

Thalassaemia International Federation to Deploy FerriSmart®

Highlights

- Patient Access Agreement signed with Thalassaemia International Federation (“TIF”)
- TIF to deploy FerriSmart® to Thalassaemia patients in low-and-middle-income nations
- Resonance Health to provide 500 FerriSmart® vouchers + salary support for a dedicated TIF executive
- A dedicated and experienced TIF executive to manage patient access to deployment of FerriSmart®
- TIF to work with National Thalassaemia Associations + physicians to facilitate FerriSmart® utilisation
- TIF’s International Scientific Advisory Board to oversee and guide the initiative

Deployment of FerriSmart®

Resonance Health Ltd (ASX: RHT) (“Resonance Health” or “Company”) has today signed a Patient Access to FerriSmart® Letter of Agreement (“LoA”) with the World Health Organization (“WHO”) related Cyprus based, Thalassaemia International Federation (“TIF”) (the “FerriSmart® Access Initiative”).

Pursuant to the LoA, TIF will deploy 500 FerriSmart® vouchers, provided by Resonance Health at no cost, across targeted low-and-middle income countries in Asia, West Pacific, and Europe. To support TIF’s distribution, management, and administration, of the FerriSmart® Access Initiative, the Company will also provide salary support of EU10K paid in installments over 12 months, for a dedicated and experienced TIF executive.

Under the LoA, TIF will engage with National Thalassaemia Associations and physicians to facilitate utilisation of FerriSmart®, and with national health authorities and key opinion leaders (“KOLs”) on the value and cost effectiveness of integrating regular iron-load monitoring into clinical management protocols (establishing local standards of care). TIF will also introduce Resonance Health to local KOLs, which is a critical part of establishing long-term sustainable commercial product success in new markets.

Resonance Health will provide TIF, KOLs, customers, and patients, with product education and information, and customer product support consistent with its standard practice. The Company will also respond to requests for product material requests appropriate to specific markets and will be equipped to do so with its team of sales and marketing executives trained in the products (ASX release, 14 October 2021).

Data collected from the FerriSmart® Access Initiative will be used in TIF’s Global Thalassaemia Review and by Resonance Health to improve and refine its product offerings, subject to applicable laws and regulations including with respect to patient privacy.

Importantly, TIF’s International Scientific Advisory Board will guide the FerriSmart® Access Initiative and advise and educate when required and assess the initiative outcomes. The LoA has an initial term of 12 months commencing December 2021 following which any unused vouchers will expire (unless extended by the Company), at which time Resonance Health and TIF will assess the success of FerriSmart’s® establishment and uptake in the new markets.

Thalassaemia International Federation Comment

Executive Director of TIF, Dr. Androulla Eleftheriou, said the following of the new agreement:

“TIF’s vision is to ensure equal access to quality healthcare for every patient with thalassaemia and other haemoglobin disorders across the world. Iron chelation is one of the two cornerstones of thalassaemia management (the other being blood transfusion) and accurate iron load monitoring of the heart and liver contributes immensely to the assessment of the effectiveness of chelation therapy. Thus, the development of iron-related complications is prevented while at the same time allowing for better resource distribution for healthcare system improvements and developments.

To that end, we are delighted to reach this important agreement with Resonance Health for the rollout of FerriSmart® into low-and-middle income countries, starting with nations in Asia, West Pacific, and Europe. Resonance Health’s FerriScan® product is the only global gold standard to-date for measuring liver-iron-concentrate (LIC) which is critical to managing thalassaemia. While many of the developed world’s reference centres and KOLs have adapted FerriScan®, its application in the more thalassaemia-prone low-and-middle income countries has been severely hindered mainly due to FerriScan’s® reliance on highly trained personnel, which adds significantly to its cost and renders it unaffordable and unscalable in many lower income regions.

We are thus thrilled with Resonance Health’s development of FerriSmart®, a new automated AI product calibrated against the FerriScan® gold standard and now available for patients globally. FerriSmart® uses the same non-invasive R2 MRI approach as FerriScan®, which TIF acknowledges its contribution as the most accurate and safest LIC diagnosis, and which has been thoroughly used in clinical trials for reliable iron measurements. To that end, in 2017 TIF released a global alert cautioning clinicians from using untested, non-standardized methods of iron assessment, which can be highly unreliable particularly at elevated iron levels and may jeopardize the health of the patients.

FerriSmart® is a breakthrough for Thalassaemia patients in low-and-middle income countries where thalassaemia is unfortunately and sadly often sub-optimally managed and the inability to accurately assess LIC contributes to this. Committed to improving the lives of patients globally, I am delighted to see the conclusion of this agreement with Resonance Health as a great step forward for better health outcomes of thalassaemia patients and we hope this is the first step in a multi-year sustained rollout of FerriSmart®. Moreover, TIF looks forward to the development and approval of additional iron load monitoring tools that will be of equal reliability and quality, and that will meet the approval processes of the EMA and FDA so as patients and healthcare professionals will have the opportunity to choose the tool they wish or prefer to use.

Resonance Health Comment

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

“Resonance Health has great admiration of TIF and the work it does improving the lives of patients with thalassaemia. We are delighted to partner with them on the deployment of FerriSmart® into new markets where our device is needed. TIF has the experience and contacts in these markets to accelerate the uptake in adoption and usage of our new AI devices. Our immediate objective is to ensure that patients and clinicians across the world learn of FerriSmart® and have an opportunity to use it and benefit from it. We are proud to support TIF in this initiative and we are positioned to do so with our enhanced sales and marketing resources.”

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 Thalassaemia International Federation

TIF is a non-profit, non-governmental organisation founded in 1986 by a small group of patients and parents representing mainly National Thalassaemia Associations in Cyprus, Greece, UK, USA and Italy. Through the years, TIF has established collaborations and networks with other official health orientated agencies and associations, and patient orientated organizations at the national, regional and international level.

Today, TIF has evolved into an Umbrella Federation, with 240 member associations, in 62 countries of the world (Last update: December 2020), safeguarding the rights of patients to quality health and other care.

TIF's vision is to ensure equal access to quality health care for every patient with thalassaemia and other haemoglobin disorders across the world. TIF's mission is to promote and implement national control programmes for the prevention and treatment of thalassaemia and other haemoglobin disorders in every affected country.

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.