ResApp Provides Updated Top-line Results from SMARTCOUGH-C-2 Study

Brisbane, Australia, 18 March 2019 – ResApp Health Limited (ASX:RAP), a leading digital health company developing smartphone applications for the diagnosis and management of respiratory disease, today provided top-line results for croup and updated top-line results for primary upper respiratory tract disease (URTD) from its SMARTCOUGH-C-2 study. SMARTCOUGH-C-2 is a double-blind, prospective study evaluating the efficacy of the ResAppDx smartphone application to diagnose childhood acute respiratory disease.

Due to a technical issue encountered while providing cough recordings to the clinical adjudicators, croup results were not available in the preliminary results and were delayed until adjudicators listened to all cough recordings and re-reviewed each patient's medical records.

ResAppDx achieved a positive percent agreement (PPA) of 74% and a negative percent agreement (NPA) of 74% when compared to a clinical diagnosis for croup. Analysis of the adjudication data showed that in 52% of cases a final clinical diagnosis of croup required a third adjudicator to resolve disagreement between the first two adjudicators, illustrating the difficulty that even experienced clinicians have in identifying croup. The PPA of ResAppDx also exceeded that of the individual treating team clinicians (who saw and treated study participants as part of routine standard of care) who had a 65% PPA when compared to the final adjudicated outcome.

"The accuracy of ResApp's algorithms for croup is very good, especially when consideration is given to the degree of disagreement observed between adjudicators and the performance of the treating team," said Dr Paul Porter, ResApp Scientific Advisory Board member and Principal Investigator of ResApp's Breathe Easy Australian clinical study. "Although the high level of disagreement between clinicians for croup in the SMARTCOUGH-C-2 study is surprising, we saw only a slightly lower level of disagreement (40%) during the Breathe Easy study, indicating that substantial interobserver variability clearly exists for croup diagnosis."

Only 2% of the study population (29 patients) were clinically diagnosed as having croup which resulted in a wide PPA 95% confidence interval. A larger population would be required to support a US regulatory filing for croup.

As primary URTD patients are defined by the study case definitions as patients not having a clinical diagnosis of either croup or lower respiratory tract disease, the PPA and NPA for primary URTD have been updated but have not materially changed.

Tony Keating, CEO and Managing Director of ResApp commented, "The low incidence of croup in the study population demonstrates the relative rarity of croup in this setting and prevents us

from including it in our FDA submission, however we are very satisfied with the diagnostic results that we achieved, especially when compared to the treating team's accuracy. We expect to file a De Novo submission to the US FDA this month for three of the most clinically-important indications: lower respiratory tract disease, asthma/reactive airways disease and primary URTD. These three indications provide valuable information to clinicians at key decision points and are relevant to every single patient who presents with signs or symptoms of respiratory disease."

A summary of the number of patients, PPA and NPA for croup and primary URTD is presented in the table below.

	Patients[1]		Positive Percent Agreement	Negative Percent Agreement
	Y	N		
Croup	29	1207	74% (95% CI, 53-87%)	74% (95% CI, 71-76%)
Primary URTD	722	453	76% (95% CI, 73-79%)	70% (95% CI, 66-74%)

1. Number of patients clinically diagnosed as having disease (Y) or not having disease (N).

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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 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 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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