



## New Randomized Trial Shows ReCell® Heals Donor Sites Faster

June 20, 2017

### Highlights

- *Skin donor sites heal just over 30% faster with ReCell® in 106-patient randomized controlled trial*
- *Superior wound healing and aesthetic appearance in ReCell®-group*
- *The 3rd positive clinical trial recently announced by Avita Medical*

**Valencia, CA, USA, Perth, Australia and Cambridge, United Kingdom, 20 June 2017** —Deploying a suspension of cells generated from a ReCell® medical device onto a skin donor site can speed up healing by 30.7% and deliver a superior final outcome, according to the results of a randomized controlled trial involving 106 patients who received skin grafts, Avita Medical (ASX:AVH; OTCQX:AVMXY), said today.

Avita, a regenerative medicine company focused on the treatment of wounds and skin defects, said the findings reported in *the British Journal of Surgery* (BJS) further supported its growing data package around its ReCell® autologous cell harvesting device. This is the 3<sup>rd</sup> randomized controlled trial announced in recent weeks: last month, the Company presented data from two trials conducted at leading burns centers across the US, including successful results from its pivotal trial needed for PMA approval with the Food and Drug Administration.

"We are excited about these results, as together, the data show that ReCell® can be deployed both to reduce patient trauma, and to help patients heal faster," said Avita's CEO Mike Perry. "Our pivotal trial in the US, announced last month, showed how ReCell® allowed doctors to successfully treat burns using about 30% less donor skin. Now, in China, surgeons have shown that the donor site itself can heal some 30% faster when treated with Regenerative Epithelial Suspension™ made using the ReCell® device.

Demonstration of clinical benefit for treatment of burn injuries and treatment of donor sites further substantiates the key, versatile role for ReCell® in burn care."

The BJS paper -- a *Randomized clinical trial of autologous skin cell suspension for accelerating re-epithelialization of split-thickness donor sites* -- was based on work by a team of burns and plastic surgeons at the Sun Yat Sen University Hospital, in Guangzhou, China, led by Prof. J. Zhu. The Chinese investigators wished to explore whether donor sites for skin grafts healed faster and better if ReCell® was deployed alongside the main standard of care, which was a hydrocolloid dressing. Over a period of some 18 months, a total of 106 patients were recruited, with 53 in either the Control or ReCell®-treated groups, amongst patients who presented at the hospital requiring split-thickness skin grafts.

The researchers evaluated how long it took for the epithelial layer of skin to restore on donor sites, with and without ReCell®, a device that allows surgeons to deliver a suspension of skin cells to aid tissue

repair and skin regeneration. They reported that the median time to complete re-epithelialization was

9.0 days in the ReCell®-treated group, compared with 13.0 days in the control group, a 30.7% difference that was a statistically significant ( $p < 0.001$ ).

The authors said both patients and independent observers evaluated that the donor sites treated with autologous skin cell suspension displayed better physical attributes and patients were more satisfied with healing quality. Early and rapid re-epithelialization is thought to enhance wound healing, improve long-term aesthetic appearance, and deliver 'appropriate pigmentation,' they said.

"The autologous skin cell suspension is produced quickly and is available immediately for wound application," the investigators said. "This study suggests that its use [on] skin graft donor [sites] should promote healing and improve long-term aesthetic results."

Avita said the positive data reflected the growing interest about ReCell® amongst burns surgeons in China. In an earlier trial, Zhu's team in Guangzhou showed successful healing of chronic wounds with the ReCell® device.

###

## ABOUT AVITA MEDICAL LIMITED

Avita's patented and proprietary collection and application technology provides innovative treatment solutions derived from the regenerative properties of a patient's own skin. Our medical devices work by preparing a Regenerative Epithelial Suspension (RES™), an autologous suspension comprised of the

patients' own skin cells and wound healing factors that are necessary to regenerate natural healthy skin. This is then applied to the area to be treated.

In all countries outside of Europe, our portfolio is marketed under the ReCell® brand to promote skin healing in a wide range of applications including burns, chronic wounds and aesthetics.

ReCell® is TGA-registered in Australia, and CFDA-cleared in China. In the United States, ReCell® is an investigational device limited by federal law to investigational and compassionate use.

In Europe, our portfolio of medical device products received CE-mark approval as three tailored product presentations, with three individual brand

names. ReCell® is designed for the treatment of burns and plastic reconstructive procedures; ReGenerCell™ has been formulated for chronic wounds including leg and foot ulcers; and ReNovaCell™ is tailored for aesthetic applications including the restoration of pigmentation.

To learn more, visit [www.avitamedical.com](http://www.avitamedical.com).

#### **CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

*This letter includes forward-looking statements. These forward-looking statements generally can be identified by the use of words such as “anticipate,” “expect,” “intend,” “could,” “may,” “will,” “believe,” “estimate,” “look forward,” “forecast,” “goal,” “target,” “project,” “continue,” “outlook,” “guidance,” “future,” other words of similar meaning and the use of future dates. Forward-looking statements in this letter include, but are not limited to, statements concerning, among other things, our ongoing clinical trials and product development activities, regulatory approval of our products, the potential for future growth in our business, and our ability to achieve our key strategic, operational and financial goal. Forward-looking statements by their nature address matters that are, to different degrees, uncertain. Each forward-looking statement contained in this letter is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statement. Applicable risks and uncertainties include, among others, the timing of regulatory approvals of our products; physician acceptance, endorsement, and use of our products; failure to achieve the anticipated benefits from approval of our products; the effect of*

*regulatory actions; product liability claims; risks associated with international operations and expansion; and other business effects, including the effects of industry, economic or political conditions outside of the company’s control. Investors should not place considerable reliance on the forward-looking statements contained in this letter. Investors are encouraged to read our publicly available filings for a discussion of these and other risks and uncertainties. The forward-looking statements in this letter speak only as of the date of this release, and we undertake no obligation to update or revise any of these statements.*

###

#### **FOR FURTHER INFORMATION:**

##### **Australia**

##### **Monsoon Communications**

Sarah Kemter

Phone: +61 (0)3 9620 3333 Mobile: +61 (0)407 162

530 [sarahk@monsoon.com.au](mailto:sarahk@monsoon.com.au)

##### **USA**

##### **Westwicke Partners**

Jamar Ismail

Phone +1 (415) 513-1282

[jamar.ismail@westwicke.com](mailto:jamar.ismail@westwicke.com)