ResApp Completes Successful Pre-Submission Meeting with the US FDA

Perth, Western Australia, 14 March 2016 -- ResApp Health Limited (ASX: RAP), announced today a positive outcome from its recent Pre-Submission Meeting with the United States Food and Drug Administration (FDA) regarding ResApp's diagnostic mobile software application, ResAppDx. During the meeting ResApp received targeted feedback from the FDA regarding the proposed US regulatory pathway, clinical study protocols, planned non-clinical evaluations and data requirements.

ResApp can now confirm that it will pursue a direct *de novo* premarket submission for ResAppDx, initially for paediatric use. A submission for adult use will be prepared in parallel and will be submitted shortly after the paediatric submission. The *de novo* pathway is designed for innovative medical devices (i.e. those which have no predicate device) where controls provide a reasonable assurance of safety and effectiveness. The *de novo* process leads to a Class I or Class II classification and has a 120-day review cycle, compared to a 90-day review period for a 510(k).

The Company also confirms that it will perform pivotal clinical studies at one or more US hospitals to provide a key portion of the clinical data required to support both paediatric and adult submissions. The balance of the required data will be gathered from pivotal studies at previously established Australian sites.

Dr Tony Keating, CEO and Managing Director of ResApp, said "Our Pre-Submission Meeting with the FDA was very productive and we were encouraged by the high level of engagement exhibited by the FDA team. We have obtained the clarity required to optimise our clinical and regulatory pathway and we are on track to reach our announced regulatory milestones."

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About ResApp Health Limited

ResApp Health Limited, founded in 2014, is developing smartphone medical applications for the diagnosis and management of respiratory disease. The technology is based on machine learning algorithms that use sound alone to diagnose and measure the severity of respiratory conditions without the need for additional hardware. The algorithms were initially developed by The University of Queensland with funding from the Bill and Melinda Gates Foundation. ResApp has a multi-site clinical study underway and preliminary results demonstrated accurate diagnosis of pneumonia, asthma/viral wheeze, bronchiolitis, croup and upper respiratory tract infections in children. Approval has been recently received to extend the study to adults at two major Australian hospitals. Markets for ResApp's technology include telehealth use through partnerships with telehealth service providers, emergency department and regular clinic use by healthcare providers, at-home use by consumers and working with global aid and humanitarian organisations to deliver tools for the developing world.

For more information on ResApp, visit www.resapphealth.com.au.

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