



## **ResApp Receives CE Mark Approval for Smartphone-based Diagnostic Test for Adult and Paediatric Respiratory Disease**

**Brisbane, Australia, 26 September 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 received CE Mark approval for ResAppDx-EU version 2, the latest version of the world's first smartphone-based diagnostic test for respiratory disease which now addresses both adults and children. This CE Mark approval is an extension of the existing CE Mark approval for ResAppDx-EU, adding the ability to test adults for lower respiratory tract disease, pneumonia, asthma exacerbation and chronic obstructive pulmonary disease (COPD) exacerbation. CE Mark certification indicates that ResAppDx-EU version 2 meets the essential requirements of all the applicable European regulations as a class IIa medical device and allows for its sale throughout the European Economic Area.

Most people will develop an acute respiratory tract infection every year and such infections are the most common acute illnesses seen in primary care. Diagnosis of acute respiratory disease is a complex, subjective process, combining clinical judgement with diagnostic aids such as auscultation with a stethoscope, imaging, blood and sputum tests. ResApp's cough-based diagnostic algorithms have been shown in pivotal clinical studies to accurately diagnose the most common adult and paediatric acute respiratory diseases when compared with a panel of experienced clinicians.

ResAppDx-EU version 2 is a mobile software application to be used by clinicians for the diagnosis of lower respiratory tract disease, croup (in children only), pneumonia, asthma exacerbation/reactive airway disease, COPD exacerbation (in adults only) and bronchiolitis (in children only). The software uses machine learning algorithms that analyse a patient's cough sounds to diagnose disease. ResAppDx-EU version 2 is a software-only solution that runs on a smartphone and does not require any additional hardware or accessories.

"Achieving CE Mark approval allows us to commercialise our novel smartphone-based test for diagnosing acute respiratory disease in adults and children across the European Economic Area as well as in other regions that recognise the CE Mark," said Tony Keating, CEO and Managing Director of ResApp. "A large percentage of general practitioner, emergency department and telehealth consultations are for respiratory disease and now, for the first time, clinicians in Europe will have access to a fast and accurate point-of-care diagnostic test that will improve care and reduce costs for patients of all ages."

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### **About Lower Respiratory Tract Disease**

A lower respiratory tract disease is any condition affecting the airway below the trachea, including an asthma exacerbation, chronic obstructive pulmonary disease (COPD), COPD exacerbation, bronchitis, pneumonia and other lower respiratory tract infections.

### **About Pneumonia**

Pneumonia is an inflammation in one or both lungs, usually caused by bacterial, viral or fungal infection. It is one of the leading causes of hospitalisation and death among adults.

### **About Asthma**

Asthma is a chronic disease characterised by airway inflammation and bronchoconstriction. The Global Asthma Report 2018 estimates that asthma affects around 339 million people globally. An acute asthma exacerbation occurs when a person with asthma comes in contact with an asthma trigger (infections, pollen, smoke) causing their airways to become inflamed and leading to progressive worsening of symptoms such as shortness of breath, wheezing, cough and chest tightness. Asthma cannot be cured; however appropriate management can control the disease in the majority of patients.

### **About Chronic Obstructive Pulmonary Disease**

Chronic obstructive pulmonary disease (COPD) is a progressive disease caused by the narrowing of the bronchial tubes in the lungs. The Global Burden of Disease Study reports that there were 251 million cases of COPD globally in 2016. The primary cause of COPD is exposure to tobacco smoke, and it is the third leading cause of death worldwide. An acute exacerbation of COPD is a sudden worsening of COPD symptoms that is triggered by an infection or by environmental factors. COPD cannot be cured; however treatment can help relieve symptoms, improve quality of life and reduce the risk of death.

### **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 have demonstrated accurate diagnosis of lower respiratory tract disease, upper respiratory tract infection, pneumonia, bronchiolitis, croup, asthma exacerbation/reactive airway disease, chronic obstructive pulmonary disease, chronic obstructive pulmonary disease exacerbation, and obstructive sleep apnoea. ResApp's smartphone-based acute respiratory disease diagnostic test, ResAppDx-EU, is CE Marked in the European Union. 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](http://www.resapphealth.com.au).



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