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SLEEP APNEA TRIAL OF INPEAP TECHNOLOGY RECEIVES ETHICS APPROVAL

KEY HIGHLIGHTS:

- **Ethics approval granted for PHASE 1 pilot study of novel Intranasal Positive Expiratory Airway Pressure (INPEAP) device to treat moderate Obstructive Sleep Apnea (OSA).**
- **Total of 20 moderate OSA patients to be enrolled in a Polysomnography in-clinic study and 14 day in-home tolerance trial.**
- **The primary endpoint to confirm that moderate OSA is attenuated (through EPAP) with the Rhinomed INPEAP device.**
- **Results expected late 2015 and anticipated to add to evidence that a well-tolerated intranasal device can radically change adoption of, and compliance with, OSA treatment.**

June 15, 2015. Melbourne, Australia. Rhinomed Ltd (ASX:RNO), an Australian company focused on the development of novel nasal and respiratory technologies, today announced that it has received Monash Health Human Research Ethics Committee (HREC) approval for its inaugural Phase 1 sleep apnea trial featuring its new Intra-nasal Positive Expiratory Airway Pressure (INPEAP) technology.

Rhinomed's INPEAP technology is being developed as a potential new therapy for the US$13billion dollar Obstructive Sleep Apnea (OSA) market. According to the seminal Wisconsin Sleep Cohort Study, moderate OSA represents 70% of all sleep apnea patients.

Currently, 80% of OSA patients remain undiagnosed, partly due to attitudes towards invasive existing therapies, including CPAP and mandibular splint devices, with compliance rates for CPAP currently below 40%. This represents a significant opportunity for the INPEAP device.

Rhinomed CEO, Michael Johnson, commented, "This is a pivotal moment for Rhinomed. The work carried out establishing the Turbine™ in sport and exercise and Mute™ in the OTC snoring space continues to socialise people with the idea of using a nasal stent. The INPEAP technology leverages this acceptance of a nasal solution and seeks to address the appalling compliance rates that currently exist in the OSA market."

"This innovative technology aims to provide clinicians with an effective therapy they can be confident the patient will adopt, accept and continue to use," Johnson said.

The trial will be conducted at the Monash Lung and Sleep Department, Monash Health. Importantly, the trial will consist of both an in-clinic study and a 14-day in-home trial to demonstrate that INPEAP is well tolerated by patients over a 14-day period.

The cohort will consist of 20 healthy subjects with moderate OSA (AHI 14-29), and the primary endpoint, using Polysonography, seeks to confirm that moderate OSA can be attenuated (through EPAP) with the Rhinomed INPEAP device.

Preclinical work to date has indicated that the INPEAP technology creates Expiratory Positive Airway Pressure, a valid treatment for patients suffering from moderate OSA.

The trial results will be available in Q4 2015.

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CLINICAL TRIAL OVERVIEW

Name of Trial: Pilot Study of novel Intranasal Positive Expiratory Airway Pressure device to treat moderate Obstructive Sleep Apnea (OSA)

Study design: A Polysomnography in-clinic study and 14 day in-home tolerance trial. 20 subjects with moderate OSA (AHI-14-29)

Primary endpoints:
The trial is being conducted at the Monash Lung and Sleep Department, Monash Health, Monash Medical Centre, one of Australia's leading sleep research centres. Twenty subjects with moderate OSA (AHI 14-29) are being screened for inclusion/exclusion criteria*. The trial will seek to measure, using Polysomnography, the efficacy and tolerability of the INPEAP device on reducing the Apnea-Hypopnea Index of patients with moderate OSA as well as other markers of severity such as arousals, pulse oximetry and oxygen desaturation and sleep quality.

Secondary endpoints:
Additionally, measures of comfort (analogue scale) and self reported estimates of nightly usage, plus partner rated subjective snoring reduction through the use of analogue scales will identify any treatment effect.

Subject selection criteria*:

Volunteers will undergo a medical and physical examination to ensure they are in good health. Subjects with severe or mild OSA will be excluded, as well as subjects who have active cardiovascular disease, nasal infections or mucosal irritation. People already on treatment for moderate OSA, which is well tolerated, will also be excluded. Subjects sleeping alone at night who are unable to provide witnesses to snoring frequency and intensity will not be included.

Trial location:

Monash Lung and Sleep Department, Monash Health, Monash Medical Centre, Melbourne, Australia

Principal Investigator: Dr Darren Mansfield

About Rhinomed Limited (ASX: RNO)
Rhinomed Limited is a Melbourne based technology firm with a focus on nasal, respiratory and breathing management technologies. The company is seeking to monetise applications of its technology portfolio in the Sport, Sleep, Wellbeing and Drug Delivery markets. For more information go to **www.rhinomed.global**