Pre-Submission package lodged with the US FDA

Brisbane, Australia, 10 February 2021 – ResApp Health Limited (ASX:RAP), a leading digital health company developing smartphone applications for the diagnosis and management of respiratory disease, is pleased to advise that it has filed a Pre-Submission package with the United States (US) Food and Drug Administration (FDA) and requested a meeting with the agency to progress the potential clearance of a prescription-only software as a medical device application to detect lower respiratory tract illness in children and adults.

The application uses ResApp's proprietary machine-learning technology to analyse signatures in cough sounds recorded using a smartphone's built-in microphone to assist healthcare professionals in the identification of patients with lung sounds suggestive of lower respiratory tract illness. The algorithms have been validated in ResApp's SMARTCOUGH-C-2 and Breathe Easy prospective clinical trials.

The application is positioned as a broadly applicable triage tool for healthcare professionals to support their clinical decision making.

The package has been lodged as part of the FDA's Pre-Submission program, which provides applicants with the opportunity to obtain targeted feedback from the regulator in response to questions related to data requirements and marketing applications prior to a pre-market submission.

ResApp will schedule a Pre-Submission meeting with the FDA to discuss potential approval pathways for the application and any further requirements.

CEO and Managing Director Dr Tony Keating said: *"Submitting this Pre-Submission package and meeting request is an important first step in our re-engagement with the FDA that will provide a valuable opportunity for the company to discuss the potential pathways for the clearance of our cough-based analysis technology for use in the US.*

"Management is confident that the application will have considerable scope in the US and can be used as a broadly applicable triage tool, which will assist in improving patient care.

"We expect to have a number of meetings with the agency this year to ensure that the company is well positioned and to provide any additional details that might be required.

"ResApp looks forward to working cooperatively with the FDA over the coming months to delineate a path forward for its offering."

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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 the respiratory disease. ResApp's machine learning algorithms use sound to diagnose and measure the severity of respiratory conditions without the need for additional accessories or hardware. ResApp's regulatory-approved and clinically validated products include ResAppDx, a smartphone-based acute respiratory disease diagnostic test for use in telehealth, emergency department and primary care settings; and SleepCheck, a smartphone application which allows consumers to self-assess their risk of sleep apnoea. Both products are CE Marked in Europe and TGA approved in Australia. 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.