ResApp Receives Australian TGA Approval for Smartphone-based Diagnostic Test for Paediatric Respiratory Disease

Brisbane, Australia, 2 October 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 ResAppDx-EU, the world's first smartphone-based diagnostic test for acute paediatric respiratory disease, has received Australian Therapeutics Goods Administration (TGA) approval as a Class IIa medical device and is now listed on the Australian Register of Therapeutic Goods (ARTG).

Most people will develop an acute respiratory tract infection every year and these infections are the most common acute illnesses seen in primary care. In Australia, upper respiratory tract infections account for 3-4 million visits to general practitioners (GPs) every year while lower respiratory tract infections cause an additional 3 million visits. Bronchiolitis and croup account for the majority of winter hospitalisations for children.

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 a smartphone and does not require any additional hardware or accessories.

"Achieving TGA approval is an important regulatory milestone that allows us to sell ResAppDx-EU in Australia, our home market," said Tony Keating, CEO and Managing Director of ResApp. "We believe that ResAppDx-EU will deliver strong health and economic benefits when used by clinicians in Australian emergency departments, urgent care clinics, GP offices and in the Australian telehealth industry, which has grown markedly in the last year."

ResAppDx-EU recently received CE Mark approval in the European Union for both adult and paediatric use, and is currently pending De Novo classification for paediatric use in the United States. A follow-on TGA submission for adult use will be made shortly.

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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).

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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. ResApp's smartphone-based acute respiratory disease diagnostic test, ResAppDx-EU, is CE Marked in the European Union and ARTG listed 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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