4DMedical receives U.S. FDA clearance for IQ-UIP™

7 January 2025

Highlights

- 4DMedical receives U.S. FDA clearance for IQ-UIP™
- IQ-UIP™ is a novel AI product that provides a highly accurate diagnostic tool for Usual Interstitial Pneumonia, the hallmark radiological pattern for diagnosing Interstitial Pulmonary Fibrosis
- The global IPF treatment market was US$4.01 billion in 2024 and is expected to grow to US$7.81 billion over the next 10 years

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Melbourne, Australia, **7 January 2025**: 4DMedical Limited (ASX: 4DX) ("4DMedical" or the "Company"), a leading innovator in respiratory imaging technology, today announces it has received clearance from the U.S. Food and Drug Administration (FDA) for its IQ-UIP™ product, an advanced AI-driven lung diagnostic tool designed to revolutionise the diagnosis of Usual Interstitial Pneumonia (UIP), the hallmark radiological pattern for diagnosing Interstitial Pulmonary Fibrosis (IPF).

Clinical challenges of UIP and IPF

Usual Interstitial Pneumonia (UIP), often linked to Idiopathic Pulmonary Fibrosis (IPF), is a rare yet severe condition characterised by chronic inflammation and progressive lung fibrosis. The median survival post-diagnosis ranges from 1 to 2 years, and the condition affects approximately 140,000 individuals annually in the United States alone, with over 50,000 new cases diagnosed each year. The global IPF treatment market was US$4.01 billion in 2024 and is expected to grow to US$7.81 billion over the next 10 years.

Diagnosing UIP poses a significant clinical challenge due to its nonspecific symptomatology, often mimicking more prevalent respiratory conditions like COPD, bronchitis, or asthma. In fact, more than 50% of UIP cases are initially misdiagnosed, with the average patient requiring three traditional CT scans before a definitive diagnosis is made. The subsequent delay in referral to an interstitial lung disease (ILD) specialist further hampers timely interventions that could extend life expectancy and highlights the urgent need for innovative solutions such as IQ-UIP™.

A huge boost to pharmaceutical development

In addition to its diagnostic applications, IQ-UIP™ has the potential to shorten clinical trial timelines and reduce costs for pharmaceutical companies by providing a reliable imaging biomarker and patient selection tool. Clinical trials in this sector cost over US$115 million per trial, whilst the total cost to develop new drugs and take them to market can be as high as US$4.5 billion. IQ-UIP™ has the potential to dramatically reduce the costs and time taken for clinical trials, which will benefit pharmaceutical companies, and also deliver better health outcomes to patients in a faster time frame.

Advantages of IQ-UIP™

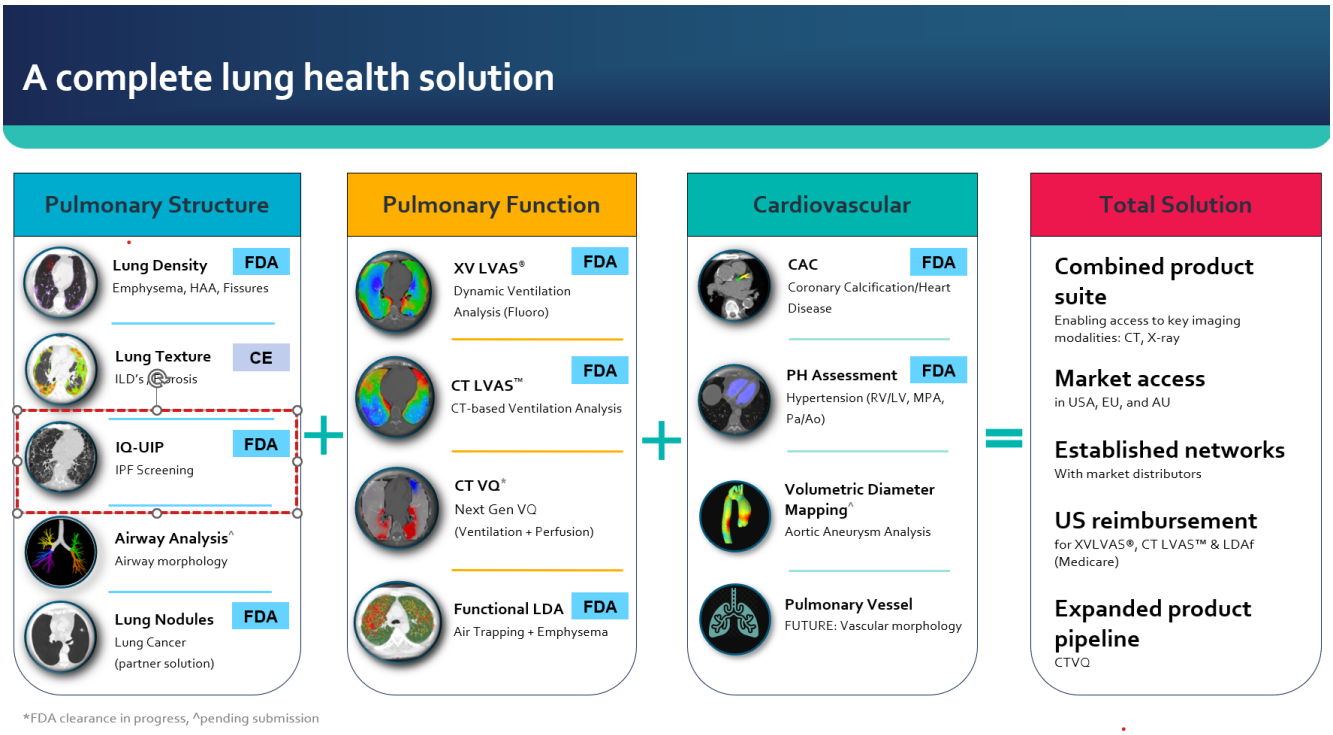
IQ-UIP™ is an innovative AI product that leverages deep learning technology to provide a highly accurate classification of UIP. IQ-UIP™ is a first of its kind product winning coveted Breakthrough Device Designation from the FDA in November 2023. Seamlessly integrating with standard CT scans, IQ-UIP™ facilitates instant, automated analysis that bypasses traditional diagnostic protocols, which often involve multiple high-resolution computed tomography (HRCT) scans and invasive biopsies.

By addressing the diagnostic challenges associated with UIP, IQ-UIP™ can provide the following benefits to healthcare providers:

- Enhanced Diagnostic Accuracy – quickly and accurately identifies UIP patterns such as subpleural fibrosis and honeycombing,
- Early Specialist Intervention – automatically generates referral workflows for specialists, enabling faster patient access to expert care,
- Democratised Screening – expands access to advanced diagnostics across healthcare settings, including underserved populations, and
- Improved Patient Outcomes – enables earlier intervention and management, potentially extending survival rates and improving quality of life.

FDA approval for IQ-UIP™ broadens 4DMedical's product portfolio

4DMedical's strategic acquisition of Imbio in 2023 enabled it to provide its referrers with a comprehensive portfolio of functional and structural lung analysis tools. This portfolio, coupled with a cardiology analysis suite, is unique to 4DMedical and provides a meaningful current revenue stream as well as the opportunity for significant growth.



The FDA clearance of IQ-UIP™ adds another important component to this portfolio (see figure below) and will be actively offered to referrers in Australia and the U.S.. This offering, combined with CMS reimbursement in the U.S., facilitates growth opportunities across various markets including the VA, private radiology, respiratory and cardiology specialists.

Earnout payment

The FDA clearance of IQ-UIP™ is one of three products that can trigger the obligation to pay earnout consideration of U5$5 million in 4DMedical shares to the sellers of Imbio Inc, the issue of such shares having been approved at the Company's EGM held on 22 January 2024. Once the issue of shares is finalised, shareholders will be updated.

4DMedical MD/CEO and Founder Andreas Fouras said:

IQ-UIP™ represents a transformative step forward in addressing the challenges of diagnosing and managing UIP. Its deployment promises to shift the standard of care from reactive to proactive, improving patient outcomes while offering significant benefits to healthcare providers and pharmaceutical developers. UIP and IPF are an important and expensive part of healthcare, and there has been strong interest in this offering from both doctors and drug developers since winning FDA Breakthrough Device Designation in 2023.

–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 hospital imaging equipment or the Company's revolutionary XV Scanner.

In December 2023, 4DMedical acquired Imbio, a leader in artificial intelligence medical imaging solutions for chronic lung and cardiothoracic diseases. Imbio's regulatory-cleared solutions transform the way patients are discovered, diagnosed, and treated, enabling physician productivity, and more personalised care for patients.

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