ASX Announcement – 3 December 2021

LiverSmart™ Submitted to FDA for US Regulatory Clearance

Highlights

- Application submitted to the FDA for US regulatory clearance of LiverSmart™
- LiverSmart™ is a new AI medical device combining FerriSmart® and HepaFat-AI®
- Provides a comprehensive assessment of a person's liver, reporting both iron and fat
- Avoids two separate MRI scanning sessions saving cost and enhancing convenience
- Artificial Intelligence (AI) based, enabling rapid delivery of results and scalability

LiverSmart™ Dossier Submitted to US FDA

Resonance Health Ltd (ASX: RHT) ("Resonance Health" or "Company") advises that, further to its announcement on 13 October 2021 entitled "New AI Medical Device", the LiverSmart™ application dossier has been submitted to the United States ("US") Food & Drug Administration ("FDA") for a Special 510k medical device regulatory clearance.

The FDA application process for a medical device clearance can take between several weeks and several months depending on feedback received from the FDA including whether the FDA has substantive questions on the LiverSmart™ dossier and whether additional information is required. The Company will advise if and when LiverSmart™ obtains FDA regulatory clearance.

Background on LiverSmart™

LiverSmart™ is the Company's newest AI medical device that combines two existing regulatory-cleared Resonance Health products, FerriSmart® and HepaFat-AI®, into a single multi-parametric MRI session, avoiding the need for multiple MRI appointments, and delivering a more complete and comprehensive assessment of a person's liver.

Instead of obtaining individual FerriSmart® and HepaFat-AI® reports via separate scanner sessions, which adds to cost and inconvenience, patients and clinicians could soon be able to obtain both analyses at the same time with one referral, and in one consolidated report. Clinicians seeking both analyses will simply refer for a LiverSmart™ assessment, by Resonance Health.

Importantly, the Company believes that LiverSmart™ may be eligible for two new US (Category III) Current Procedural Technology ("CPT") codes recently published by the American Medical Association ("AMA") and which become active on 1 January 2022. The Company is awaiting definitive determination of LiverSmart's eligibility for these codes, from a US certified CPT coder.

LiverSmart's use remains subject to regulatory clearances including with the US FDA.

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This announcement has been authorised for release in accordance with the delegated authority of the Board of Directors of Resonance Health Ltd.

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About Resonance Health

Resonance Health is an Australian healthcare technology and services company, specialising in the development and delivery of noninvasive medical imaging software and services.

The Company's products are used globally by clinicians in the diagnosis and management of human diseases and by pharmaceutical and therapeutic companies in their clinical trials. Resonance Health has gained endorsement by leading physicians worldwide for consistently providing high quality quantitative measurements essential in the management of diseases.

Resonance Health's dedication to scientific rigour and quality management has enabled it to achieve regulatory clearances for a range of Software as a Medical Device (**SaMD**) products in the USA, Europe, and Australia and to proudly carry ISO 13485 certification for the design and manufacture of medical devices. A number of these SaMD products incorporate the use of Artificial Intelligence (**AI**):

- **FerriScan®** - provides an accurate measurement of liver iron concentration (**LIC**) through a non-invasive MRI-based technology, for use in the assessment of individuals with iron overload conditions. FerriScan® is internationally recognised as the gold standard in LIC assessment.
- **FerriSmart® -** an AI-driven system for the automated real-time measurement of LIC in patients using non-invasive MRI-based technology.
- **HepaFat-AI® -** an AI-driven system for the automated real-time multi-metric measurement of liver fat in patients using non-invasive MRI-based technology, for use in the assessment of individuals with confirmed or suspected fatty liver disease.
- **CardiacT2*** – the most widely accepted MRI based method for assessing heart iron loading. Resonance Health also offers a dual analysis of FerriScan® and CardiacT2*. CardiacT2* has regulatory clearance from the FDA, TGA and CE Mark.

The Company has an active development pipeline of additional medical imaging analysis products and services, including, **LiverSmart™** and **Alert-PE™,** an AI tool for the automated review of chest CT scans of patients with suspected pulmonary embolism.