

#### **ASX / MEDIA RELEASE**

# **ResApp Provides SMARTCOUGH-C-2 Study Update**

**Brisbane, Australia, 31 May 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 that recruitment in its SMARTCOUGH-C-2 study remains on track to complete in the middle of this calendar year. The study is evaluating the efficacy of the ResAppDx smartphone application for the diagnosis of childhood acute respiratory disease using cough sounds and will enrol up to 1,667 patients at the three participating hospital sites in the United States (US).

The study is recruiting to plan, with 1,277 patients recruited as of 30 May 2018. The incidence of the various diseases among study participants has been as expected which should ensure the study generates statistically strong results. Independent quality assurance of the cough audio recordings has been performed on-site weekly, as per the study protocol, with a sample of the audio recordings also being reviewed directly by ResApp. Only approximately 1% of recordings have been found in the quality assurance process to be unacceptable.

"The SMARTCOUGH-C-2 study recruited very well during the severe flu season in the US and continues to recruit as planned," said Tony Keating, CEO and Managing Director of ResApp Health. "We are gratified to see that the improved study training and processes continue to yield high quality audio and we have taken several large steps forward to ensure that the clinical adjudication is consistent. We now look forward to obtaining results from the study in the middle of this calendar year and submitting our de novo application to the US Food and Drug Administration for the world's first smartphone application for the digital diagnosis of respiratory disease shortly thereafter."

### 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 plans to enrol up to 1,667 patients aged 29 days to 12 years of age who present 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, viral lower respiratory tract infection, 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. Adult and paediatric clinical studies underway 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 proof-of-concept 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.

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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