Major success as Vanderbilt 'burn pit' trial hits primary endpoint

31 August 2022

Highlights

- Data from the Vanderbilt 'burn pit' clinical trial shows that 4DMedical's XV Technology® can detect the presence of constrictive bronchiolitis ('CB').

- Until now, highly invasive surgical biopsy has been the only way to diagnose CB, with CT and pulmonary function testing appearing normal in this population.

- The successful trial result opens the door for non-invasive and scalable XV Technology® to replace surgical biopsy as the preferred diagnostic tool for CB.

- PACT Act provides USD $280 billion in additional healthcare benefits over ten years for Veterans exposed to burn pits and other harmful toxins and requires the Veterans Health Administration (VHA) to provide toxic exposure screening to each of the 9 million Veterans enrolled in the VHA health care program.

- 4DMedical has a pre-agreed pricing structure with VHA at USD $171 per scan without the need for reimbursement.

Melbourne, Australia, 31 August 2022: Respiratory imaging technology company 4DMedical Limited (ASX:4DX, '4DMedical', or the 'Company') today announces a major success in the 'burn pit' clinical trial being conducted by Vanderbilt University Medical Center ('Vanderbilt') in Nashville, Tennessee. Preliminary analysis shows that 4DMedical's XV Technology® can detect constrictive bronchiolitis ('CB') in Veterans where pulmonary function tests ('PFTs') and CT scans failed to do so.

Exposure to burn pits causes lung damage—but diagnosis is difficult

The U.S. military constructed burn pits near bases across the Middle East to dispose of hazardous and non-hazardous waste. A wide range of materials, including uniforms, chemicals, tyres, and even medical, animal and human waste, were burned in pits using jet fuel as an accelerant. It is estimated that 3.5 million Veterans have been exposed to harmful toxins whilst deployed on operations since 2001. After exposure to these burn pit environments, many previously combat-ready troops returned from deployment with a range of disabling respiratory symptoms, including shortness of breath and cough, that prevent them from performing basic physical activities.

For the past 17 years, Dr Robert Miller, Professor of Allergy, Pulmonary and Critical Care at Vanderbilt, has gathered evidence, testified before Congress and medical panels, and worked with the military to explore concerns that soldiers exposed to airborne toxins were left with potentially permanent lung damage. In a 2011 report published in the New England Journal of Medicine, Dr Miller and his team describe examining a group of soldiers who recently returned from deployment complaining of shortness of breath. Conventional respiratory tests, including lung imaging and PFTs, were nearly all normal. However, surgical lung biopsies on all but a few soldiers led to a diagnosis of CB, a narrowing of the smallest and deepest airways of the lungs.
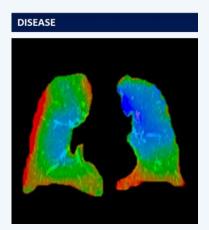
Vanderbilt 'burn pit' clinical trial results

Due to its invasiveness and potential adverse side effects, clinicians are reluctant to recommend surgical lung biopsies to patients with unexplained shortness of breath, even if they suspect injury to the smaller airways. As a result of this and the lack of a non-invasive, sensitive, and cost-effective test, the Vanderbilt clinical trial was designed to test the capability of XV Technology® to determine the presence of respiratory disease in Veterans exposed to airborne hazards while on deployment.

The clinical trial enrolled a group of Veterans who had undergone surgical lung biopsy and a control group. The data from the trial showed that XV Technology® confirmed the diagnosis of CB with <0.001% uncertainty, setting it apart from conventional diagnostic methods such as lung imaging and PFTs, and as a dramatically safer and less expensive alternative to surgical biopsy.

Single slices of 4DMedical XV scans from the Vanderbilt 'burn pit' clinical trial (left) from a healthy/control subject and (right) from a veteran exposed to burn pits with biopsy confirmed constrictive bronchiolitis. The image on the left visualises principally as green representing average levels of ventilation. In contrast, the image on the right shows significant regions of both red (low) and blue (high) ventilation. In addition to the visualisations shown here, additional quantitative scores and assessments identify the differences between Veterans with constrictive bronchiolitis and healthy controls.

Commenting on the clinical trial results, principal investigator, Dr Bradley Richmond, M.D., PhD, Vanderbilt, said: "We see many Iraq and Afghanistan Veterans who have lung biopsies showing significant damage, but traditional non-invasive testing appears normal. We are hopeful that 4DMedical's technology can help us diagnose lung disease in these Veterans without the need for a surgical lung biopsy. If our efforts are successful, we expect this technology can also be used to detect other lung diseases earlier than traditional testing, so patients get started on treatment sooner."

Ongoing assessment of the Vanderbilt clinical trial data is expected to lead to the publication of the results in the peer-reviewed scientific literature.

U.S. Senate Veterans Affairs Committee cites 4DMedical XV Technology®

The validation of 4DMedical's XV Technology® as an effective respiratory assessment tool is particularly salient given the media coverage, congressional support, and newly signed legislation to facilitate financial support for Veterans affected by airborne hazards.

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Last month, the Committee on Appropriations report for the Military Constructions, Veterans Affairs, and Related Agencies Appropriations Bill, made specific reference to 'emerging technology that uses existing x-ray imaging equipment to derive four-dimensional models of lung function to identify respiratory illnesses and accompanying loss of lung function.' As well, the Committee urged the Department 'to evaluate this technology for the purposes of conducting population-wide surveillance of Veterans who have been exposed to airborne hazards in order to conduct a full accounting of the health impacts suffered by Veterans and to provide full and effective medical care to this population.'

On 10 August 2022, President Joe Biden signed into law a broad expansion of healthcare benefits for millions of Veterans exposed to toxic burn pits. The estimated 3.5 million Veterans exposed to harmful toxins whilst deployed on operations since 2001 will now have access to an additional USD $280 billion healthcare commitment over ten years. Importantly, the new law also relieves the Veteran of the burden of proof that an illness is associated with exposure to toxic substances, with CB listed as a presumptive condition. Included in this legislation is the requirement for the VHA to provide toxic exposure screening to each of the 9 million Veterans enrolled in the VHA health care program.

4DMedical CEO and Founder Andreas Fouras said:

"Vanderbilt is one of the world's foremost medical research institutions. Validating the utility of our XV Technology® in application to CB in such a setting of excellence builds upon recent successes confirming the value of our core product to clinicians.

With the passage of the PACT Act, it is imperative clinicians be able to rapidly and effectively screen large numbers of Veterans safely, efficiently and economically. XV Technology® clearly has the potential to differentiate between healthy and diseased lungs related to overseas deployment."

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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®), which is the first and only modality that can dynamically quantify ventilation throughout the lungs. It additionally exposes the patient to lower levels of radiation relative to other diagnostic methods, a clear advantage when disease progression and therapeutic effectiveness need to be regularly

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monitored.

XV LVAS® reports are prepared to utilise 4DMedical's Software as a Service delivery model using existing hospital imaging equipment or the Company's own revolutionary XV Scanner.

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

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