ResApp Clears Major Milestone for CE Mark and TGA Approval with ISO 13485 Compliance

Brisbane, Australia, 14 November 2018 -- 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 its quality management system is now International Organization of Standardization (ISO) 13485:2016 compliant, following a successful Stage Two Audit by BSI (The British Standards Institution). ResApp expects to receive a formal certificate within two weeks. ISO 13485 is an essential step in obtaining European CE Mark and Australian Therapeutic Goods Administration (TGA) approval for all of ResApp's products.

In order to achieve ISO 13485 compliance, a company must demonstrate to an authorized third party that it meets the ISO requirements for a comprehensive quality management system for the design and manufacture of medical devices.

"Obtaining ISO 13485 certification is a significant accomplishment and an important milestone as we approach commercialisation in Europe and Australia," said Tony Keating, CEO and Managing Director of ResApp. "In Australia there are 150 million general practitioner (GP) visits annually, with acute upper respiratory tract infections being the most commonly managed illnesses for patients under 45. Europe represents an even larger opportunity, with more than 6.8 billion GP visits annually. In the UK alone, a quarter of the population visit their GP for a respiratory tract infection at least once per year, while in the Netherlands 15% of all GP visits relate to a respiratory tract infection. National health services across Europe are adopting new technologies such as telehealth and AI to deliver more effective primary healthcare. Our products fit perfectly into this growing trend. With ISO 13485 compliance now complete, we are well on our way towards obtaining CE marking and TGA approval for our suite of smartphone applications."

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 on ResApp, visit www.resapphealth.com.au

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