ASX / MEDIA RELEASE

ResApp Announces Further Positive Results from Australian Adult Clinical Studies

- *Demonstrated, for the first time, accurate differential diagnosis of community-acquired pneumonia and acute asthma within an adult intended use population (those experiencing a broad range of respiratory illness) at 90-91% positive percent agreement and 88% negative percent agreement with clinical diagnosis*
- *Accurately identified chronic obstructive pulmonary disease (COPD) and chronic asthma in adult patients at 87-89% sensitivity and 87-90% specificity compared to the gold standard of lung function testing*
- *Correctly identified infective exacerbations in adult patients with COPD with 91% positive percent agreement and 90% negative percent agreement*

Brisbane, Australia, 18 December 2017 -- ResApp Health Limited (ASX:RAP), a leading digital health company developing smartphone applications for the diagnosis and management of respiratory disease, today announced further positive results from its Australian adult clinical study. These results demonstrate, for the first time, accurate differential diagnosis of pneumonia and acute asthma in a real-world intended use population of adult patients with a board range of respiratory illnesses. The results also demonstrate accurate identification of chronic obstructive pulmonary disease (COPD) and chronic asthma in patients referred for lung function testing (the gold standard for chronic respiratory disease diagnosis), as well as the ability to identify infective exacerbations in COPD patients.

The analysis was performed by the team led by Associate Professor Udantha Abeyratne at The University of Queensland. All results are from leave-one-out cross-validation.

For US adults, pneumonia is the most common cause of hospital admission other than women giving birth. For US seniors in particular, hospitalisation for pneumonia has a greater risk of death compared to any of the other top 10 reasons for hospitalisation.

ResApp's algorithms were able to identify community-acquired pneumonia in all adult patients with acute respiratory symptoms or clinical normalcy at a positive percent agreement (PPA) of 90% (95% confidence interval [CI], 86-93) and a negative percent agreement (NPA) of 88% (95% CI, 83-92) with a clinical diagnosis made using all available clinical data, including radiology and microbiology. The results are from 360 subjects with pneumonia and 251 subjects with other diseases including asthma and URTI or those without any clinically discernible respiratory symptoms. Patients with a known chronic respiratory disease were excluded. ResApp's algorithms were also able to identify acute asthma (54 subjects) in this group of patients with a PPA of 91% (95% CI, 80-97) and NPA of 88% (95% CI, 85-91).

Obstructive lung diseases, such as asthma and COPD, result in a narrowing of airways and reduce the ability to expel air from the lungs. Globally, asthma affects as many as 334 million people and COPD affects 65 million. Patients with restrictive lung disease, such as pulmonary fibrosis and interstitial lung disease, cannot fully fill their lungs with air due to stiffness in the lungs. Lung function tests, which include spirometry and bronchodilator response, are clinically used for diagnosing chronic lung disease and are considered a "gold standard".

In patients referred to lung function testing, ResApp's algorithms were able to correctly identify chronic asthma (confirmed by lung function tests) with sensitivity of 87% (95% CI, 73-97) and specificity of 90% (95% CI, 83-95) and COPD with sensitivity of 89% (95% CI, 74-96) and specificity of 87% (95% CI, 79-92). The results are from 153 subjects who were referred for lung function testing. 34 patients were diagnosed as having chronic asthma, 41 patients had COPD and 83 patients which were diagnosed as having either restrictive lung disease or found to not have lung disease.

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. Hospitalisations for acute exacerbation of COPD account for $13.2 billion in direct costs in the US and one-in-five patients hospitalised for a COPD exacerbation will require rehospitalisation within 30 days.

ResApp's algorithms were able to identify infective COPD exacerbations in patients with known COPD with 91% (95% CI, 84-96) PPA and 90% (95% CI, 80-96) NPA with clinical diagnosis. The dataset included 103 subjects with infective COPD exacerbations and 62 subjects who were diagnosed with COPD who were not having an exacerbation.

"Exacerbation of COPD is a major contributor to the cost of managing the disease due to hospitalisation and also has a major impact on patient quality of life," said Dr Scott Claxton, Respiratory Physician, GenesisCare. "Early diagnosis allowing for outpatient management and even assisting with patient self-management can help maintain patient well-being."

"Delivering accurate results within an adult intended use population is an excellent step forward, further demonstrating that ResApp's algorithms can be applied effectively in a group of patients with a very broad range of respiratory illnesses," said Tony Keating, CEO and Managing Director of ResApp Health. "We now have a strong foundation from which we can pursue pivotal adult clinical studies in support of regulatory submissions. In particular, this new comparison to the gold standard of lung function testing provides an exceptional opportunity to run well-controlled studies for a number of diagnostic tests which have a significant clinical need and outstanding commercial opportunities."

ResApp is continuing to enrol both children and adults in its Australian clinical studies, and is recruiting patients for prospective, double-blind testing.

About Positive and Negative Percent Agreement

Published guidance by the US FDA recommends the terms positive and negative percent agreement be 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 Leave-One-Out Cross-Validation

Cross-validation is a statistical method to evaluate the predictive performance (generalisation error) of a model. In leave-one-out cross-validation a dataset of size *n* is partitioned into a model training dataset of size *n*-1 and a model testing dataset of size 1. The training data is used to train the model and the testing data is used to assess the predictive performance. This process is repeated *n* times until each sample in the overall dataset of size *n* is used exactly once as the testing data. The performance of the model is then computed over all of the *n* repetitions of the process.

About ResApp Health Limited

ResApp Health Limited (ASX: RAP) is a digital health company developing smartphone applications for the diagnosis and management of respiratory disease. The technology is based on machine learning algorithms that use cough sounds to diagnose and measure the severity of respiratory conditions without the need for additional hardware. The algorithms were initially developed by The University of Queensland with funding from the Bill and Melinda Gates Foundation. ResApp has adult and paediatric clinical studies underway at leading US and Australian hospitals with results demonstrating accurate diagnosis of pneumonia, asthma/reactive airways disease, bronchiolitis, croup, chronic obstructive pulmonary disease and upper respiratory tract infections. 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.

In the United States, ResAppDx is an investigational device and is not available for sale.

For more information on ResApp, visit www.resapphealth.com.au

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