

AVITA MEDICAL AU\$2M GRANT FROM US ARMED FORCES TO ACCELERATE PRODUCT APPROVAL

- **Awarded AU\$2m to accelerate approval of ReCell in US market to make available for military and civilian population**
- **Potential to accelerate US FDA approval process**
- **ReCell recognised as ‘transformational technology’ at the forefront of regenerative medicine**

27 May 2009: Avita Medical Ltd (ASX: AVH) has been awarded US\$1.45 million (AU\$2 million) from the US Armed Forces Institute of Regenerative Medicine (AFIRM) to accelerate approval of the company’s ReCell Autologous Cell Harvesting device in the US market. The intent of all parties is to make the product available to soldiers and the civilian population in an accelerated timeframe.

AFIRM has a special interest in using the most advanced regenerative medicine for its wounded soldiers and recognises Avita’s innovative treatment for burns and other skin injuries has the benefits of using the patient’s own skin to yield improved and accelerated healing rates, reduced scar formation and reintroduction of pigmentation into the skin.

Avita was awarded the grant following a highly competitive approval process. Avita competed against project submissions from over 25 other companies and universities.

The award of the AFIRM grant may also accelerate the US FDA approval process for ReCell—an important milestone in Avita’s commercialisation of ReCell.

The AFIRM program, established in April 2008, is dedicated to bringing ‘transformational technologies’ in regenerative medicine to wounded soldiers by developing clinical therapies and advanced treatment options.

The award will provide funding for a 100-patient, multi-centre trial of ReCell. Up to 10 US investigational sites will participate; the study site selection process will begin in the coming weeks. The study will yield direct clinical comparison with the current standard of care in treating burn wounds.

As a major goal of AFIRM is to expedite and accelerate FDA clearance of the product, a subset of the 100 patients in the AFIRM study will be included in the US FDA trial. Updates to the FDA trials will be released in separate announcements.

Avita Medical CEO Dr William Dolphin said the grant from the US Armed Forces, which closely follows the funding of a medico-economic study by the French Ministry of Health, is another compelling endorsement of ReCell.

“ReCell has been chosen from a field of excellent projects. There is significant potential for this technology,” said Dr Dolphin.

“The selection process was based on the identification of high impact, highly innovative technologies with the greatest likelihood of delivering clinical benefit. ReCell is a disruptive technology which we believe will redefine the clinical treatment of burns, scar remodeling and other skin defects and injuries. The underlying technology has enormous application in the field of regenerative medicine and tissue engineering.

“We continue to receive extremely encouraging feedback on the ReCell product and are seeing positive indications of acceptance from leading clinicians and increasing sales,” he said.

In addition to developing clinical treatments, AFIRM will serve as a training facility to develop experts in treating trauma using regenerative medicine, likely to positively impact the uptake of ReCell as a new standard of care for burns and wounds treatment in the future.

“I am overjoyed!” said Professor Fiona Wood, developer of the ReCell technology and Non-Executive Director of Avita Medical. “The awarding of the AFIRM grant indicates the degree of interest and confidence in the ReCell technology. The ability to reduce the time to healing with limited donor sites is critical in burn wound care. With the support of the AFIRM grant the potential of ReCell can be realised.”

Dr James Holmes, Assistant Professor of Surgery at Wake Forest University School of Medicine and the Director of the Wake Forest University Baptist Medical Burn Center in North Carolina, USA, said ReCell had the potential to revolutionise the clinical treatment of burns, wounds and trauma due to illness or injury.

“We believe that this study represents an exceptional and truly viable opportunity to rapidly advance burn care for our wounded military personnel by gaining FDA approval of ReCell, and at the same time generating Level 1/Class 1/ Class A clinical burn data. We’re all excited to be participating in this important study,” said Dr Holmes.

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ABOUT AFIRM

The US Army Medical Research and Materiel Command has established the Armed Forces Institute of Regenerative Medicine (AFIRM) dedicated to repairing battlefield injuries through the use of regenerative medicine. The AFIRM program was established in April 2008 in conjunction with the Office of Naval Research, the National Institutes of Health, the Air Force, Office of the Surgeon General and the Department of Veterans Affairs.

AFIRM is made up of two multi-institutional consortia comprised of over 20 academic and commercial entities spearheaded by the Institute for Regenerative Medicine at Wake Forest University Baptist Medical Center (see press release at <http://www1.wfubmc.edu/news/NewsArticle.htm?Articleid=2350>) and Rutgers University (see press release at <http://news.rutgers.edu/medrel/news-releases/2008/04/rutgers-led-team-pur-20080410>) working closely with the U.S. Army Institute of Surgical Research in San Antonio, Texas.

AFIRM is dedicated to developing the science of regenerative medicine and bringing transformational technologies to wounded soldiers. Regenerative medicine takes advantage of the body's natural healing powers to restore or replace damaged tissue and organs. Regenerative medicine encompasses many novel approaches for the treatment of damaged tissues and organs by using therapies that prompt the body to autonomously regenerate, and by using the patient's own cells, for the creation of engineered tissues or organs for therapy.

Therapies developed by AFIRM will also benefit people in the civilian population with burns or severe trauma.

ABOUT AVITA MEDICAL LIMITED

Avita Medical Limited (www.avitamedical.com) is a publicly listed, global medical technology company. The company is active in the regenerative medicine and respiratory markets.

Regenerative Medicine

The company develops and distributes regenerative and tissue-engineered products for the treatment of a wide range of wounds, scars and skin defects. Using proprietary tissue-culture/collection technology, the company is able to provide innovative treatment solutions derived from the patient's own skin (autologous cells), to enhance healing rates, reduce scar formation and reintroduce pigmentation into the skin.

ReCell[®] is a stand-alone, rapid cell harvesting device that enables surgeons to treat skin defects using the patient's own cells. The surgeon can prepare a small quantity of cells within 30 minutes on site rather than having to send a biopsy to the laboratory for culturing and largely replaces the current standard skin graft treatment which dates from the 1860's and is associated with acute and chronic risks and complications. ReCell[®] has been designed for use in a wide variety of plastic, reconstructive and cosmetic procedures. ReCell[®] is gaining acceptance in a number of indications including Vitiligo, a common skin pigmentation disease.

ReCell[®] is patented, CE marked for the EU and TGA registered in Australia

Respiratory

The company commercialises innovative medical technologies for improved medication delivery and adherence in patients suffering from chronic respiratory diseases. The company manufactures and sells a range of spacers for the paediatric, adolescent and adult market and is the leading provider of spacers in Australia.

The Funhaler[®] incentive asthma spacer has been designed specifically for the paediatric market, incorporating auditory and visual incentives to encourage children to comply with their medication plan and has been clinically demonstrated to improve compliance to prescribed medication and increase proper inhalation technique. The Funhaler[®] is patented, CE marked for the EU, FDA cleared for the US and TGA registered in Australia.

Breath-A-Tech is the leading spacer for adolescents and adults in Australia. The product is effective, compact, easy to use and competitively priced. The Breath-A-Tech hospital-grade spacer can also be autoclaved in the hospital or clinical setting.