ASX / MEDIA RELEASE

ResApp Reports Preliminary Top-line Results from SMARTCOUGH-C Study for Diagnosis of Childhood Respiratory Disease using Cough Sounds

- *Analysis of the SMARTCOUGH-C study data revealed many issues in the quality of cough recordings and that many patients were treated before their coughs were recorded*
- *Preliminary analysis of study data shows predefined endpoints for positive percent agreement and negative percent agreement with clinical diagnosis are unlikely to be met for pneumonia, croup, URTI, LRTD, asthma/RAD and bronchiolitis*
- *Full analysis on a case-by-case basis will need to be completed and an additional US paediatric study will be launched with a refined protocol to coincide with the upcoming US winter*
- *ResApp intends to continue its Australian adult program in parallel and initiate a US adult clinical study this US winter*

Brisbane, Australia, 9 August 2017 -- ResApp Health Limited (ASX:RAP), a leading digital health company developing smartphone applications for the diagnosis and management of respiratory disease, today announced top-line data from its multi-site, double blind, prospective clinical study to investigate ResAppDx for the diagnosis of respiratory disease in infants and children using cough sounds.

The predefined study endpoints were based on achieving greater than 75% for positive percent agreement (PPA) and negative percent agreement (NPA) for the diagnosis of pneumonia, croup, bronchiolitis, asthma/reactive airways disease (RAD), lower respiratory tract disease (LRTD) and upper respiratory tract infection (URTI).

In the final data review, prior to the un-blinding of the study data, ResApp identified at least two issues with the clinical data. Contrary to instructions and training, a high number of patients were treated before clinical research staff recorded their cough sounds. A high number of recordings were also found to contain a second person's cough sounds or an unacceptable amount of background noise and interference. These issues are known to affect cough sound analysis and their presence has skewed these preliminary results.

A preliminary analysis indicates that the study is unlikely to meet its predefined endpoints for diagnosis of childhood respiratory disease with the lower bound of the 95% confidence interval of both PPA and NPA with clinical diagnosis being below 75% of all diseases. The most promising result was for bronchiolitis, which achieved an 80%

(95%CI 66%-91%) PPA and 95% (95%CI 94%-97%) NPA with clinical diagnosis, although due to the reduced number of bronchiolitis patients (caused by removing recordings with obvious issues) this result does not meet the predefined study endpoint. Following the final review, the company may proceed with an FDA submission for bronchiolitis.

"These are not the results that we expected given our experience in Australia. It is obvious that a large number of tests have been affected by procedural anomalies and we now need to go through each case one by one to fully understand the results. I am confident that we can add another layer of detail to the next set of study protocols to deliver robust results and that we have adequate funding to complete a second US paediatric pivotal clinical study this US winter as well as continue and complete our adult program, including our US adult pivotal study which is also set to begin this US winter," said Tony Keating, CEO and Managing Director of ResApp Health.

"The results from SMARTCOUGH-C did not meet our expectations based on previous studies, including our limited prospective testing done in Australia. The SMARTCOUGH-C data provides a valuable insight into the recruited US population and into US diagnosis practices," said Dr Udantha Abeyratne, Chief Scientist of ResApp Health and lead inventor of the ResApp algorithms. "We can use this study data to retrain the algorithms to capture such differences and significantly boost the robustness of our algorithms as well as refine study procedures at the participating hospitals to deliver results which are more representative of the algorithms' capabilities."

The following table shows the positive percent agreement (PPA) and negative percent agreement (NPA) with clinical diagnosis and the corresponding 95% confidence intervals for each endpoint. Patients which were identified as having obvious background noise have been excluded from this analysis. The final number of croup patients, after removing those who were treated prior to cough recording, did not allow for a statistically meaningful analysis.

Disease	Positive Percent Agreement	Negative Percent Agreement
Primary Upper Respiratory Tract Infection (470 patients)		
(cough alone)	47% (95%CI 42%-51%)	69% (95%CI 65%-73%)
(cough, age, gender & symptoms)	49% (95%CI 44%-53%)	74% (95%CI 70%-78%)
Lower Respiratory Tract Involvement (363 patients)		
(cough alone)	64% (95%CI 59%-69%)	54% (95%CI 49%-58%)
(cough, age, gender & symptoms)	83% (95%CI 78%-86%)	47% (95%CI 43%-51%)

Asthma/Reactive Airways Disease (213 patients)		
(cough alone)	36% (95%CI 29%-43%)	79% (95%CI 76%-82%)
(cough, age, gender & symptoms)	62% (95%CI 56%-69%)	83% (95%CI 80%-97%)
Bronchiolitis (46 patients)		
(cough alone)	89% (95%CI 76%-96%)	84% (95%CI 81%-86%)
(cough, age, gender & symptoms)	80% (95%CI 66%-91%)	95% (95%CI 94%-97%)
Pneumonia (88 patients)		
(cough alone)	47% (95%CI 36%-58%)	65% (95%CI 62%-68%)
(cough, age, gender & symptoms)	56% (95%CI 45%-66%)	64% (95%CI 61%-67%)

About the SMARTCOUGH-C Study

SMARTCOUGH-C is a multi-site, double blind, prospective clinical study to investigate ResAppDx for the diagnosis of respiratory disease in infants and children using cough sounds. The study has enrolled 1,245 patients aged 29 days to 12 years. The co-primary endpoints of the study are the diagnosis of pneumonia compared to clinical and radiologic diagnosis. Secondary endpoints are diagnosis of upper respiratory tract infection, lower respiratory involvement, croup, asthma/reactive airways disease and bronchiolitis compared with a clinical diagnosis. A range of smartphone models are used. Details of the study can be found at www.clinicaltrials.gov (NCT02973282).

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 and upper respiratory tract infections in children as well as chronic obstructive pulmonary disease, asthma, pneumonia and upper respiratory tract infections in adults. Potential customers of ResApp's products include healthcare providers in telehealth, emergency department, urgent care and primary care settings as well as global aid and humanitarian organisations in the developing world.

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

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