those patients covered by United States Centres for Medicare & Medicaid (CMS)
- 15% of the US population, or 64 million beneficiaries currently enrolled in the US Medicare program
- Oventus technology now available to all patients including those whose healthcare is funded by the US federal government

Brisbane, Australia 14 February 2020: Obstructive Sleep Apnoea (OSA) treatment innovator, Oventus Medical Ltd (ASX: OVN) is delighted to announce that it has been notified by the Pricing, Analysis and Coding (PDAC) contractors which support The Centers for Medicare & Medicaid Services (CMS) in the United States that O₂Vent Optima has been approved for Medicare reimbursement. This is a significant milestone that will further support the roll out of the O₂Vent Optima. Dentists can now bill and be reimbursed not only by Medicare but other commercial payers that follow CMS policy.

CMS is part of the U.S. Department of Health and Human Services. CMS oversees many federal healthcare programs, including those that involve medical device reimbursement. PDAC approval removes barriers for the prescribing physicians and enables dentists to deliver O₂Vent Optima regardless of the patient's payer type.

In 2019, of the 330 million-strong US population, 64 million¹ people were enrolled in the US Medicare system. It is estimated that only six million people have been diagnosed and treated out of 30 million² OSA sufferers in the US population. This US Medicare reimbursement approval provides an opportunity to access and treat an additional large population of OSA sufferers.

Oventus CEO, Dr Chris Hart commented, "This is a very significant development for Oventus. It means that patients accessing government-funded healthcare in the US can now access our treatment which has been proven to have exceptional efficacy, both in our clinical trials and when used by patients for the treatment of their Obstructive Sleep Apnoea. It opens up a whole market that may not have previously been able to afford our treatment and we expect further increased demand for our 'lab in lab' model as a result."

¹ https://www.kff.org/medicare/fact-sheet/medicare-advantage/

² https://aasm.org/resources/pdf/sleep-apnea-economic-crisis.pdf

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"Given we were only granted FDA clearance for the Optima last September, the Board considers this an outstanding outcome and thanks go to the Oventus team for the substantial effort which went into achieving it."

Correction to announcement of 13 February 2020

Oventus released an update on 13 February 2020 noting the launch of three additional clinical sites, providing a pipeline update and stating that cash burn had been reduced for the current quarter over what was originally forecast. The announcement noted "Q3 FY2019" in the second last paragraph. In line with the above, the statement was intended to note cash burn had been reduced for Q3 FY2020, or the current quarter.

-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, 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 designed for any patient that is deemed appropriate for oral appliance therapy, but especially beneficial for the many people that suffer with nasal congestion, obstruction and mouth breathing. The O2Vent allows nasal breathing when the nose is unobstructed, but when obstruction is present, breathing is supplemented via the airway integrated in the appliance.

The ExVent™ is a valve accessory that fits into the open airway of the O2Vent Optima device, to augment traditional oral appliance therapy by stabilizing 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).

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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 apnoea³.

Continuous positive airway pressure (CPAP) is the most definitive medical therapy for obstructive sleep apnea, however many patients have difficulty tolerating CPAP⁴. Oral appliances have emerged as an alternative to CPAP for obstructive sleep apnea treatment⁵. The O2Vent Optima and ExVent provide a discreet and comfortable alternative to CPAP for the treatment of OSA.

³ Deloitte Access Economics. Reawakening Australia: the economic cost of sleep disorders in Australia, 2010. Canberra, Australia.

⁴ Beecroft, et al. Oral continuous positive airway pressure for sleep apnea; effectiveness, patient preference, and adherence. Chest 124:2200–2208, 2003

⁵ Sutherland et al. Oral appliance treatment for obstructive sleep apnea: An updated Journal of Clinical Sleep Medicine. February 2014.