BETTER SLEEP, BETTER HEALTH and a BETTER LIFE

ASX Release

Recall for product correction following return of a small number of O_2Vent™ T devices

Brisbane, Australia 1st February 2017: Oventus Medical Ltd has advised that it has issued a recall for product correction of O_2Vent™ T devices manufactured between 1st September 2016 and 30th November 2016.

The correction is related to the Adjuster Assembly component of the device that allows adjustment of the screw and hook for appropriate titration. The correction was identified through post-market surveillance data after 12 devices were returned to the company (representing 6% of the devices manufactured during the period). A total of 191 devices were possibly affected during this period, these devices are being recalled as a precautionary measure, to be checked and if necessary, reworked in production with an improved manufacturing process.

The manufacturing process that contributed to the correction has now been addressed, and all devices manufactured after 30th November 2016 have been checked and verified as safe and in full working order. The devices that have been recalled for correction, represent a small percentage of the devices that have been manufactured and delivered to patients.

"Oventus takes its commitment to device efficacy and patient safety very seriously. The recall for product correction has been implemented in compliance with all TGA requirements. Importantly, the cause of the issue has been identified and addressed in our manufacturing process," said Neil Anderson, Managing Director and CEO of Oventus Medical.

"The recall will not be material to revenue, as the devices will be checked, reworked if necessary and returned to the patient. It is our priority to complete this is as efficiently as possible, to minimise disruption to our valued patients."

-ENDS-

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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 CPAP[2]. 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.*