SOMNOMED RECEIVES FDA 510(k) APPROVAL FOR SOMNODENT® DEVICES WITH WEARABLE COMPLIANCE MICRO-RECORDING.

22nd June 2015, SomnoMed Limited (SOM: ASX) announced today that it had received FDA approval to commercialize their wearable SomnoDent devices fitted with DentiTrac® Micro-Recorders. SomnoMed is the first and only company in the world to receive FDA clearance to offer the advanced compliance recording feature for their oral devices in the USA.

SomnoMed is partnering with Braebon Medical Corp., maker of the DentiTrac, to introduce SomnoDent with DentiTrac, designed to capture and store compliance data in the cloud for patients undergoing Continuous Open Airway Therapy (COAT™). Until now, compliance data for COAT was only available by way of patients self-reporting their use of the oral device. SomnoDent with a DentiTrac micro-recorder objectively captures patients' usage of the device on a minute by minute basis. The recorded compliance data is uploaded to a HIPAA secure cloud and can be easily accessed by the physician treating the patient's condition. Additionally, clinicians can remotely create, view and keep records of patients' historic compliance data taken in minute intervals during the time the device is worn.

The ability to objectively measure patient compliance is an important feature for COAT when compared to other treatment modalities. This unique feature gives SomnoDent devices a competitive advantage, as physicians and payers require objective evidence that patients are wearing their SomnoDents and receiving treatment as prescribed.

"We believe the use of the SomnoDent Compliance Control system is of great importance in our strategy to obtain a greater acceptance of COAT from medical specialists and insurers in the US. It offers physicians ongoing control of patients by monitoring the progress of the treatment of their sleep apnea conditions. This is expected to assist in our endeavours to change the prescribing behaviour of physicians and increase the use of COAT in the US, which runs well behind a number of other countries around the world where SomnoMed operates," said SomnoMed Executive Chairman Dr. Peter Neustadt.

"Early compliance control tests conducted by SomnoMed in Australia during the last few months indicate that the SomnoDent device achieves an 84% objective compliance rate on an "all night/every night" basis. Further, it was shown that where SomnoDent was tested using the standard definition of compliance used for CPAP (based on only 21 nights in a month, for a minimum of only 4 hours per night) an objective compliance rate of 95% was achieved. This exceptional rate of compliance compares very favorably with that of CPAP, which is usually stated to be around 60-70%," commented Dr. Peter Neustadt.

"Objective compliance reporting is also very important to the transportation industry. For the first time in the US, transportation employees needing to demonstrate compliance with OSA treatment will have an alternative therapy option to CPAP with a COAT device," said Dr. Kien Nguyen, President – SomnoMed North America.

The launch of the compliance control system in the US has been prepared in anticipation of the FDA approval. SomnoDent devices fitted with DentiTrac will be available from July this year onwards.

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About SomnoMed

SomnoMed is a public company providing diagnostic and treatment solutions for Sleep-related Breathing Disorders including obstructive sleep apnea, snoring and bruxism. SomnoMed was commercialized on the basis of extensive clinical research. Supporting independent clinical research, continuous innovation and instituting medical manufacturing standards has resulted in SomnoDent® becoming the state-of-the-art and clinically proven medical oral appliance therapy for obstructive sleep apnea. SomnoDent® is the most comfortable and effective design and treatment solution for over 200,000 patients in 26 countries.

For additional information, visit SomnoMed at http://www.somnomed.com.au

*DentiTrac is a registered trademark of BRAEBON Medical Corporation.