TGA clearance achieved for wearable

Brisbane, Australia, 25 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 Australian Therapeutics Goods Administration (TGA) clearance for its wearable as a Class I medical device and it is now listed on the Australian Register of Therapeutic Goods (ARTG). The development follows ResApp receiving CE Mark certification for the device earlier this month (refer ASX announcement: 2 March 2021).

TGA clearance will allow ResApp to progress the sale and marketing of the wearable in Australia.

ResApp's wearable is an easily worn, clip-on, unobtrusive device, which allows for continuous 24-hour patient monitoring using cough audio. When used in conjunction with ResApp's proprietary algorithms, the wearable has very high accuracy and precision – identifying over 93% of coughs events, with less than 1% of identified events being false positives.

The device has a number of applications. Initially, ResApp will introduce it into clinical trial settings to measure cough frequency. Cough frequency is a key factor in determining and managing respiratory disease progression and may also be a valuable outcome measure in clinical trials involving a broad range of disease states where cough is implicated.

CEO and Managing Director Dr Tony Keating said: *"We are pleased to have secured TGA clearance for our wearable which allows us to market and sell the product in Australia, our home market.*

"We have achieved a considerable amount in a short time period in relation to our wearable device and cough counting technology. Since we secured CE Mark certification for the wearable earlier this month and announced our recent deal with AstraZeneca Japan, we have witnessed increased interest in our cough counting technology. We are particularly excited about the level of enquiry shown by large pharmaceutical and biotech companies that recognise the strong value proposition that our offering provides."

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About the Australian Register of Therapeutic Goods (ARTG)
The Australian Register of Therapeutic Goods (ARTG) is the central point of control for the legal supply of therapeutic goods in Australia. The ARTG is a database of information about therapeutic goods for human use approved for supply in, or exported from, Australia. It is the reference database of the Therapeutic Goods Administration (TGA).

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.