ASX Release – 06 October 2020

R&D Update: New Pulmonary Embolism AI Solution Developed

Further to the Company's announcement on 17 October 2017 ('Collaborative Partnership commences to develop new AI diagnostic tools'), Resonance Health Ltd (ASX: RHT) ("Resonance Health" or "Company") is pleased to advise that it has developed a new artificial intelligence ("AI") tool for the automated review of chest computed tomography ("CT") scans of patients with suspected pulmonary embolism ("PE").

This new product, named 'ALERT-PE', has been produced by the Company's AI R&D workstream. Neural network training has been performed using datasets of the lungs provided via the collaboration with Perth Radiological Clinic ("PRC"), one of Western Australia's largest radiology practices.

The Company advises that it has filed a Pre-Submission to the United States Food & Drug Administration (" FDA") to discuss the requirements for a potential future submission for FDA clearance of ALERT-PE. The Pre-Submission meeting is scheduled to take place in November 2020.

A Pre-Submission is a process that includes a formal written request from a submitter for feedback from the FDA to guide product development and/or submission preparation prior to an intended premarket submission[1].

The Company considers that ALERT-PE is able to perform as an AI-based radiological computer-assisted triage and notification software for PE. It is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communicating suspected PE pathologies, with the user presented with alert notifications for cases that have suspected PE findings.

PE is part of the venous thromboembolism (VTE) spectrum, which ranges from asymptomatic deep vein thrombosis (DVT) to fatal PE, and is a blockage of the pulmonary arteries in the lungs caused by blood clots[2].

With at least 650,000 cases occurring annually, PE is the third most common cause of death in hospitalised patients. Autopsy studies have shown that approximately 60% of patients who have died in hospital had PE, with the diagnosis having been missed in up to 70% of the cases[3].

It is estimated that there are 1 million cases of VTE and over 500,000 hospital admissions in the United States, with annual costs exceeding an estimated 10 billion dollars[2]. With prompt treatment, medical intervention can be highly effective and it has been shown to greatly reduce the likelihood of death[4].

Symptoms and signs of PE are typically non-specific, when the pre-test probability is high (PE likely), imaging becomes the first-line test to confirm the existence of PE. CT Pulmonary Angiogram ("CTPA") imaging is widely used for this purpose. It is sufficiently sensitive and specific to exclude the diagnosis of PE when it is negative and to confirm it when positive[5].

As positive patient outcomes are extremely time sensitive, triage PE tools (such as ALERT-PE) may be very beneficial in drawing immediate attention to cases of suspected PE for medical specialists.

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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 non-invasive medical imaging software and services. Resonance Health has gained endorsement by leading physicians worldwide for consistently providing highest 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 companies in their clinical trials. Resonance Health's dedication to scientific rigour in the development and implementation of its analysis services has enabled it to achieve regulatory clearances on a number of products (SaMD) in the US, Europe and Australia.

In addition to these medical devices, Resonance Health has an existing artificial intelligence tool with international regulatory clearances (FerriSmart), and a dossier for a second artificial intelligence tool (HepaFat-AI) has recently been submitted to the US FDA.

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