Update on US FDA De Novo Classification Request

Brisbane, Australia, 11 March 2020 – ResApp Health Limited (ASX:RAP), a leading digital health company developing smartphone applications for the diagnosis and management of respiratory disease, today announced that the US Food and Drug Administration (FDA) has advised that, based on the information submitted, ResApp's De Novo classification request for ResAppDx-US has not been approved and that additional information is required to demonstrate that the probable benefits of the device outweigh its probable risks. ResApp and our regulatory consultants, Experien Group, will now request an in-person meeting with the FDA review team to determine our next steps in the US, which may include a resubmission.

Tony Keating, CEO and Managing Director of ResApp, commented, "We are understandably disappointed by the FDA's decision, especially after recently receiving European (CE Mark) and Australian (TGA) regulatory approvals. Following positive discussions during the review process last year with the FDA and submitting a detailed response to the FDA's request for additional information in December, we were anticipating either approval of the De Novo or further dialogue as the next steps in the process. We will now work closely with the FDA and Experien Group to plan our next steps in pursuing regulatory approval in the US. In parallel, we will also continue to focus our commercialisation efforts in Europe and Asia-Pacific, where we have the appropriate regulatory approvals and a growing list of commercial opportunities."

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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 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.