MCRI/MCTC PRESENT RESULTS FROM RHINOSWAB FOR DIAGNOSIS OF RESPIRATORY VIRUSES IN CHILDREN CLINICAL TRIAL

- **Clinical trial at Murdoch Children's Research Institute (MCRI) /Melbourne Children's Trial Centre completed with Rhinoswab Junior™ meeting its primary efficacy endpoint and demonstrating laboratory equivalence (96.2% sensitivity) when compared to the current standard of care combined throat and nose swab.**
- **Trial also demonstrated a compelling preference for Rhinoswab Junior over the existing standard of care combined throat and nose swab.**
    - **82% of children preferred the Rhinoswab Junior to the standard of care combined throat and nose swab.**
    - **79% of parents would prefer their children to be tested with the Rhinoswab Junior.**
    - **82% of nurses prefer to test children with the Rhinoswab Junior.**

21 December 2021: Rhinomed Limited (ASX:RNO OTCQB:RHNMF), a leader in wearable nasal and respiratory technology is pleased to announce the interim results in the world first "*Rhinoswab for diagnosis of respiratory virus in children"* trial, which was carried out by clinical scientists at the Murdoch Children's Research Institute at the Melbourne Children Trials Centre (Royal Children's Hospital.)

The preliminary results were presented at a research briefing to both local and international key opinion leaders with the full results to be submitted to a medical journal early in the new year.

The "*Rhinoswab for diagnosis of respiratory virus in children*" trial investigated the diagnosis of respiratory viruses in children with the novel Rhinoswab Junior, which is designed to collect a nasal sample from children without the discomfort and distress associated with the combined throat and deep nasal (CTDN) swabs. Rhinoswab Junior is a smaller version of the Rhinoswab device with child friendly features to engage children in the sampling process. Rhinoswab Junior's design also allows for standardisation of the site of biological sampling as well as self collection, as compared with CTDN swabs, which are operator dependent.

Methodology

The trial recruited 254 symptomatic children, aged 4-18 years, who presented at the Respiratory infection Clinic at The Royal Children's Hospital (RCH) Melbourne, Australia. Each child was sampled with the standard of care combined nose and throat swab and the Rhinoswab Junior with the order randomised. Samples were assessed on RT-PCR using an Ausdiagnostics respiratory pathogens 16-well multiplex panel that could identify multiple pathogens including SARS-CoV-2 (2 assays), Influenza A and B, RSV, Rhinovirus/Enterovirus Parechovirus, Parainfluenza 1,2,3,4, Adenovirus groups B,C,E some A,D, Metapneumovirus, Bordetella spp and Mycoplasma Pneumoniae.

The objectives of the study were to investigate:

1. The laboratory test performance of the Rhinoswab compared with the current standard of care CTDN swab
2. The comfort and preference of Rhinoswab compared to the CTDN swab

3. If laboratory handling of Rhinoswab is equivalent to the CTDN swab.

The study also recruited nursing and laboratory staff to evaluate Rhinoswab against clinical, laboratory handling, process and workflow requirements.

Laboratory performance results

Across the 12 different targets on the Ausdiagnostics assay panel the Rhinoswab Junior achieved comparable sensitivity to the combined nose and throat swab.

	Rhinoswab Junior
Sensitivity (95% CI)	96.2% (91.8, 98.3)
Specificity (95% CI)	99.6% (99.6, 99.9)

It is worthy of note in the current climate that the Rhinoswab Junior detected 100% of the patients who presented with SARS-COV-2.

Preference results

An online survey was completed on site. Children, parents and nursing staff were asked their opinions across a range of issues.

82.2% of children preferred the Rhinoswab Junior, 6.7% had no preference and 11.5% preferred the standard swab. 79% of parents preferred the Rhinoswab while 82% of the nursing staff preferred the use of the Rhinoswab in the sample collection process. Further details will be discussed in the publication.

The introduction of the Rhinoswab Junior into the laboratory does require changes to occur and some new workflows to be introduced. Specific details as to these changes are being incorporated into the pathology laboratory instructions and information packs that accompany the Rhinoswab Junior.

Results from the use of the Rhinoswab published by NSWHealth Pathology https://www.pathology.health.nsw.gov.au/research-and-innovation/research-forum/christopher-kot support the introduction of these new works flows to not only provide a better user experience but also to "*protect healthcare workers and improve result turnaround times.*"

Michael Johnson CEO of Rhinomed commented, "*The results of this world first study come at a vitally important time. Testing of children has always been problematic with high testing reluctance due in no small part to the fear and anxiety families have toward the testing process. These results confirm that not only is the Rhinoswab Junior comparable to the highly invasive gold standard nose and throat swab in terms of lab performance, it is overwhelmingly preferred by children, parents and nurses.*

As we continue to deal with SARS-CoV-2 and its variants it is critically important that we enable mass, high frequency testing of children. The results of this trial and the previously published results from NSW Health Pathology provide clear evidence that we can easily and quickly test kids. These results provide confidence that the Rhinoswab Junior can, and will, make a significant difference across the global testing market."

For more information about the Rhinoswab Junior visit https://www.rhinomed.global/about-rhinomed/sample-collection/rhinoswab-junior/

This report has been authorised for release to the market by the Board.

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About Rhinomed Limited (ASX: RNO, OTCQB:RHNMF)

Rhinomed Limited is a Melbourne, Australia based ASX listed medical device company that has developed a novel wearable nasal technology platform that can improve air flow and provide both drug delivery and diagnostic capabilities.