ResApp Submits De Novo Application to the FDA for Smartphone-based Diagnosis of Paediatric Respiratory Disease

Brisbane, Australia, 15 April 2019 – 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 it has submitted an application to the US Food and Drug Administration (FDA) for De Novo classification of ResAppDx-US, a mobile software application for the diagnosis of paediatric respiratory disease using cough sounds.

Respiratory disease causes a major portion of healthcare concerns in children; with cough being the most common illness-related reason for ambulatory visits in the US and among the top two principal reasons for children to visit the emergency department (ED). The single most common diagnosis from a child's ED visit is an acute upper respiratory tract infection, with lower respiratory tract diseases also among the most frequent diagnoses.

ResAppDx-US is intended to be used by clinicians as an aid in the diagnosis of primary upper respiratory tract disease, lower respiratory tract disease and asthma/reactive airway disease. ResAppDx-US has the potential to improve diagnostic accuracy, shorten time to treatment and improve access to diagnostic testing, all using only a smartphone. The De Novo application is supported by the SMARTCOUGH-C-2 clinical study which recruited over 1,400 patients at three hospital sites in the US.

"This submission represents the culmination of years of development work and marks a significant milestone towards commercialisation," said Tony Keating, CEO and Managing Director. "These respiratory diseases are the most common illnesses seen in healthcare, and once cleared by the FDA ResAppDx-US will deliver substantial clinical benefits by providing actionable information to clinicians sooner. We are now entering a new and exciting phase in ResApp's evolution as we prepare for the commercial launch of ResAppDx-US."

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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 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.

ResAppDx-US is pending review of a request for De Novo classification and is not available for sale in the United States.

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