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ASX ANNOUNCEMENT

POSITIVE DATA ON CARDIOCEL® PUBLISHED IN LEADING JOURNAL

- Largest multi-centre study of CardioCel[®] to date. 501 implants, in 377 patients across three sites (AU and UK)
- 96% freedom from reintervention at a median follow-up of 3 years for patients
- No evidence of bioscaffold calcification via echocardiography or radiology
- CardioCel[®] has good durability and performs comparably on the systemic and pulmonary circulations
- There was no difference in performance for neonates, infants and older children
- CardioCel[®] reduced re-operations, increased quality of life and offered cost savings to alternative implants

Admedus Ltd (ASX: AHZ) announces the publication of an independent study assessing the performance of CardioCel[®] in the prestigious peer-reviewed journal, *The Annals of Thoracic Surgery*.

The manuscript, "Multi-centre experience with 500 CardioCel[®] implants used for the repair of congenital heart defects"¹, delivers the important and positive finding that CardioCel[®] has good durability in pediatric patients, performs comparably on the systemic and pulmonary circulations with no evidence of patch calcification and shows 96% of patients free from reintervention at three and five years.

The performance was consistent across the three patient groups (babies 28 days and younger, infants aged from one month to one year and children older than one year).

The study collected data over five years (October 2012 to November 2017) across 377 patients in Brisbane, and two UK sites (Bristol and Leicester). It is the largest series of data collected on the use of CardioCel[®] in humans.

The primary endpoint of the study was freedom from implant related reintervention (transcatheter or surgical) and secondary endpoints included interoperative and perioperative mortality, calcification, infection and thrombosis.

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¹ Bell D, Betts K, Justo R, Forde N, Venugopal P, Corno AF, Smith P, Caputo M, Marsico R, Karl TR, Alphonso N, Multi-centre experience with 500 CardioCel® implants used for the repair of congenital defects, *The Annals of Thoracic Surgery (2019)*



The secondary endpoints demonstrated an excellent safety and durability profile, with one case of thrombosis and one case of patch dehiscence (separation) recorded across the entire patient population. There was no evidence of calcification through echocardiography or CT screening.

The manuscript also discussed the cost-benefit analysis of CardioCel[®]; highlighting CardioCel[®] as a cost-effective solution compared with other bioscaffolds, given the reduced need for repeat surgery and improved quality of life.

"The results of this study are overwhelmingly positive for Admedus. It reinforces the evidence that ADAPT[®] tissue has superior durability. It demonstrates, across a large patient population presenting with a range of disease types, that CardioCel[®] provides a solution with few complications and minimal chance of required intervention. This is particularly relevant for paediatric patients who need to lead healthy and active lives, without the need for ongoing surgery," Dr Kiran Bhirangi, AHZ's Chief Medical Officer, said.

According to AHZ's CEO, Wayne Paterson, "the study reinforces the clinical superiority of CardioCel[®] which uses our proprietary ADAPT[®] tissue. This large body of independent data, published in a highly respected peer-review journal, is a very important milestone. The data will support further market adoption not only for CardioCel[®] but our entire ADAPT[®] portfolio.

"It also reinforces the clinical and commercial potential of our 3D single piece aortic valve and TAVR devices in development. Each will have the same anti-calcification properties, key differentiators and improvement on existing solutions. We are now rapidly progressing towards first-in-human studies and look forward to providing an update in due course".

A link to purchase a copy of the manuscript can be found here.

ENDS

For more information, please contact: Admedus@we-buchan.com

About Admedus Limited

Admedus (ASX: AHZ) is a structural heart company delivering clinically superior solutions helping healthcare professionals create life-changing outcomes for patients. Its focus is on investing in and developing next-generation technologies with world-class partners, acquiring strategic assets to grow product and service offerings and expanding revenues from our existing medical sales and distribution business. The Company has assets from research & development through clinical development and sales, marketing and distribution.

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