New AI Medical Device

Highlights

- 'LiverSmart' planned for official launch as early as December 2021

- Combines FerriSmart® and HepaFat-AI® into a single MRI scanning appointment

- Provides a more comprehensive assessment of a person's liver, reporting both iron and fat

- Avoids the need for separate MRI scanning sessions, saving cost and enhancing convenience

- Artificial Intelligence (AI) based, enabling results to be rapidly delivered to clinicians and patients

- Appears to fulfill the requirements for two new US CPT Codes which become effective on 1 Jan 2022

- Awaiting definitive determination of CPT Code eligibility by US Code Certifier

Introducing "LiverSmart"

Resonance Health Ltd (ASX: RHT) ("Resonance Health" or the "Company") announces the development of its newest AI medical device, LiverSmart, which is now undergoing final quality and verification checks prior to its submission to the United States ("US") Food & Drug Administration ("FDA") for regulatory clearance.

LiverSmart 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 will 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. LiverSmart's use remains subject to regulatory clearances including with the US FDA which is expected to take approximately 45 days from submission, or longer if the FDA have queries.

LiverSmart is currently undergoing final quality and verification checks and the Company anticipates being in a position to submit LiverSmart's application for FDA clearance within the coming weeks. The Company's AI, technical, quality assurance, and regulatory personnel, are focused on achieving this by the end of 2021, and potentially in time for featuring at the RSNA conference in Chicago in early December 2021.

New CPT Codes & Reimbursement

Importantly, the Company believes that LiverSmart may be eligible for two new United States (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.

CPT codes are a national procedural coding set maintained by the AMA, and recognised by US government agencies, used to describe medical services for reimbursement by both government payers such as Medicare,

Medicaid, and private payers including private health insurers. The codes are used by physicians and health care professionals for reporting and tracking medical services performed by healthcare providers.

CPT codes start as temporary Category III codes and, when there is sufficient reporting of the codes over a period, they are upgraded to Category I, at which point they become permanent and reimbursable. Assuming LiverSmart is eligible for the new codes, hospitals and MRI imaging centres will be able to use the codes when using LiverSmart for clinical purposes and the service will be systematically tracked through the US healthcare system, which is a critical element of demonstrating the clinical need for the service in the US.

If the codes, which become active on 1 January 2022, are confirmed as applicable to LiverSmart it will be another milestone in the pathway to widespread payer and insurer reimbursement in the US and will better facilitate LiverSmart being reimbursed by private payers such as private health insurers, as well as Medicare and Medicaid.

Managing Director Comment

Managing Director of Resonance Health, Mitchell Wells, said the following:

"LiverSmart is an evolution of our existing product offering and it responds to the growing trend in medical imaging for more holistic assessment of human organs using AI for rapid turnaround and enhanced scalability.

The LiverSmart device focusses on our core expertise in the liver and it leverages our global standing in liver-iron and liver-fat assessment through our existing regulatory-cleared liver products. LiverSmart provides a more complete assessment of the liver by combining multiple MRI appointments and assessments into a singular multi-parametric scanning session which will enhance patient convenience and should reduce cost.

Importantly, we believe that LiverSmart may be eligible for two new United States (Category III) CPT Codes, and we are now awaiting a definitive determination from a US code certifier. If the codes are determined to be applicable to LiverSmart this will represent a major milestone on our pathway to more widespread reimbursement in the USA."

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

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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

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