

ResApp Receives Australian TGA Approval for Smartphonebased Diagnostic Test for Adult Respiratory Disease

Brisbane, Australia, 20 February 2020 – 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 today received notification from the Australian Therapeutics Goods Administration (TGA) that its smartphone application, ResAppDx-EU version 2, which diagnoses respiratory disease in both adults and children, is approved as a Class IIa medical device and is now listed on the Australian Register of Therapeutic Goods (ARTG). The TGA approval is an extension of the existing 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.

Most people will develop an acute respiratory tract infection every year and such infections are the most common acute illnesses seen in primary care. Currently, 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.

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 exacerbation, COPD exacerbation and bronchiolitis. 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 a smartphone and does not require any additional hardware or accessories.

"We are pleased that our lead product, ResAppDx-EU is now approved for use on both adults and children in Australia and Europe," said Tony Keating, CEO and Managing Director of ResApp. "ResAppDx-EU offers strong health and economic benefits to telehealth providers, emergency departments and urgent care clinics in Australia and Europe, and we are excited by the scale of the opportunity and our unique position in the market. We are now growing our commercial team to support our sales, marketing and business development activities in these regions, and we are pleased to have a growing number of opportunities at various stages in our commercial pipeline."

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About the Australian Register of Therapeutic Goods (ARTG)

The Australian Register of Therapeutic Goods (ARTG) is the central point of control for the legal supply of therapeutic goods in Australia. The ARTG is a database of information about therapeutic goods for human use approved for supply in, or exported from, Australia. It is the reference database of the Therapeutic Goods Administration (TGA).



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 infections, pneumonia, bronchiolitis, croup, asthma/reactive airway disease exacerbation, 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 and TGA approved in Australia. 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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This ASX announcement was approved and authorised for release by the board of directors of ResApp Health.