**ASX Release – 24 February 2021**

## HepaFat-AI Receives CE Marking

- **HepaFat-AI, Resonance Health's fully automated AI software that assesses liver fat, receives CE marking;**
- **The product is now registered for sale within the European Economic Area;**
- **HepaFat-AI received United States FDA clearance in December 2020, and Australian TGA approval in February 2021;**
- **Resonance Health will market HepaFat-AI to radiologists and physicians involved in the routine clinical diagnosis and management of patients with confirmed or suspected fatty liver disease;**
- **HepaFat-AI will also be marketed to pharmaceutical companies engaged in non-alcoholic steatohepatitis (NASH) drug development;**
- **With an estimated global prevalence of between 24-30%[1], NAFLD affects up to 2.3 billion people, a figure expected to grow year-on-year. Of these, about 470 million people (or 20%) will develop NASH[2].**

Resonance Health Ltd (ASX: RHT) ("Resonance Health" or "Company") is pleased to announce that it has received CE mark for HepaFat-AI, the Company's fully automated artificial intelligence ("AI") software that assesses liver fat (the "Device").

CE marking signifies that the Device is compliant with the requirements of Medical Device Directive 93/42/EEC for CE Marking and is registered for sale within the European Economic Area ("EEA").

The Company obtained United States Food & Drug Administration ("FDA") clearance for the Device in December 2020 (see ASX release dated 9 December 2020 entitled "HepaFat-AI Gains US FDA Clearance"), and Australian Therapeutic Goods Administration ("TGA") approval in February 2021 (see ASX release dated 18 February 2021 entitled "HepaFat-AI Receives TGA Approval").

Collectively, these clearances allow the Company to lawfully distribute and supply the Device into Australia, the EEA, and the United States of America (and their territories).

HepaFat-AI automatically analyses magnetic resonance imaging ("MRI") datasets to assess liver fat in patients, providing doctors with a comprehensive, multi-metric solution for use in the assessment of individuals with confirmed or suspected fatty liver disease.

HepaFat-AI assesses these images and provides the following information on the resultant patient report (a sample report can be seen in Annex A to this announcement):

1. **NASH-CRN Steatosis Grading** - HepaFat AI is the only regulatory cleared imaging technology capable of reporting a standardised steatosis grade that is substantially equivalent to a histopathologist NASH-CRN score. Steatosis grading until now has required a histopathological assessment of a patient's liver fat levels from a liver biopsy (this has previously been considered the gold standard for clinical assessment of liver fat).
2. **Proton Density Fat Fraction (PDFF)** - Provides the commonly reported liver MR fat metric from imaging and spectroscopy. PDFF has been widely shown to correlate with the degree of hepatic steatosis, with a cut-off of 5% being indicative of non-alcoholic fatty liver disease ("NAFLD").
3. **Volumetric Liver Fat Fraction (VLFF)** - Provides an MR liver fat metric that correlates with hepatocyte macro-vesicular fat volume.
4. Includes a **Liver Fat Distribution Map** for illustrative purposes.

The treating physician can use this information to: monitor patients undergoing weight loss management; to screen the livers of live donors for transplant suitability; monitor patients with or suspected to have NAFLD or the more serious subtype, non-alcoholic steatohepatitis ("NASH"); drug induced fatty liver; pancreatic insufficiency.

The Company will market HepaFat-AI to radiologists and physicians involved in the routine clinical diagnosis and management of patients with confirmed or suspected fatty liver disease. Clinicians and radiologists will soon be able to access HepaFat-AI via Resonance Health's own cloud-based portal. The Company is also assessing the use of radiology-based channel partners for direct route to market.

HepaFat-AI will also be marketed to pharmaceutical companies engaged in NASH drug development due to the highly standardised and reproducible nature of the AI solution. As HepaFat-AI is validated for all the major MRI scanner makes and models, it is ideally suited for these purposes, particularly in NASH multi-center trials which require standardised workflows to ensure clinically meaningful data is generated. Moreover, as HepaFat-AI can deliver data in near real-time, investigators can respond rapidly if adaptive trial protocols are implemented, which is particularly advantageous in recently designed NASH studies. Additionally, HepaFat-AI's unique capability of reporting a 'pathologist's equivalent' steatosis grade could help bridge the gap caused by the reportedly high screening failure rates (up to 50%) as evidenced by liver biopsy in patients recruited to NASH trials[3].

The Company has commenced investigating reimbursement for HepaFat-AI in the United States of America.

Additional work in machine learning is continuing with the Company remaining focused on developing and deploying cutting-edge assistance tools for clinicians and radiologists for various disease states. Further updates will be provided as work progresses.

## Authorised by

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

## About Resonance Health

Resonance Health is an Australian healthcare company specialising in the development and delivery of noninvasive medical imaging software and services. Resonance Health has gained endorsement by leading physicians worldwide for consistently providing high quality quantitative measurements essential in the management of particular diseases. 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's dedication to scientific rigour has enabled it to achieve regulatory clearances on a number of software products (SaMD) in the US, Europe, and Australia, including FerriSmart®, an artificial intelligence product that quantifies iron concentration in the liver. The Company has also recently received US FDA regulatory clearance for a second artificial intelligence tool, HepaFat-AI. The Company is working on several other developments including, among others, ALERTE-PE, which is an AI tool for the automated review of chest CT scans of patients with suspected pulmonary embolism.

**For further information please contact:**

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1. Sayiner M, Koenig A, Henry L, Younossi ZM. Epidemiology of nonalcoholic fatty liver disease and nonalcoholic steatohepatitis in the United States and the rest of the world. Clinics in Liver Disease. 2016;20:205-214
2. Kaufmann, B., Reca, A., Wang, B. et al. Mechanisms of nonalcoholic fatty liver disease and implications for surgery. Langenbecks Arch Surg (2020). https://doi.org/10.1007/s00423-020-01965-1
3. Loomba et al (2018), The ASK1 Inhibitor Selonsertib in Patients With Nonalcoholic Steatohepatitis: A Randomized, Phase 2 Trial. Hepatology: 67 (2), 549-559.

**Annex A**

HepaFat-AI

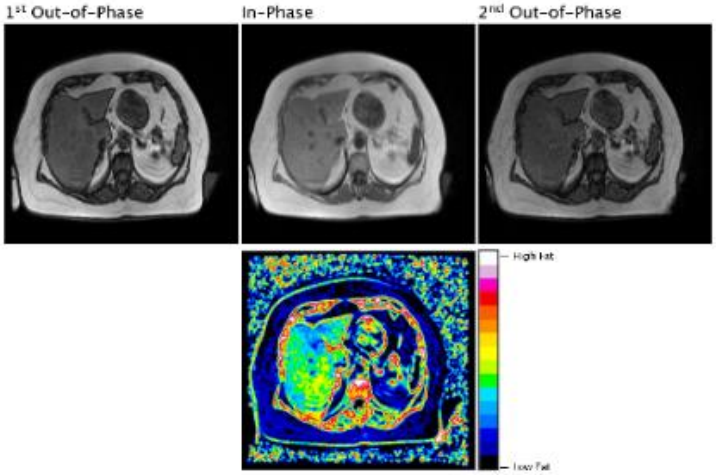
## Liver Fat Assessment Report

| | | | |
|---|---|---|---|
| Patient ID: | 111 | Scan Date: | 1 Jan 1900 |
| Name: | Name | Analysis Date: | 1 Jan 1900 |
| Birth Date: | 01 Jan 1900 | Referrer: | |
| | | MRI Center: | Hospital |

| | Result | 95% CI (confidence interval) | Normal Range |
|---|---|---|---|
| VLFF (Volumetric Liver Fat Fraction) | 11.2% | 8.9 – 14.3 | 0 – 4.1[1] |
| PDFF (Proton Density Fat Fraction) | 13.0% | 10.3 – 16.5 | 0 – 4.8[2] |
| Steatosis Grade | 1 | | 0[3] |

1) The normal VLFF range is derived from direct comparison between VLFF measurements and NASH CRN grading of biopsy (St. Pierre et al., PLoS One. 2016;11 (5)).
2) The normal PDFF range is derived from the calibration between VLFF and PDFF measurements.
3) Refer to the NASH-CRN steatosis grading guide below for interpreting Steatosis Grade (Kleiner DE et al. Hepatology. 2005 Jun;41(6):1313-21).

| | NASH-CRN Steatosis Grading Guide |
|---|---|
| 0 | Involvement by steatosis in < 5% of hepatocytes |
| 1 | Involvement by steatosis in 5 to 33% of hepatocytes |
| 2 | Involvement by steatosis in 33 to 66% of hepatocytes |
| 3 | Involvement by steatosis in > 66% of hepatocytes |




Liver Fat Distribution Map[4]

4) The Liver Fat Distribution Map is a guide to illustrate the distribution of fat in the liver. The colour display is relevant to the liver region only and colours outside the liver are not related to fat content. The colour lookup table is specific to each individual case. It should not be used for diagnostic purposes.

If you have questions on the current analysis result and/or slice selected, please contact Resonance Health at support@resonancehealth.com.

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