

FerriScan receives FDA authorisation to market FerriScan as an imaging companion diagnostic device

The US Food and Drug Administration today announced the authorisation of FerriScan to be marketed as an imaging companion diagnostic device for the safe and effective use of Exjade in patients with non-transfusion-dependent thalassemia (NTDT). Exjade is a drug marketed by Novartis to remove excess iron in patients with genetic blood disorders. The FDA announcement can be viewed at the following link: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm336478.htm>

FerriScan has previously been cleared for marketing by the FDA for measuring liver iron concentration (LIC) using magnetic resonance imaging.

“The FerriScan device is a non-invasive test that helps physicians to select appropriate patients [with NTDT] for Exjade therapy as well as monitor their response to the drug, and discontinue therapy when LIC reaches safe levels,” said the director of the Office of In Vitro Diagnostic and Radiological Health in the FDA.

There are at least three quarters of a million people worldwide that have non-transfusion-dependent thalassemia (NTDT) and many patients are not diagnosed until they develop serious symptoms which begin to appear as early as age 10. Most patients with NTDT are of South and Southeast Asian, Mediterranean or Middle Eastern origin, with immigration broadening the global presence of this condition.

FerriScan has been used extensively in the clinical trials of pharmaceutical companies developing drugs for chronic iron overload since 2004. This FDA announcement of FerriScan as a companion diagnostic for the safe and effective use of a drug recognises the important role of FerriScan in the clinical management of patients outside of clinical trials.

FerriScan is currently used in many hospitals around the world and this authorisation by the FDA will assist in expanding the use of FerriScan in the identification and management of patients with iron overload. It will also assist in the Company’s efforts to gain insurance coverage for FerriScan within the US, enabling more patients to access FerriScan.

At this point in time the Company does not have details concerning how often a patient with NTDT and prescribed Exjade will require a measurement of their liver iron concentration. As further details become known, Resonance Health will update its shareholders of the potential revenue implications for FerriScan.

By Order of the Board
Resonance Health Limited

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Resonance Health Ltd (ASX: RHT) (www.resonancehealth.com) is a medical device company providing imaging core laboratory services for the quantitative analysis of medical images, with a subspecialty in the liver. Resonance Health’s patented FerriScan technology provides a safe and accurate alternative for measuring liver iron concentration, and research continues into the development of new technology for the accurate assessment of liver fat and liver fibrosis.