PRESS RELEASE

**Results of clinical trial involving ReCell® ‘Spray On Skin’ device from**

**Avita Medical represents key step towards ‘game changing’ treatment for Burns Victims**

*“We are pleased to see further evidence that using a medical technology such as ReCell® is not only clinically appropriate, but can also improve patient experience for burns victims at what is an extremely distressing time.”*

MrBruce Philp, Consultant Burns, Laser and Reconstructive Plastic Surgeon,

Mid Essex Hospital NHS Trust

* First ‘skin sparing’ trial of its kind for years achieves primary clinical aims
* Multi-centre randomised controlled trial involving 30 deep burns patients shows use of ReCell®, combined with skin grafting, required 1/3 less donor skin than with grafting alone
* Full trial data to be submitted to the FDA mid 2017, ahead of possible US market approval by mid 2018

**London, United Kingdom, 6th June 2017 —** In recent decades, few new treatments have emerged to treat serious burns, and standard protocols mostly involve painful skin grafts, whereby healthy skin from the patient (donor skin) is harvested for grafting onto the burn area; so-called meshed autografting. However, today, the results are announced of a randomised controlled trial involving the ReCell® medical device showing that burns patients may need significantly less skin for grafting. ReCell®, made by Avita Medical Ltd, is a ‘spray on skin’ device that is CE-approved and has been used in the UK for a decade, with over 7,500 patients safely treated around the world. The battery-powered, lunchbox-sized device contains all that is needed to generate normal, healthy skin in just 4 steps whereby a skin suspension – RES™ (Regenerative Epithelial Suspension) – is produced, ready to spray onto the wound in as little as 30 minutes, triggering an immediate healing response. The device needs just a few sq cms of skin to produce enough suspension to cover an average male adult torso, potentially reducing the need for extensive grafting.

The skin is the largest of our organs, regulating our body temperature, keeping in ‘the good’ (moisture, nutrients etc) and keeping out ‘the bad’ (pathogens, toxins, etc). So, for patients with serious burns over a high percentage of their body, having enough healthy skin for harvesting, and ensuring wound closure, can be a life-or-death issue. As such, the results of this latest clinical study validating ReCell® as a ‘skin-saving’ solution for patients has clinical, social and economic implications. The study adds to a growing body of evidence showing ReCell® treatment can deliver less pain, faster healing, shorter lengths of stay in hospital and better cosmetic results, compared to the conventional standard of care.

This latest trial concluded that ReCell® is safe and effective when used in combination with meshed autografting (a standard burns treatment) and furthermore, its use led to an average 32% reduction in the amount of donor skin required. It also showed a non-inferior incidence of healing, and no compromise to the scar outcome. For a patient enduring painful and distressing graft surgery, use of ReCell® in combination with meshed autografting could translate to less donor skin required, and fewer graft operations to ensure their wound closes and they get an optimal outcome. In the words of Mr Bruce Philp, Consultant Burns, Laser and Reconstructive Plastic Surgeon at Mid Essex Hospital NHS Trust, “We arepleased to see further evidence that using a medical technology such as ReCell® is not only clinically appropriate, but can also improve patient experience for burns victims, during what is always an extremely distressing time.”

This randomised controlled trial involved 30 patients who had suffered second-degree burns at 7 specialist burns centres in the USA. The findings will form part of Avita Medical Limited’s submission for approval of the ReCell® device by the US Food and Drug Administration (FDA) in mid 2017, ahead of possible US market approval by mid 2018.

An earlier randomised trial involving ReCell®, which took place from 2010 – 2014 and involved 101 patients at 12 US centres, concluded ReCell® is a safe and effective treatment for deep partial-thickness burns. Relative to conventional 2:1 meshed autografting, it achieved comparable definitive wound closure, smaller, less painful donor sites that healed faster, and better scar outcomes for the donor and wound site. Andrew Quick, Senior VP of Clinical Development at Avita Medical Limited notes, “Taken together, the data show closure akin to autografting, but with minimal donor sites, and a superior scar in terms of height. This is significant because we haven’t seen any innovation in autograft-sparing in years.”

**DEVICE BEING STOCK-PILED BY U.S. DEFENCE PREPAREDNESS GROUP, BARDA, IN CASE OF MASS CASUALTY EVENT**

Last month, Avita Medical announced it had been notified that the FDA had reviewed an Emergency Use Authorisation submission to allow emergency deployment of ReCell® for a mass casualty event involving burn injuries. The FDA review was submitted by the Biomedical Advanced Research and Development Authority (BARDA), a US federal agency instructed to prepare the US public for possible mass disasters. Avita has a $61.9m contract with the Authority, and the EUA is a procedure under which BARDA could purchase ReCell® devices in advance of FDA market approval.

**WHAT IS RECELL®? HOW DOES IT WORK?**

The body’s natural healing response to burns is to generate new skin cells, which typically migrate into the wound from the periphery. For major burns, this takes time, during which, the wound can become infected, and grafts sometimes fail completely. ReCell® can ‘short circuit’ and speed up the body’s natural healing process. The device uses healthy skin cells and wound healing factors harvested from a non-affected area of the body, which are ‘freed’ (disaggregated) to produce a liquid skin cell suspension (RESTM). The cells are then sprayed onto the burn site, promoting an instant healing response. The ReCell® procedure takes just 30 minutes, offering clear advantages over other treatments, such as culturing skin in a lab, which can take weeks. It can also be used in parallel with standard burns surgery procedures, with healthy skin being harvested at the same time while other activities take place in theatre. Dr James Holmes, a burns surgeon at Wake Forest Medical Center, North Carolina, who was involved in the trial, explains: "Treatments for serious burns have been starved of innovation for too long. Unlike advancements in most areas of medicine, we've been using the same operative treatments for the past 30 years. Removing substantial areas of healthy skin from the unharmed area of a seriously burned patient, for use in a graft, has obvious limitations, particularly when we have a shortage of donor sites. So, new technologies such as ReCell will help surgeons get around this problem, and move to a new standard of care for burn patients."

**ABOUT THE CLINICAL TRIAL**

This latest trial involving ReCell® was designed to compare two different treatments for patients who had endured 5-50% TBSA acute thermal injuries requiring autograft for closure, such as burns caused by a vehicle or house fire. Participants were aged 5 years and older. The 30 patients participating in the trial were followed for 52 weeks to look at the durability of the healed burn-injury areas, and aesthetic outcomes. Conducted between 2015-2017, it involved 7 leading US burns centres, and was designed to demonstrate the effectiveness of ReCell® when combined with skin grafting in the closure of mixed depth burns, including full thickdeep partial- and full-thickness burn injuries. In this within-patient trial, the ‘control’ area of the burn received a standard autologous meshed skin graft, whilst the other area of the burn received ReCell® in combination with the mesh graft, whereby the RESTM (skin suspension) was sprayed into perforations in the graft. The study also looked at use of ReCell® when applied to autografts meshed more widely than conventional practices: When carrying out a meshed autograft, there is a trade-off between stretching the graft as far as possible so that less healthy skin needs harvesting, and the graft tearing.

A key finding was that the burn sites treated with ReCell® plus the graft required 32% less skin removing at the donor site. By extension, this ‘saving of skin’ has the potential to reduce the number of painful skin graft operations a patient must endure. (Often several grafts are required as part of standard care – with all the associated human and financial resources involved.) The trial also proved ReCell® *not* to be inferior to the control group in terms of the healing incidence, as measured by the cosmetic outcome for each patient (which was rated by both patient and observer). Avita Medical CEO, Dr Michael S. Perry, notes, “As we head towards launching ReCell® into the US burns market, our team will continue to complete and submit the PMA.”

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**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. Its medical devices work by preparing a Regenerative Epithelial Suspension (RESTM), an autologous suspension comprised of the patient’s 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; ReGenerCellTM has been formulated for chronic wounds including leg and foot ulcers; and ReNovaCellTM is tailored for aesthetic applications including the restoration of pigmentation. To learn more, visit [www.avitamedical.com](http://www.avitamedical.com)

**FOR FURTHER INFORMATION:**

Expert user videos:

Miss Alex Murray, Stoke Mandeville Hospital: <https://www.youtube.com/watch?v=YLGpbLac7zU>

Dr Jimmy Holmes, Wake Forest University, USA: https://www.youtube.com/watch?v=PfPgx3OduDc

News: <http://avitamedical.com/media-centre/news/>

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**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.*

**MEDIA ENQUIRIES**

For all enquiries,including **interview requests** for those quoted above**, patient case studies, hi-res images + video** please contact: Hannah Kapff or Siena Clarke at Curious PR [Hannah@CuriousPR.com](mailto:Hannah@CuriousPR.com) or [Siena@CuriousPR.com](mailto:Siena@CuriousPR.com)

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