



## **ResApp Provides Update on Australian Adult Study and FDA De Novo Submission**

**Brisbane, Australia, 29 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 an update on its Australian Breathe Easy adult prospective, double-blind clinical study and its planned De Novo submission to the US Food and Drug Administration (FDA) for clearance of ResAppDx-US, a smartphone application for the diagnosis of respiratory disease using cough sounds.

The Breathe Easy adult prospective study has completed recruitment, with 956 patients recruited. The study targeted diagnosis of lower respiratory tract disease, pneumonia, asthma exacerbations and chronic obstructive pulmonary disease (COPD) exacerbations. These indications cover the most prevalent adult respiratory conditions. They have wide application in telehealth, emergency department, urgent care and primary care settings, as well as in chronic disease management programs. Clinical adjudication is nearly complete, with 11 subjects to be finalised. The clinical dataset is now undergoing quality assurance before the data is locked and unblinded, with top-line results expected within three weeks.

ResApp has been working closely with Experien Group and Australian-based consultants and is pleased to announce that the documentation for its De Novo submission to the US FDA is complete. The documentation will now undergo a final two-week internal review process at Experien and at ResApp prior to its submission to the US FDA.

Tony Keating, CEO and Managing Director commented, “These are pivotal activities for ResApp, and they are progressing very well. We were recently advised that two additional weeks for the De Novo submission and three weeks for the adult study results are required to ensure that we generate the best possible outcome – and we firmly believe that it’s worth the short wait. Positive prospective adult results would greatly expand our addressable market and FDA clearance would unlock the entire US healthcare market, including its large and fast-growing telehealth sector.”

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### **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

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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](http://www.resapphealth.com.au).

ResAppDx-US is an investigational device and is not available for sale in the United States.

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