ResApp Receives CE Mark for the World's First Smartphone-based Diagnostic Test for Respiratory Disease

Brisbane, Australia, 23 August 2019 – ResApp Health Limited (ASX:RAP), a leading digital health company developing smartphone applications for the diagnosis and management of respiratory disease, today announced that its first commercial product, ResAppDx-EU, has received CE Mark certification as a Class IIa medical device. ResAppDx-EU is the world's first smartphone-based diagnostic test for acute paediatric respiratory disease. CE Mark certification indicates that ResAppDx-EU meets the essential requirements of all the applicable European regulations as a medical device and allows for the sale of ResAppDx-EU in the European Economic Area.

Most people will develop an acute respiratory tract infection every year and these infections are the most common acute illnesses seen in primary care. Today, acute respiratory disease diagnosis, especially in children, is a complex, subjective process, combining clinical judgement with diagnostic aids such as auscultation with a stethoscope, imaging, blood and sputum tests.

ResAppDx-EU is a mobile software application to be used by clinicians for the diagnosis of lower respiratory tract disease, croup, pneumonia, asthma/reactive airway disease and bronchiolitis in infants and children. The software uses machine learning algorithms that analyse a patient's cough sounds to diagnose disease. ResAppDx-EU is a software-only solution that runs on an off-the-shelf smartphone and does not require any additional hardware or accessories.

The CE Mark approval was supported by data collected in ResApp's Breath Easy paediatric clinical study. The Breath Easy study was a double-blind, prospective study which evaluated the efficacy of ResApp's cough-based diagnosis algorithms in diagnosing acute respiratory disease in children. The study collected data from 585 patients and demonstrated that ResApp's algorithms had excellent agreement with a clinical diagnosis. Results from the study were recently published in the peer-reviewed journal *Respiratory Research*.

"We are very excited about receiving our first regulatory approval for ResAppDx-EU, our flagship acute diagnostic product," said Tony Keating, CEO and Managing Director of ResApp. "This is our biggest achievement yet and results from many years of hard work by our dedicated team. For the first time clinicians in Europe will have access to a rapid and accurate diagnostic test for the most commonly seen acute respiratory conditions in children. ResAppDx-EU has the potential to have far-reaching benefits in the healthcare system and we will now rapidly move ahead with our European commercialisation strategy."

CE Mark certification will facilitate further regulatory submissions in Australia, Canada and Singapore. In April, ResApp submitted a De Novo classification request to the US Food and Drug Administration which is currently pending review.

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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.

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