



Positive Results from Australian Prospective Clinical Study Confirm ResApp's Algorithms Deliver High Accuracy When Diagnosing Respiratory Disease in Adults

- *ResApp's smartphone-based algorithms have demonstrated a high degree of accuracy in diagnosing acute respiratory disease in a pivotal adult clinical study – achieving greater than 86% positive and negative percent agreement for lower respiratory tract disease and pneumonia when compared with clinical diagnosis*
- *Study also showed that ResApp's algorithms accurately identified acute exacerbations in patients with chronic obstructive pulmonary disease (COPD) or asthma, and were able to accurately screen for COPD in a broad general population*

Brisbane, Australia, 23 April 2019 – ResApp Health Limited (ASX:RAP), a leading digital health company developing smartphone applications for the diagnosis and management of respiratory disease, is pleased to announce positive top-line results from its Australian Breathe Easy adult prospective, double-blind clinical study. ResApp's smartphone-based algorithms were found to accurately diagnose all respiratory diseases included in the study: lower respiratory tract disease, pneumonia, asthma exacerbations, chronic obstructive pulmonary disease (COPD) and COPD exacerbations.

"The breadth of these results is exciting. Not only do we have outstanding results for the diagnosis of acute respiratory disease in adults, we also have compelling data on the identification of exacerbations in patients with asthma and COPD, as well as the ability to screen for COPD in the general population," said Tony Keating, CEO and Managing Director of ResApp. "These results underpin the commercialisation of a range of smartphone-based acute diagnostic and chronic disease management tools, and we intend to use this data to support CE and TGA regulatory submissions."

The study recruited a total of 979 subjects. Performance of ResApp's algorithms was evaluated using positive percent agreement (PPA) and negative percent agreement (NPA) compared to a clinical diagnosis reached by expert clinicians with full examination and results of investigations (including, where applicable, microbiology, chest x-ray, CT, spirometry and bronchodilator testing).

For identification of lower respiratory tract disease, the first critical step in the clinical diagnostic pathway, ResApp's algorithms achieved an 88% PPA and an 89% NPA when compared to clinical diagnosis in patients with acute respiratory symptoms or clinical normalcy. Similar levels of accuracy were demonstrated for pneumonia, the most common illness-related cause of adult hospital admission, with an 86% PPA and an 87% NPA when compared to a clinical diagnosis.

As many as 339 million people are estimated to have asthma and the ability to identify asthma exacerbations, a worsening of asthma symptoms due to infection or irritants, is an important part

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of effective asthma management plans, leading to earlier, more effective treatment. In patients with a history of asthma, ResApp’s algorithms achieved an 89% PPA and an 84% NPA when compared to a clinical diagnosis for the identification of acute asthma exacerbations.

An estimated 251 million people have COPD and it is the third leading cause of mortality worldwide, however, 50-90% of people with COPD remain undiagnosed. Earlier detection of undiagnosed COPD could improve patient outcomes and reduce healthcare costs. In a broad population of patients, ResApp’s algorithms were able to identify COPD with an 86% PPA and an 85% NPA compared to a clinical diagnosis which was confirmed by lung function testing. COPD exacerbations, triggered by inflammation in the lungs caused by infection or irritants, are among the leading causes of adult hospital admissions and readmissions worldwide. In patients with a history of COPD, ResApp’s algorithms were able to identify COPD exacerbations with an 83% PPA and a 91% NPA compared with a clinical diagnosis.

“Asthma and COPD exacerbations have a major impact on patient quality of life and the ability to identify exacerbations early will help patients and their doctors better manage their disease,” said Dr Scott Claxton, Respiratory Physician, GenesisCare, one of the study Principal Investigators and a member of ResApp’s Scientific Advisory Board. “COPD screening in primary care has the potential to reduce the significant number of people who have undiagnosed, untreated COPD and provide them with treatment that can help improve their quality of life and reduce their risk of death.”

A summary of the number of patients with each disease, PPA, NPA and associated 95% confidence intervals (CI) for each of the study endpoints is presented in the table below.

	Subjects ¹		Positive Percent Agreement	Negative Percent Agreement
	Y	N		
Lower respiratory tract disease ²	358	163	88% (95% CI, 84-91%)	89% (95% CI, 83-93%)
Pneumonia ³	159	163	86% (95% CI, 80-91%)	87% (95% CI, 80-91%)
Asthma exacerbation ⁴	46	73	89% (95% CI, 76-96%)	84% (95% CI, 73-91%)
COPD ⁵	117	381	86% (95% CI, 79-92%)	85% (95% CI, 81-89%)
COPD exacerbation ⁶	86	78	83% (95% CI, 73-90%)	91% (95% CI, 82-96%)

1. Number of subjects clinically diagnosed as having disease (Y) or not having disease (N).
2. Intended use population of patients with acute respiratory symptoms or clinical normalcy.
3. Intended use population of patients with acute respiratory symptoms or clinical normalcy, excludes patients with chronic respiratory disease. Pneumonia includes patients with chest x-ray or CT

confirmed pneumonia and patients with serious chest infections requiring immediate antibiotic treatment, emergency assessment and investigation.

4. Intended use population of patients with history of asthma.
5. Intended use population of patients with respiratory symptoms or clinical normalcy, excludes patients with history of asthma.
6. Intended use population of patients with history of COPD.

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About Pneumonia

Pneumonia is an inflammation in one or both lungs, usually caused by bacterial, viral or fungal infection. It is one of the leading causes of hospitalisation and death among adults globally.

About Asthma

Asthma is a chronic disease characterised by airway inflammation and bronchoconstriction. The Global Asthma Report 2018 estimates that asthma affects around 339 million people globally. An acute asthma exacerbation occurs when a person with asthma comes in contact with an asthma trigger (infections, pollen, smoke) causing their airways to become inflamed and leading to progressive worsening of symptoms such as shortness of breath, wheezing, cough and chest tightness. Asthma cannot be cured; however appropriate management can control the disease in the majority of patients.

About Chronic Obstructive Pulmonary Disease

Chronic obstructive pulmonary disease (COPD) is a progressive disease caused by the narrowing of the bronchial tubes in the lungs. The Global Burden of Disease Study reports that there were 251 million cases of COPD globally in 2016. The primary cause of COPD is exposure to tobacco smoke, and it is the third leading cause of death worldwide. An acute exacerbation of COPD is a sudden worsening of COPD symptoms that is triggered by an infection or by environmental factors. COPD cannot be cured; however treatment can help relieve symptoms, improve quality of life and reduce the risk of death.

About Positive and Negative Percent Agreement

The terms positive and negative percent agreement are used instead of sensitivity and specificity when a new test is compared to a non-reference standard such as a clinical diagnosis. Positive percent agreement (the substitute for sensitivity) is the proportion of patients with the disease that test positive. Negative percent agreement (specificity) is the proportion of patients without the disease that test negative.

About ResApp Health Limited

ResApp Health Limited (ASX: RAP) is a leading digital health company developing smartphone applications for the diagnosis and management of respiratory disease. ResApp's machine learning algorithms use sound to diagnose and measure the severity of respiratory conditions without the need for additional hardware. Clinical studies at leading hospitals in Australia and the United States have demonstrated accurate diagnosis of lower respiratory tract disease, upper

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respiratory tract infections, asthma/reactive airway disease, pneumonia, bronchiolitis, croup, chronic obstructive pulmonary disease and obstructive sleep apnoea. Potential customers of ResApp's products include healthcare providers in telehealth, emergency department, urgent care and primary care settings as well as humanitarian organisations in the developing world. For more information, please visit www.resapphealth.com.au.

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