ASX / MEDIA RELEASE

ResApp Reports Positive Preliminary Results from SMARTCOUGH-C-2 Study for Diagnosis of Childhood Respiratory Disease using Cough Sounds

Brisbane, Australia, 30 October 2018 -- 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 preliminary results from its SMARTCOUGH-C-2 study, a double-blind, prospective study to evaluate the efficacy of the ResAppDx smartphone application for the diagnosis of childhood acute respiratory disease.

ResAppDx achieved a positive percent agreement (PPA) between 73% and 78% and a negative percent agreement (NPA) between 71% and 86% when compared to a clinical diagnosis for lower respiratory tract disease, asthma/reactive airway disease (for children over 2 years of age) and primary upper respiratory tract disease. ResApp intends to submit a *de novo* premarket submission to the United States Food and Drug Administration (FDA) for approval in these three indications. Results for pneumonia and bronchiolitis were less than 70% at this stage and submission for these diseases will occur in a second phase.

A total of 1,470 patients were recruited into the study with 1,251 patients completing the study and analysable. The age of study participants ranged from 29 days to 12 years. The clinical diagnosis was made by an independent, centralised clinical adjudication committee using all available clinical data, including radiology and microbiology. In the case of 429 patients (33% of the total) agreement on the clinical diagnosis was not reached between two adjudicators and a third adjudicator was required to reach a majority consensus, which highlights the scale of the challenge faced when diagnosing respiratory illnesses.

A summary of the number of patients with each disease, PPA and NPA for the study endpoints is presented in the table below.

	Patients[1]		Positive Percent Agreement	Negative Percent Agreement
	Y	N		
Lower respiratory tract disease	412	775	73% (95% CI, 68-77%)	77% (95% CI, 74-80%)
Asthma/reactive airway disease	176	886	71% (95% CI, 64-78%)	86% (95% CI, 83-88%)
Asthma/reactive airway disease (children aged > 2 years old)	166	779	75% (95% CI 68-82%)	84% (95% CI, 82-87%)
Primary upper respiratory tract	727	453	77%	71%

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disease			(95% CI, 73-80%)	(95% CI, 66-75%)
Pneumonia (Focal)[2]	52	1027	67% (95% CI, 53-80%)	64% (95% CI, 61-67%)
Pneumonia	100	1150	63% (95% CI, 53-72%)	62% (95% CI, 59-65%)
Bronchiolitis (children aged < 2 years old)	42	89	76% (95% CI, 60-88%)	60% (95% CI, 59-70%)

1. Number of patients clinically diagnosed as having disease (Y) or not having disease (N).
2. Pneumonia (Focal) is defined as clinical pneumonia in the absence of wheeze, which is closely aligned with the pneumonia definition used in the Australian Breathe Easy studies.

Because of a technical issue in providing cough audio files to adjudicators for review, results for croup are now expected in November.

Tony Keating, CEO and Managing Director of ResApp said, "The results for lower respiratory tract disease, asthma/reactive airways disease (for children over 2 years of age) and primary upper respiratory tract disease demonstrate that our algorithms effectively aid clinicians in making important clinical diagnostic decisions. Asthma, in particular, is the most common chronic lower respiratory tract disease in childhood throughout the world. Our diagnoses are especially useful in settings such as telehealth, where a stethoscope and additional diagnostic tests such as a chest x-ray or blood tests are not available. We plan to pursue FDA submissions for these three diseases in parallel to CE and TGA submissions for six diseases being prepared following the recent Australian study results."

"Comparing these results to our Australian Breathe Easy study, we see the result of differing clinical practices between Australia and the United States, driven by a substantially different healthcare and insurance system. We also see a large number of patients (33%) requiring a third adjudicator, illustrating the difficulty in making a clinical diagnosis even with access to all the tests available in a modern tertiary hospital."

"Our imminent FDA, CE and TGA submissions unlock an exciting phase for ResApp as we make tangible progression towards commercialising our unique technology in multiple markets worldwide."

Detailed results of the SMARTCOUGH-C-2 study are planned to be presented at an upcoming scientific meeting. Detailed results from the Australian Breathe Easy study have recently been submitted for publication in a peer-reviewed medical journal.

About the SMARTCOUGH-C-2 study

SMARTCOUGH-C-2 is a multi-site, prospective, double-blind study evaluating the efficacy of the ResAppDx smartphone application in the diagnosis of childhood acute respiratory disease using cough sounds. The study planned to enrol up to 1,667 patients aged 29 days to 12 years of age

who presented to one of the three participating sites in the United States with signs or symptoms of acute respiratory disease. The study's co-primary endpoints are positive and negative percent agreement with clinical diagnosis for pneumonia, lower respiratory tract disease, bronchiolitis, asthma/reactive airway disease, upper respiratory tract disease and croup. The clinical diagnosis will be made by an independent, centralised clinical adjudication committee using all available clinical data, including radiology and microbiology.

More information on the study is available at www.clinicaltrials.gov (NCT03392363).

About Positive and Negative Percent Agreement

Published guidance by the US Food and Drug Administration 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 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 the United States and Australia have demonstrated accurate diagnosis of pneumonia, asthma/reactive airway disease, bronchiolitis, croup, chronic obstructive pulmonary disease and upper respiratory tract infections. ResApp has also obtained excellent results for screening of obstructive sleep apnoea in a double-blind, prospective clinical study. 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 on ResApp, visit www.resapphealth.com.au

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