ASX / MEDIA RELEASE

SMARTCOUGH-C Study and Paediatric Clinical Strategy Update

- *Discussions with the principal investigators and further analysis of SMARTCOUGH-C confirm that the study was not an accurate nor reliable evaluation of ResApp's algorithms*
- *All parties have reaffirmed their support for a follow-up revised US study this US winter*
- *This revised study will incorporate a refined protocol, improved training and monitoring, an enhanced data collection interface, and key improvements to clinical adjudication*
- *Recruitment in the Australian paediatric study at Joondalup Hospital will continue in parallel, with prospective data to be used for CE and TGA submissions*

Brisbane, Australia, 4 September 2017 -- ResApp Health Limited (ASX:RAP), a leading digital health company developing smartphone applications for the diagnosis and management of respiratory disease, is pleased to provide an update on the SMARTCOUGH-C study and its revised paediatric clinical strategy moving forward. Further analysis of SMARTCOUGH-C data and reviews with principal investigators confirm that the study was not a representative evaluation of ResAppDx due to a range of issues during execution and adjudication. As previously announced, ResApp plans to restart the study this US winter after implementing an array of enhanced procedures and features developed in collaboration with the participating hospitals.

To improve the data-gathering element of the study ResApp will regularly be present onsite conducting clinical study team training, reviewing enrolment procedures and verifying data to help ensure that high-quality cough sounds are collected as early as possible during the patient's hospital visit and prior to any treatment known to affect cough analysis. Every cough sound collected will be quality checked within days of its recording to ensure that all of the data used to subsequently analyse the performance of the algorithm is uncorrupted and high fidelity. An improved audio recording smartphone application incorporating built-in checklists, automated background noise estimation and additional visual aids will be deployed to further support the data collection teams and eliminate inappropriate collection of cough data with background noise contamination. ResApp's algorithms have also been modified to reduce the impact of the low frequency electronic interference found in nearly 15% of the SMARTCOUGH-C study recordings.

To improve consistency within the adjudication process the clinical adjudicators will apply a tightened set of clinical case definitions specifically designed to reduce the subjectivity of the clinical diagnosis. The adjudicators will also focus on providing a final diagnosis that is consistent with the patient's signs and symptoms (including any response to treatment) at the actual time of the audio recording.

ResApp Health Limited ABN 51 094 468 318
Headquarters: Level 8, 127 Creek St, Brisbane QLD 4000 Australia
Registered Office: Level 22, 44 St Georges Tce, Perth WA 6000 Australia
T +61 8 6211 5099 **E** info@resapphealth.com.au **W** www.resapphealth.com.au

In September, the study principal investigators and ResApp senior management and advisors will meet to finalise study design, incorporating the key improvements already identified. All sites have reaffirmed their intention to rerun the updated study and are targeting to restart the study before the beginning of the US winter season.

ResApp also plans to broaden its paediatric clinical strategy by reconfiguring its Australian study to directly support European (CE) and Australian (TGA) regulatory filings. Since earlier this year, the Australian paediatric study at Joondalup Hospital has been recruiting patients for double-blind prospective analysis with 230 patients recruited to date. To support regulatory submissions, a team of clinicians will perform adjudication and Curtin University health researchers will provide independent statistical analysis.

"Having completed a review with all relevant parties it is clear that the first US study was not a reliable evaluation of ResApp's algorithms and that the top line results do not reflect the actual performance of ResApp's technology," said Tony Keating, CEO and Managing Director of ResApp. "The environment and the clinical diagnostic procedures in busy US hospitals differed more than expected from those encountered during our Australian studies. It is now clear that we must employ several enhancements to properly execute our second US study. We are very fortunate to work with such excellent principal investigators; their professionalism and enthusiasm is invaluable when conducting such a complex clinical trial. Having taken their suggestions in combination with all the other learnings on board, we are confident that the next study will be robust."

About the SMARTCOUGH-C Study

SMARTCOUGH-C is a multi-site, double blind, prospective US 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

Contacts

Dr Tony Keating
CEO and Managing Director
+61 430 180 659
tony@resapphealth.com.au

Mr Brian Leedman
Executive Director and
Vice President, Corporate Affairs
+61 412 281 780
brian@resapphealth.com.au