

21 June 2017

Leading Patient NGO Endorses FerriScan and Artificial Intelligence Technology

Resonance Health (ASX:RHT) is pleased to provide a progress update in relation to addressing the urgent clinical need for an affordable solution for measuring liver iron concentration (LIC) in emerging growth markets, as announced by the Company on 14 June 2017. Substantial progress has been made towards partnering with patient advocacy organisations to escalate safety concernsⁱ in relation to an unvalidated T2* technique and to promote Resonance Health's prototype artificial intelligence (AI) solution.

The Thalassaemia International Federation (TIF)ⁱⁱ, a leading patient organisation in the field of iron overload, is fully supporting the Company's efforts to address this crisis. TIF has today released a **Media Release and Clinical Alert** to warn of the potential dangers of the unsafe T2* technique and the critical need to use validated techniques, such as Resonance Health's. The full media release, *New study highlights 'unsafe' T2* MRI method being used for iron overload assessment in thousands of patients*, is enclosed with this announcement and is also available on TIF's website (www.thalassaemia.org.cy) and on Resonance Health's website by [clicking here](#).

The **Media Release and Clinical Alert** warns "*The Thalassaemia International Federation (TIF) is now urging all hospitals and centres using non-regulated or non-calibrated MRI methods to measure LIC, to review their techniques and re-call patients, at least those whose clinical status mandates the need for accurate measurement of liver iron content, to proceed to the measurement by a validated method.*"

Panos Englezos, President of the TIF Board of Directors, George Constantinou, Key Member of TIF Advocate Board, and Dr Eletheriou, Executive Director of TIF commented:

"TIF feels strongly that the issue of iron monitoring by MRI should be given immediate and serious attention and priority by all involved in the care of these patients so that patients' rights for access to quality healthcare services cease to be violated..."

"We urge all centres and health care professionals to ensure that they are using only validated techniques. TIF is seeking collaboration with all Governments, other involved stakeholders, the industry, and in particular Resonance Health, who at the moment are providing the only validated tool to date, so as to identify ways to expand to the maximum access of its patients for LIC measurements globally.

TIF has been also informed that Resonance Health have now developed a prototype for a new affordable MRI test and it is within our scope to partner with Resonance Health to expedite the development and access pathways for this new test that would offer a solution for those centres with very large numbers of patients, in economically disadvantaged regions to enable access to a reliable and validated MRI technique."

In addition to the **Media Release and Clinical Alert**, TIF is hosting a round table meeting at the European Haematology Association's 22nd Congress this week with key opinion leaders, pharmaceutical companies, Resonance Health, and other stakeholders to escalate the warnings against the unvalidated T2* technique and to progress Resonance Health's AI solution (see Company announcement on 14 June 2017).

This powerful patient advocacy group's education of the iron overload clinical community on the potential dangers of the unvalidated T2* technique and the associated endorsement of Resonance Health's validated LIC measurement technology, positions the Company favourably for commercial growth of FerriScan®, the Company's regulatory-cleared and globally recognised gold standard for LIC measurement.

Additionally, the support of TIF to expedite the development and access pathways for the Company's new AI test (see Company announcement on 14 June 2017) will be invaluable in the testing and ultimate rollout of the safe and affordable LIC measurement tool to emerging growth markets, in which cost is a barrier to FerriScan use.

Following the highly encouraging results announced on 14 June 2017 on an AI prototype for assessing iron overload, Resonance Health is delighted with the collaboration with TIF, who is a key strategic partner in accessing the emerging growth markets in need of an immediate solution. The Company looks forward to updating the market as progress continues.

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i Abstract Presentation at the European Haematology Association (EHA)

The abstract of a recent study has been accepted by EHA for a presentation at their 22nd Congress. The abstract, *Assessment of the performance of a widely available T2*/R2* liver iron concentration method used in clinical practice in a population of Thalassaemia patients* (Trang et al, 2017), is now available online to those registered for EHA and will be published later in the year. Resonance Health's Chief Scientific Officer, Prof. Tim St Pierre, who is highly respected in the clinical community, will present the results of the study at EHA on 23rd June 2017 in Madrid, Spain.

ii About the Thalassaemia International Federation (TIF)

TIF is a globally renowned not-for-profit, non-government organisation founded in 1987 by a small group of patients and parents who represented various national Thalassaemia Associations in Cyprus, Greece, UK, USA, and Italy. Since its creation, TIF has worked in official relations with various official health bodies and patient orientated organisations, including the World Health Organisation (WHO) since 1997.

Within the last thirty years, TIF has developed into an umbrella federation that consists of 102 member associations from over 60 countries worldwide, all committed to safeguarding the rights of patients for quality health care. TIF has published over 15 books to date in more than 50 countries worldwide, with topics ranging from patient rights, thalassaemia management and patient guidelines, the prevention and diagnosis of haemoglobinopathies, and various texts on sickle cell disease.

TIF has also been responsible for organising over 60 national conferences, six regional workshops, and 14 international conferences, including this years' 14th *International Conference on Thalassaemia & Haemoglobinopathies*, and the 16th *International Conference for Patients & Parents*, to be held in Thessaloniki, Greece, on the 17th of November 2017.

MEDIA RELEASE & CLINICAL ALERT

New study highlights ‘unsafe’ T2* MRI method being used for iron overload assessment in thousands of patients

TIF became aware of the results from a new study, to be presented at the European Haematology Association (EHA) congress on 23rd June 2017, which have confirmed that a ‘T2*’ technique used widely for estimating liver iron concentration (LIC) by magnetic resonance imaging (MRI) may not be reliable in giving accurate and consistent results.

This T2* technique using the ‘Iron Health Calculator’ (www.ironcalculator.com) has been promoted as an alternative to FerriScan globally, and in particular in developing countries, to centres with large numbers of patients requiring MRI assessment of LIC.

This new study, labelled the “Dragon Study”, compared the LIC results of 100 patients assessed using an unvalidated Liver MRI T2* method against the validated and regulatory-cleared ‘Gold Standard’ FerriScan® R2-MRI technique

The ‘Dragon Study’ was conducted at a centre in Vietnam which treats over 1000 haemoglobinopathy patients a year and is thought to be one of many using the T2* technique.

The results revealed:

- Severe discrepancies of the T2* technique from FerriScan, the reference standard.
- The T2* technique failed to identify approximately 30% of the patients confirmed by FerriScan to be at greatly increased risk of cardiac disease and early death.
- As such, these patients are at risk of not receiving potentially life-saving treatments.
- The T2* technique results were dependent on which scanner was used, meaning results taken on different scanners cannot be compared.
- The study concluded “*the data indicate that the T2*/R2* method of measurement of LIC is not safe for routine clinical measurement of LIC*” and “*could result in inappropriate clinical decision making*”.

The Thalassaemia International Federation (TIF) is now urging all hospitals and centres using non-regulated or non-calibrated MRI methods to measure LIC, to review their techniques and re-call patients, at least those whose clinical status mandates the need for accurate measurement of liver iron content, to proceed to the measurement by a validated method.

Panos Englezos, President of the TIF Board of Directors, George Constantinou, Key Member of TIF Advocate Board, and Dr Eletheriou, Executive Director of TIF commented:

“Accurate, reliable and specific iron monitoring is a prerequisite in assessing appropriately the effectiveness of the treatments and in particular iron chelation therapy provided to each thalassaemia patient. The need for a reliable way of measuring iron load in the heart and the liver, cannot be underscored enough, first and above all for the benefit and safety of the patient but also as a tool for the cost effective use of the very costly iron chelating agents whether these are provided by Governments or by out of pocket ways by the patients themselves and/or their families.”

TIF feels strongly that the issue of iron monitoring by MRI should be given immediate and serious attention and priority by all involved in the care of these patients so that patients' rights for access to quality healthcare services cease to be violated and for TIF to update in its next edition of TIF Guidelines the relevant recommendations.

Indeed, we have been increasingly alarmed by the rise in non-standardised and non-validated MRI methods for measuring iron burden which, as demonstrated by this study, are putting patients at serious risk. At TIF, we advocate equity of access to the highest quality care for all our patients. The peer reviewed data from St Pierre and highly respected radiology colleagues in Vietnam, are very shocking and we are extremely concerned for the patients that may be affected.

We urge all centres and health care professionals to ensure that they are using only validated techniques. TIF is seeking collaboration with all Governments, other involved stakeholders, the industry, and in particular Resonance Health, who at the moment are providing the only validated tool to date, so as to identify ways to expand to the maximum access of its patients for LIC measurements globally.

TIF has been also informed that Resonance Health have now developed a prototype for a new affordable MRI test and it is within our scope to partner with Resonance Health to expedite the development and access pathways for this new test that would offer a solution for those centres with very large numbers of patients, in economically disadvantaged regions to enable access to a reliable and validated MRI technique. In addition, TIF is committed to work and encourage research with any other academic centre that would focus attention on the development of accurate, consistent tools for iron monitoring in thalassaemia. TIF's concern and commitment is to ensure safe, accurate, and quality services to our patients wherever they may live. We hope that a round table meeting taking place in the context of EHA will be only the beginning of new era of discussions on the subject as we plan to expand our discussions with all experts involved in the subject."

The number of centres using the unsafe T2* method and patients affected, is currently being explored by TIF to identify the scale of the problem. Further discussions with key opinion leaders, international MRI expert Prof. St Pierre, and other stakeholders will be sought during the EHA Congress, to address concerns raised by these new data.

Sander Bangma, General Manager of Resonance Health said:

"Whilst the results of the study are deeply concerning, we hope this new evidence will ultimately advance care for patients through exposing the pitfalls of many non-standardised MRI techniques for iron monitoring. We are delighted to be working very closely with the Thalassaemia International Federation on an immediate solution to identify and help centres who have relied upon this inferior T2 technique and advise and share best practice in MRI monitoring as global leaders in this area."*

If you believe you may have been impacted by results from the inferior T2* technique or would like further information please contact TIF at thalassaemia@cytanet.com.cy

ENDS

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