ASX Release

1 December 2018

FDA Clearance Granted for FerriSmart®

Resonance Health Limited (ASX: RHT) ("Resonance Health" or "Company") is pleased to announce that it has received 510(k) clearance from the US Food and Drug Administration ("FDA") for FerriSmart®, the Company's ground-breaking machine learning solution for the quantification of liver iron concentration.

FerriSmart® automatically analyses MRI images from most scanner makes and models, and returns a liver iron quantification result within seconds.

The FDA 510(k) clearance for FerriSmart® is in addition to regulatory clearance obtained in July 2018 from the TGA - Therapeutic Goods Administration (Australia), and CE Mark (European Union) (ASX announcement dated 11 July 2018).

The FDA has cleared FerriSmart® with the following indications:

- Measure liver iron concentration in individuals with confirmed or suspected systemic iron overload;
- Monitor liver iron burden in transfusion dependent thalassemia patients and patients with sickle cell disease receiving blood transfusions; and
- Aid in the identification and monitoring of non-transfusion-dependent thalassemia patients receiving therapy with deferasirox.

This clearance allows Resonance Health to market FerriSmart® for commercial distribution in the United States of America. Deploying FerriSmart® via channel partner platforms such as the Blackford Platform (ASX announcement dated 5 July 2018) allows FerriSmart® to integrate seamlessly into radiology workflows, delivering results efficiently to radiologists and clinicians.

The Company looks forward to continuing to provide clinicians and patients with outstanding image analysis products.

Alison Laws
Chief Executive Officer

For further information please contact:
Chad Tondut
Communications Manager, Resonance Health
E: chadt@resonancehealth.com P: +61 (0)8 9286 5300