

ASX ANNOUNCEMENT

Brisbane, 2 May, 2017

ADMEDUS RECEIVES FDA CLEARANCE FOR CARDIOCEL 3D

Admedus Limited (ASX:AHZ) today announced that it has received FDA 510(k) clearance to market CardioCel 3D in the United States effective immediately.

“The FDA approval of CardioCel 3D is an important accomplishment for Admedus as we expand our ADAPT® tissue engineering portfolio. 3D is a pioneering new product – applying our proprietary advanced technology – for which we expect growing demand during the years ahead, strongly supported by our strengthened and well trained sales team,” says Admedus CEO Wayne Paterson.

“CardioCel 3D offers a high need product which meets an unaddressed demand,” added Paterson. “It is the first product of its kind in a market where there are presently no off-the-shelf competing solutions. This is a major development in our strategy to increase Admedus’ market share in the strategically important congenital heart surgery and valve repair segments.”

CardioCel 3D is for surgeons and patients who require more than a single dimension patch material to optimize cardiac and vascular repair. As there are virtually no flat surfaces in the vascular or cardiac structure, this unique 60° shaped collagen product targets complex neonatal arch and pulmonary artery repair and is intended to help optimize suturing of central and extra-cardiac shunts. Its dimensions and specifications are designed to ‘mate’ with the triple plane anatomy found in neonatal arch and pulmonary artery repairs. Some 85% of surgeons polled by Admedus stated they would use CardioCel 3D immediately, and the first human use of the product is anticipated for this June.

Planned for launch into the US market during 2H 2017 and then expanding globally, FDA approval for CardioCel 3D is an important milestone for Admedus as the company applies the benefits of ADAPT processing to more complex applications, making it possible for surgeons to avoid known complications of degeneration, contraction, calcification and inflammation associated with other materials

CardioCel 3D marks an advancement beyond a typical product line extension, allowing Admedus to offer products with the benefits of ADAPT processing and the strength and calcium resistance in a unique, pre-shaped configuration, while avoiding the known complications associated with homograft material.

The first units of CardioCel 3D are already coming off the line at the company’s state-of-the art manufacturing facility in Malaga, Australia with plans to scale production to meet market demand.



For more information, please contact:

Dr Julian Chick
Chief Operating Officer | Admedus Limited
T: +61 (0)8 9266 0100
E: info@admedus.com

Media Europe
FTI Consulting
Simon Conway / Victoria Foster Mitchell
T: +44 (0) 20 3727 1000
E: admedus@fticonsulting.com

Signal Leadership Communication Inc.
Bob Pickard
T: +1 (647) 822 1000
E: bob.pickard@signaleadership.com

US Investor
Rx Communications Group, LLC
Melody A. Carey
T: +1 917 322 2571
E: mcarey@rxir.com

About Admedus Limited

Admedus (ASX:AHZ) is a specialist healthcare company. Our 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, profitable medical sales and distribution business. The company has assets from research & development through clinical development as well as sales, marketing and distribution.

Admedus has commercialised its innovative tissue engineering technology for regenerative medicine in four continents. We also have a major interest in developing the next generation of vaccines with a Brisbane-based research group led by Professor Ian Frazer. The vaccine programmes target disease with significant global potential, such as Herpes and Human Papillomavirus.

More information about the company can be found online:

Website: www.admedus.com

Twitter: [@ADMEDUS](https://twitter.com/ADMEDUS)