HepaFat-AI Receives TGA Approval.

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

TGA approval means that the Device conforms to Australian regulatory requirements and is approved by the TGA for inclusion in the Australian Register of Therapeutic Goods ("ARTG") and allows the Company to lawfully supply the Device in Australia. 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").

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. A number of clinical applications that may suit HepaFat-AI can be seen in Annex C of this announcement.

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], an inflammatory condition of the liver, of which an estimated 27% will develop serious fibrotic, disease increasing their risk of cirrhosis, cancer and liver failure[3]. Having surpassed viral hepatitis, NAFLD is now the leading cause of liver morbidity and mortality and the leading indicator for liver transplants in the US. It is predicted that over the next 10 years the healthcare costs associated with the management of NAFLD will exceed USD $1 trillion in the US and €334 billion in Europe (Germany, France, Italy, and the United Kingdom)[4].

The Company intends to 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. To this end, the Company has amended its existing agreement with channel partner Blackford Analysis Inc. (the "Agreement") entered into between Resonance Health and Blackford Analysis Inc. (see ASX announcements dated 5 July 2018 and 24 December 2020). The Agreement allows Blackford's current and future customers' including their channel partners such as Intelerad and eRAD, access to HepaFat-AI and FerriSmart via the Blackford platform.

HepaFat-AI is also intended to be marketed towards 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 particular if adaptive trial protocols implemented, a particular advantage when compared to current NASH studies. Additionally, HepaFat-AI's unique capability of reporting a 'pathologists 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[5].

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

The Competent Authority (the medical device regulator in EU) decision on CE marking for the product is also pending. 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.

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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Annex A

HepaFat-AI

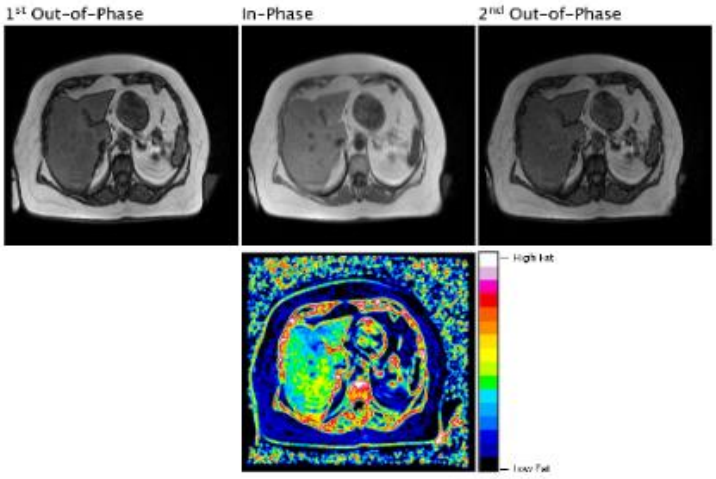
Liver Fat Assessment Report

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 (8)).
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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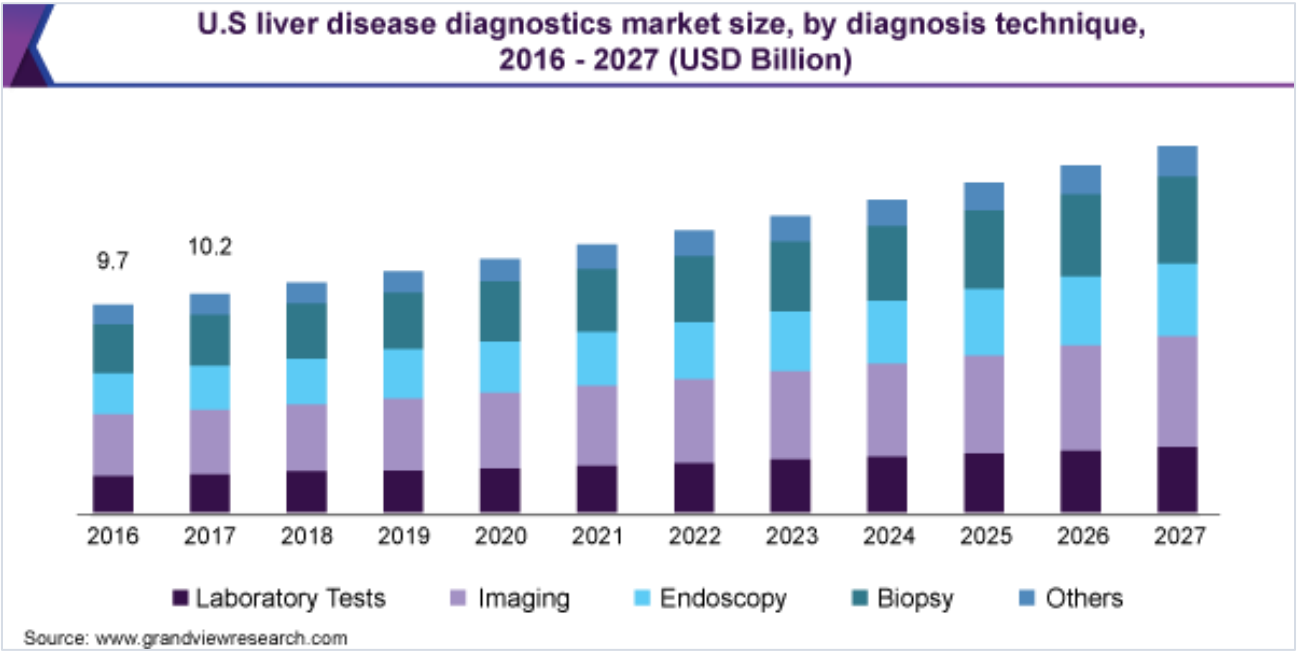
510(k):K201039

Annex B

According to a recent report by Grand View Research, Inc., the global liver disease diagnostics market size is expected to reach USD $48.7 billion by 2027[6]. The growth of imaging solutions has dominated the market in particular, holding a revenue share of 29.4% in 2019 (seen in graph below). This growth in diagnostic uptake to treat liver disease is attributed to the increasing number of initiatives taken by companies to develop advanced imaging techniques.



Annex C

HepaFat-AI may suit a number of clinical applications:

Gastroenterology and Hepatology Applications

- Initial workup for Non-alcoholic Fatty Liver Disease (NAFLD) diagnosis and for education and counselling of metabolic syndrome patients.
- Liver fat analysis on patients already being screened or monitored for fibrosis or cirrhosis. Recent research indicates that patients with NAFLD and Non-Alcoholic Steatohepatitis (NASH) can develop liver cancer without progressing through cirrhosis and that higher liver fat in NAFLD is associated with fibrosis progression.
- Screening and monitoring of participants for early-phase pharmaceutical trials of compounds to treat NASH or diabetes, which stands at over 50 with some 83 candidate drugs[7]. As HepaFat-AI is validated for all the major 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 particular if adaptive trial protocols implemented, a particular advantage when compared to current NASH studies. HepaFat-AI's unique capability of reporting a 'pathologists equivalent' steatosis grade will help bridge the gap caused by the reportedly 'high false positive rates' (up to 35 %) identified on liver biopsy in patients recruited to NASH trials.

Surgical Applications

- Pre and post-operative analysis of bariatric patients to track clinical outcomes. Bariatric patients post-surgery can see a dramatic improvement in liver fat regardless of their starting anthropometrics (e.g. weight, BMI,) or amount of weight loss following surgery.
- A high level of liver fat may have a detrimental outcome on liver surgery. A HepaFat-AI assessment of patients with liver disease or liver cancer can provide guidance with treatment planning. A quantitative measurement of liver fat may help to determine how much liver can be safely resected or to determine whether to use a surgical or non-surgical treatment.
- Screening for suitability of living donors for liver transplants by assisting in determining the viability of the donor liver.

Applications by Primary Care Physicians

- HepaFat-AI may be useful to screen patients prior to prescribing known hepatotoxic medications
- Monitoring of patients undergoing an intervention (such as lifestyle changes including limiting alcohol consumption or weight loss program). While NASH drugs remain unavailable at this stage, in some cases the disease itself can be halted and reversed if patients adopt healthier lifestyles. In these instances, the Company's HepaFat-AI solution can help clinicians manage a patient's fatty liver with the objective of preventing its progression to more severe diseases.
- Monitoring of patients prescribed medications known to induce steatosis.
- In late effects monitoring of cancer patients when looking for fatty liver changes.

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. Estes C et al (2018). Modeling the epidemic of nonalcoholic fatty liver disease demonstrates an exponential increase in burden of disease. Hepatology: 67(1), 123-133. Based on US estimates.
4. Younossi, Z. M. et al. The economic and clinical burden of nonalcoholic fatty liver disease in the United States and Europe. Hepatology 64, 1577–1586 (2016).
5. Loomba et al (2018), The ASK1 Inhibitor Selonsertib in Patients With Nonalcoholic Steatohepatitis: A Randomized, Phase 2 Trial. Hepatology: 67 (2), 549-559.
6. Grand View Research. (2020, June). 'Liver Disease Diagnostics Market Size, Share & Trends Analysis Report By Diagnosis Technique (Imaging, Laboratory Tests, Endoscopy, Biopsy, Others), End-use (Hospital, Laboratories, Others), And Segment Forecasts, 2020 – 2027. https://www.grandviewresearch.com/industry-analysis/liver-disease-diagnostics-market
7. Brent A. Neuschwander-Tetri (2020). Therapeutic Landscape for NAFLD in 2020. Gastroenterology: 58 (7), 1984-1998.e3.