4DMedical receives U.S. FDA clearance for CT LVAS™

20th November 2023

Highlights

- 4DMedical receives U.S. FDA clearance for CT LVAS™
- FDA clearance expands patient accessibility to 4DMedical's ventilation reports by leveraging readily available CT hardware in the U.S.
- Clearance for CT LVAS™ significantly de-risks the regulatory pathway for CT:VQ, 4DMedical's ventilation-perfusion product

Melbourne, Australia, 20th November 2023: Respiratory imaging technology company 4DMedical Limited (ASX:4DX, "4DMedical", or the "Company") today announces that it has received clearance for its CT-based ventilation product (CT LVAS™) from the U.S. Food and Drug Administration (FDA).

CT LVAS™ clearance broadens the accessibility of functional lung imaging in the U.S.

CT LVAS™ provides an almost identical report to 4DMedical's proven, FDA-cleared, XV LVAS® product, but utilises widely available Computed Tomography (CT) imaging infrastructure (instead of X-ray equipment), providing clinicians and patients with greater access to XV Technology®.

FDA clearance follows the rollout of CT LVAS™ in Australia, which was chosen as the Company's first market due to its high density of CT scanners per head of population. According to OECD data, the U.S. install base for CT scanners is also material, with 43 CT scanners per million population (versus Australia at 70, France at 20, and Canada at 15 per million), and will therefore significantly broaden the accessibility of functional lung imaging for people in the U.S. living with lung disease.

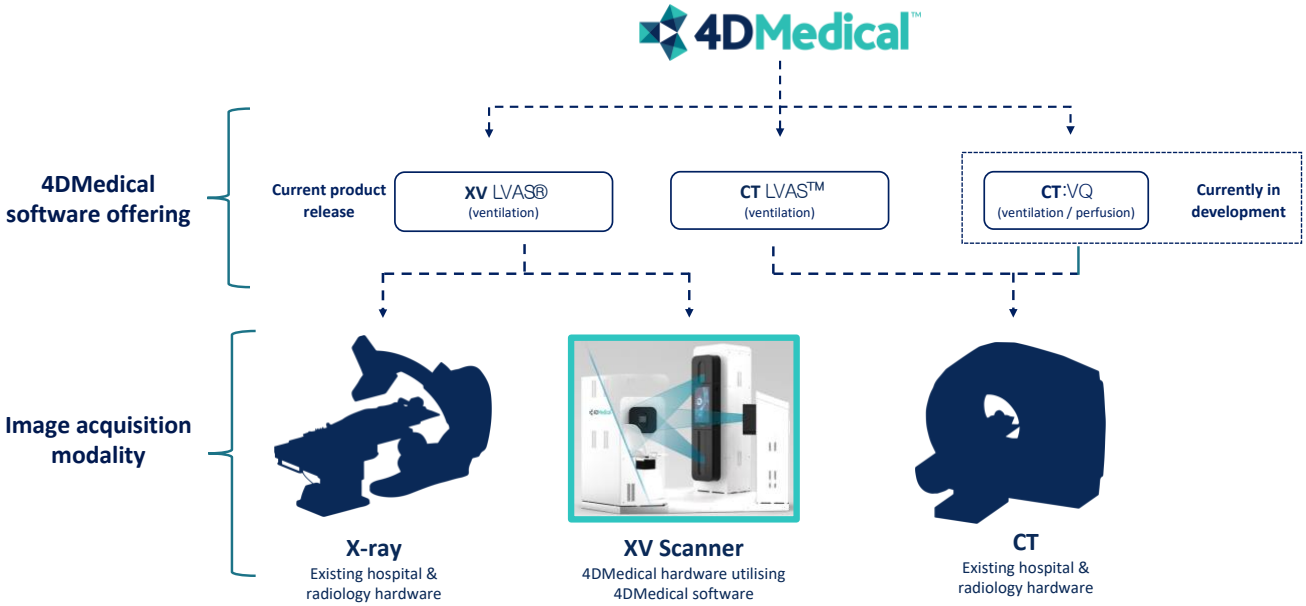
Last week, the Company announced the U.S. Centres for Medicare & Medicaid Services (CMS) had approved reimbursement for 4DMedical's XV LVAS® at a rate of US$299 per procedure effective 1 January 2024. Following FDA clearance for CT LVAS™, the Company will adopt a similar reimbursement strategy by firstly applying to the American Medical Association (AMA) to establish a new, distinct, Category III CPT code to identify the use of CT LVAS™ amongst healthcare providers and payers, and then seek to have the procedure reimbursed by public and private health insurance schemes.

De-risking the regulatory pathway for CT:VQ

In May, the Company announced a significant technological breakthrough in its product development pipeline with the release of early clinical data for its CT-based ventilation-perfusion product (CT:VQ). 4DMedical's CT:VQ technology enables quantitative perfusion (blood flow) data and visualisations to be extracted from non-contrast paired inspiratory-expiratory CT scans, and combined with the ventilation data and visualisations provided by CT LVAS™.

Quantifying and visualising the mismatch between ventilation and perfusion can provide valuable diagnostic information. In a healthy lung, ventilation and perfusion are well-matched, meaning that airflow and blood flow are evenly distributed throughout the lungs. 4DMedical's CT:VQ technology enables regional changes in ventilation and perfusion to be quantified and visualised, allowing a detailed assessment of V/Q mismatch. Clinically, these scans are primarily used for diagnosing pulmonary embolism, but they can also be employed to assess conditions such as chronic obstructive pulmonary disease, pulmonary hypertension, and to evaluate pulmonary vascular disorders.

Acute Pulmonary Embolus (PE) is a serious, yet difficult, diagnosis for clinicians, where pulmonary perfusion is a critical component in the assessment. Current imaging modalities for PE include CT Pulmonary Angiography (CTPA) and Nuclear Medicine VQ scans, with CTPA assessing pulmonary arterial flow blockages, and Nuclear Medicine VQ assessing the mismatch in ventilation and perfusion. Both of these modalities require the administration of an intravenous contrast media, and in the case of Nuclear Medicine VQ, inhalation of a radioactive contrast agent. CT:VQ, on the other hand, uses non-contrast paired inspiratory-expiratory CT scans, and therefore does not require contrast agent. The Company estimates the current US market size for Nuclear Medicine VQ assessment of PE is approximately 15% of the 4,000,000 patient procedures per annum, at an average cost of ~US$1,500 per scan.



4DMedical's current product suite delivering both ventilation and perfusion across X-ray, CT and the XV Scanner

4DMedical is aiming to submit its CT:VQ application to the FDA by the end of 2023. Having now received clearance for CT LVAS™, the Company will be able to use CT LVAS™ as the predicate for CT:VQ, which significantly de-risks the regulatory pathway.

CT LVAS™ clearance allows for commercial discussions at RSNA

FDA clearance for CT LVAS™ is perfectly timed in the lead up to the Company exhibiting at the world's largest Radiology congress, RSNA (Radiological Society of North America), in Chicago, commencing Sunday 26th through to Wednesday 29th November. Dr. Greg Mogel, MD, consultant radiologist at 4DMedical and a practising clinical radiologist, is excited by the news. Dr Mogel said, "Having assisted with image interpretation of CT LVAS™ exams with Australian radiologists, I have seen firsthand the power of adding functional assessment to the structural information provided in standard non-contrast chest CTs, those being newly acquired as well as any previously acquired study. Having access to CT LVAS™ as an FDA-cleared product will provide my U.S. radiology colleagues immense value for their referring clinicians needing answers in chest CT's, and I can't wait to share this release at the upcoming RSNA."

4DMedical MD/CEO and Founder Andreas Fouras said:

I am excited by this progress in our commercialisation and the impact that FDA clearance for CT LVAS™ will provide caregivers and patients. As we head to RSNA, I am thrilled that reimbursement has been approved for our XV LVAS® product, and to now also share that we have clearance for CT LVAS™ in the U.S, which, both in their own rights, create material impetus for doctors and patients to adopt our technology. The clearance for CT LVAS™ offers further validation of our development and represents significant progress towards commercial release of our CT:VQ technology.

–ENDS–

Authorised by the 4DMedical Board of Directors.

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About 4DMedical

4DMedical Limited (ASX:4DX) is a global medical technology company that has created a step change in the capacity to accurately and quickly understand the lung function of patients with respiratory diseases.

Through its flagship patented XV Technology®, 4DMedical enables physicians to understand regional airflow in the lungs and identify respiratory deficiencies earlier and with greater sensitivity as they breathe. This technology powers 4DMedical's FDA-cleared XV Lung Ventilation Analysis Software (XV LVAS®) - the first modality to dynamically quantify ventilation throughout the lungs, and its Computed Tomography-enabled counterpart software, CT LVAS™.

XV LVAS® and CT LVAS™ reports are prepared using 4DMedical's Software as a Service delivery model using existing clinical imaging equipment or the Company's revolutionary XV Scanner.

To learn more, please visit www.4dmedical.com.