CE Mark achieved for wearable device

Brisbane, Australia, 2 March 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 achieved CE Mark certification for the company's wearable device as a Class I medical device accessory. Achieving CE Mark certification is a major accomplishment and allows ResApp to progress the manufacture and sale of the device in Europe.

ResApp's wearable device is an easily worn, clip-on, unobtrusive platform, which allows for continuous 24-hour patient monitoring using cough audio.

This important regulatory achievement follows stringent design developments and functional testing. The wearable will be manufactured by ResApp's partner OSI Electronics, which has strategically located manufacturing facilities in the United Kingdom and South East Asia.

The device has a number of applications. Initially, ResApp will focus on introducing it into clinical trial settings to measure cough frequency. Cough frequency is a key factor in respiratory disease progression and management, and may be an important outcome measure in clinical trials involving a broad range of disease states where cough is implicated.

The device has very high accuracy and precision. It can identify over 93% of coughs events, with less than 1% of identified events being false positives. Unlike existing solutions, it does not require manual review of cough sounds by an analyst, ensuring a less labour-intensive and more rapid approach to monitoring.

Image One: *ResApp's wearable device.*

ResApp Health Limited ABN 51 094 468 318
Level 12, 100 Creek St, Brisbane QLD 4000 Australia
T +61 7 3724 0035 **E** info@resapphealth.com.au **W** www.resapphealth.com.au

The company will also use the wearable as a platform to pursue monitoring of at-risk chronic disease patients that may have chronic obstructive pulmonary disease (COPD) or asthma. Detection of exacerbations of these conditions, ahead of directing users to their healthcare provider, would be beneficial. ResApp will also collect and utilise data generated to create trend data for respiratory changes over time.

In other development work, ResApp is also working to secure CE Mark certification of a ruggedized handheld device, which will provide a low-cost option, complimentary to an off-the-shelf smartphone, focused on using ResApp's ResAppDx acute respiratory diagnostic test in specific in-person clinical environments. CE Mark certification for the handheld device is expected in the coming months.

CEO and Managing Director Dr Tony Keating said: *"Achieving CE Mark is a major achievement, and we are confident that our wearable device will provide a number of commercial opportunities.*

"Discussions with potential partners, including global pharmaceutical companies, to introduce the wearable device into clinical trial settings have already commenced. The availability of the device provides a strong value proposition to potential partners and allows ResApp another opportunity to commercialise new products aimed at assessing and predicting respiratory disease progression."

ResApp advises that this development marks the final milestone under the device development agreement for the wearable device with Avanti Med (refer ASX announcement 29 May 2019). The company will now issue Avanti 6,250,000 new fully paid ordinary shares under its 15% placement capacity.

Image Two: *ResApp's wearable device is an easily worn, clip-on, unobtrusive platform, which allows for continuous patient monitoring using cough audio.*

###

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.

Contacts

Dr Tony Keating
CEO and Managing Director
+61 430 180 659
tony@resapphealth.com.au

Mr Brian Leedman
Vice President, Corporate Affairs
+61 412 281 780
brian@resapphealth.com.au

This ASX announcement was approved and authorised for release by the board of directors of ResApp Health.