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RHINOMED REPORTS PHASE 1 PILOT SLEEP APNEA CLINICAL TRIAL RESULTS

- **19 moderate-severity Obstructive Sleep Apnea (OSA) subjects completed a Polysomnography in-clinic study and a 14 day in-home tolerance trial.**
- **Mean AHI (Apnea-Hypopnea Index) reduced from 19.2 per hour to 16.5 per hour.**
- **12 subjects showed efficacy to the primary endpoint - 7 of the respondents with an AHI reduction of >50% and 5 had an AHI reduction of 30-50%. Seven subjects did not respond to the treatment, which appears to be due to mouth breathing.**
- **The secondary endpoint showed INPEAP was well tolerated by 75% of patients over the 14-day in-home trial period with only four subjects not tolerating using the device for the 14 days.**
- **Results suggest that the INPEAP device may effectively treat some patients with moderate severity OSA, but not all.**
- **Results to be presented as an abstract and Poster at the American Academy of Sleep Medicine conference in Denver, June 2016.**

June 10, 2016. Melbourne, Australia.
Australian nasal and respiratory technology company Rhinomed (ASX:RNO), today announced its Phase I Pilot clinical trial results which support the continued development of its INPEAP (Intra Nasal Positive Expiratory Air Pressure) technology as a low-cost frontline treatment for moderate Obstructive Sleep Apnea.

The Phase 1 Pilot trial (n=19) conducted at the Lung and Sleep Institute, Monash Health, under Principal Investigator Associate Professor Darren Mansfield, consisted of both an in-clinic study using Polysomnography and a 14-day in-home tolerance trial.

The trial indicated that moderate-severity Obstructive Sleep Apnea may be attenuated through EPAP (Expiratory Positive Air Pressure), with seven patients meeting the primary end point responding positively with a 50% or more reduction in their AHI* (Apnea-Hypopnea Index) levels using the Rhinomed INPEAP device, five subjects were partial responders, obtaining an AHI reduction of 30-50% and seven did not see an improvement or had a deterioration in their AHI scores.

RHINOMED LIMITED
ABN 12 107 903 159
WWW.RHINOMED.GLOBAL

LEVEL 1, 4-10 AMSTERDAM STREET, RICHMOND 3121
TEL: +61 (0) 3 8416 0900
FAX: +61 (0) 3 8080 0796

Four of these seven who did not see an improvement or whose AHI scores deteriorated were recorded to have significantly mouth-breathed across the night, leading to inefficient intranasal pressures and making it difficult to assess the device. Mouth breathing was not identified in any of the positive responders.

The cohort consisted of 19 healthy subjects with moderately severe OSA (AHI 15-29). The secondary endpoint of device tolerability was 75% with four subjects unable to tolerate using the device for the fourteen days of the trial. Comfort was cited as the most common reason for poor tolerance of this device. The INPEAP device used in the trial was a 3D printed early stage prototype.

Subjective assessments of snoring and sleep by bed partners showed a modest reduction in snoring severity and there was a reported increase in self-assessed sleep time (6.14 to 6.38 hours (with INPEAP)).

The mean AHI reduced non significantly from 19.2/hr to 16.5/hr. Similar non-significant reductions were demonstrated in supine sleep (AHI 35.2/hr to 30.9/hr) and REM sleep (AHI 22.0 to 17.5/hr). Lateral AHI increased from 7.7/hr to 11.2/hr.

The results of this Phase 1 Pilot Trial support the Company's belief that a well-tolerated and low-cost intranasal device could provide a viable and effective treatment for some people with moderate OSA.

Associate Professor Darren Mansfield commented: *"These preliminary results show this device assists some patients with moderate obstructive sleep apnea with mouth breathing being a limitation for others. Better identification of solutions for mouth breathing will enhance the effectiveness of this treatment. In addition, evaluation of efficacy in more severe subsets of OSA will be of interest."*

Mouth breathing is recognised as an issue in all OSA trials, regardless of the technology being assessed. It is envisaged that the inclusion of a chin-strap into the trial design and protocol may resolve this issue in future trials.

Rhinomed's INPEAP technology utilises an internally applied nasal dilator and expiratory pressure valve designed to stent the anterior nasal airway and deliver positive expiratory airway pressure, whilst allowing near normal inspiratory flow. The device is contoured and lined to enable superior comfort and durability.

Rhinomed is developing INPEAP as a potential new therapy for the US$6.8 billion dollar Obstructive Sleep Apnea (OSA) market[1], which is anticipated to grow at a CAGR of 7.5% until 2020[2]. Between 2 and 8% of the adult population are currently affected by OSA[3] with moderate OSA representing 70% of all sleep apnea patients.[4]

Rhinomed intends to continue materials and product design refinement of its INPEAP device and is finalising the appointment of a Scientific Advisory Committee to help scope further work in this area.

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FAX: +61 (0) 3 8080 0796

Preliminary data on the trial will be presented in a scientific poster by the investigators at the AASM Sleep 2016 conference in Denver.

Media Enquiries
Michael Johnson, CEO & Managing Director
+61 (03) 8416 0900
mjohnson@rhinomed.global

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About Rhinomed Limited (ASX:RNO)
Rhinomed Limited is a Melbourne, Australia based technology firm with a focus on nasal, respiratory and breathing management technologies. The company is developing and commercialising applications of its technology portfolio in the sport, sleep, cough/cold and allergy, and drug delivery markets. The company has two products in market (the Turbine for sports and exercise and Mute for snoring and better sleep). For more information, go to www.rhinomed.global.

INPEAP Clinical Trial Overview:

Name of trial: Pilot study of Rhinomed's novel Intranasal Positive Expiratory Airway Pressure (INPEAP) device to treat moderate Obstructive Sleep Apnea.

Treatment method and design:
Volunteers were supplied with the INPEAP device and demonstrated its application and concept for treatment. Each volunteer was provided with a sleep diary and snoring analogue scale questionnaire, which was thoroughly explained.
1-7 days - Volunteers were asked to keep a sleep diary. Partners were asked to assist in completing the snoring analogue scale for 14 days prior to commencement of the device treatment phase.
At 7 days - Volunteers underwent repeat polysomnography using the INPEAP device, which also included a cannula to measure intranasal pressure and flow without modifying the valve characteristics. Studies were scored using AASM 2012 rules.
A further 14 days - Volunteers wore the INPEAP device at night in the home setting for 14 days, where a sleep diary was maintained. The INPEAP device was graded for 3 days of low resistance, 3 days of medium resistance and 8 days of treatment resistance to acclimatise subjects. Subjective sleep information was recorded, along with comfort and snoring.

Duration of study: 28 days.

Number of trial subjects: 19 subjects in good health with moderate OSA (AHI 15-29)

Any patients that didn't complete the study: 27 subjects were recruited, with 8 withdrawing from the study prior to implementation. The 19 subjects that started the study all completed the trial.

Subject demographics: Subjects between the ages of 18 and 75 years were screened for inclusion/exclusion criteria and all enrolled subjects received INPEAP. Subjects with severe or mild OSA were excluded, as well as subjects with other forms of sleep disordered breathing, or comorbidities such as active cardiovascular disease. People already on treatment for moderate OSA, which is well tolerated, were also excluded. Subjects sleeping alone at night and unable to provide witnesses to snoring frequency and intensity were not included. All subjects underwent a medical and physical examination to ensure they are in good health.

Primary endpoint: To measure the efficacy and tolerability of the INPEAP device on reducing the Apnea-Hypopnea Index, via Polysomnography (PSG) of patients with moderate OSA.

Secondary endpoint: Measures of comfort (analogue scale) and self reported estimates of nightly usage, plus partner rated subjective snoring reduction through an analogue scale.

AHI – Apnea Hypopnea Index: Relates to number of apneas (complete cessation of airflow, plus hypopneas (50% reduction in airflow associated with oxygen desaturation and / or arousal from sleep), divided by number of hours of recorded sleep. An AHI score of five or greater indicates the presence of OSA. A score greater than 30m is severe OSA. (Australian Sleep Association).

Sources:

1. GrandView Research 'Global Sleep Apnea Devices Market Report', 2015
2. Research and Markets 'Global Sleep Apnea Market Outlook 2020', January 2016.
3. Kushida CA et al. 'Practice parameters for the use of continuous and bilevel positive airway pressure devices to treat adult patients with sleep related breathing disorders. Sleep 2006:; 29:375-80..
4. Young T et al. 'Sleep Disordered Breathing and Mortality: Eighteen-year Follow-up of the Wisconsin Sleep Cohort', Sleep. 2008 Aug 1; 31(8): 1071–1078.