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Non-invasive Assessment of Bone Marrow Iron – Regulatory Submission

Resonance Health (ASX: RHT) is excited to announce that work has commenced on international regulatory submissions for the Company's new non-invasive technology for assessing Bone Marrow Iron using Magnetic Resonance Imaging (MRI). Submissions are planned for Australia (TGA), Europe (CE-mark), and the USA (FDA). To date, the technology has been used in research collaborations with Key Opinion Leaders. Regulatory approvals, anticipated possible by mid to late 2017, will expand the market from the research setting to the clinical community and will allow the technology to be actively marketed.

Both decreased and increased Bone Marrow Iron are of clinical significance; for example the definitive test of iron deficiency is examination of iron in bone marrow samples from needle biopsy and conversely, multiple blood transfusions can result in greatly increased Bone Marrow Iron.

Knowledge of Bone Marrow Iron is thought to have particular importance for patients being considered for a bone marrow transplant, as excess iron may increase the likelihood of complications. The Worldwide Network for Blood and Marrow Transplantation estimates that more than 50,000 patients are transplanted annually for certain cancers, such as leukaemia, lymphoma, myelodysplasia, or for diseases that affect the production of bone marrow cells, such as aplastic anemia, severe immune system illnesses, sickle cell disease, and thalassaemia. Some patients also require bone marrow transplantation because chemotherapy for other diseases has destroyed their bone marrow. Bone marrow transplantation has the potential to cure or greatly alleviate disease, but carries a risk of severe complications, that in some cases can be more severe and more costly to manage than the original disease. Mechanisms to decrease complications, such as improved monitoring and management of iron prior to transplant, would have profound health and economic benefits.

Strong clinical interest in the Bone Marrow R2-MRI technology has been expressed by Key Opinion Leaders in the field of bone marrow transplantation, who already use FerriScan to assess body iron stores prior to transplant. Dr Josu de la Fuente, a Consultant Paediatric Haematologist and Senior Lecturer at Imperial College London and Director of the Paediatric Blood and Marrow Transplant Programme, speaks about the benefits of using FerriScan in the bone marrow transplantation setting in a short video - please [click here](#) to view the video.

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Resonance Health is actively working on collaborations to further investigate the link between Bone Marrow Iron, as measured by the Company's new technology, and the frequency of transplantation complications.

General Manager, Sander Bangma commented:

"Given the interest from our existing customer network for the Bone Marrow R2-MRI technology, we have taken the initiative to commence regulatory approval submission. In parallel, the immediate studies we are pursuing aim to pave the way for the Bone Marrow R2-MRI technology to be incorporated into clinical decision making pathways for patients being considered for bone marrow transplantation. This will be required to achieve the longer term goal of inclusion in guidelines, a necessity for widespread adoption and reimbursement".

Resonance Health has a proven track record of bringing new technologies to market via regulatory clearances and estimates regulatory clearance in Australia and Europe by mid-2017 and in the US in the second half of 2017. Bone Marrow R2-MRI will join the suite of regulatory cleared technologies that currently include FerriScan® for measurement of Liver Iron Concentration, HepaFat-Scan® for measurement of Volumetric Liver Fat Fraction (VLFF), and Cardiac T2* for assessment of Cardiac Iron Loading. The current collaborations are already cementing the demand for the Bone Marrow Iron assessment in the clinical setting and the Company anticipates a positive return on its investment in this technology.

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