News Release

FDA Approves Continued Access to ReCell® in US Burns Trial

Up to 60 US burns patients could be treated under the new Ruling

Northridge, CA, Perth, Australia and London, United Kingdom, 5 October 2016 — The US Food and Drug Administration has approved Continued Access to ReCell, allowing US burn surgeons participating in Avita Medical's regulatory trial to treat new patients using the Company's cell harvesting device, while the marketing application is under preparation and review, the Company said today.

Avita Medical Ltd (ASX: AVH), (OTCQX: AVMXY), a regenerative medicine company specialising in new treatments for wounds and skin defects, said up to 60 new patients could be treated under the the FDA's approval of an application for 'Continued Access to Investigational Devices.' The Continued Access provision of the FDA's Investigational Device Exemption (IDE) guidance allows doctors to access a medical device while the marketing application is under preparation and review, if 'there is a public need for the device,' and 'there is preliminary evidence that the device is likely to be effective and no significant safety concern have been identified for the proposed indication.' The FDA's principles on granting the Continued Access further state that 'it could be contrary to public health to prevent access to potentially safe and effective new devices during an evaluation period.'

Avita has already treated all the 30 patients required for its approval trial, being conducted at seven leading burns centres across the US, and this group are now within a safety observation period. Once that phase has been completed in early 2017, the Company will submit an application for Pre Market Approval (PMA), and hopes its ReCell® device will get approval before the end of 2017. In tandem to the approval process, the Company also has FDA approval of an IDE for Compassionate Use, under which burn patients can be treated with ReCell® -- an autograft sparing device -- if their life is in danger and there is no other treatment alternative. More than 30 American burn and trauma victims, most with very large-scale injuries, have been treated to date under this protocol.

Now, under Continued Access, the surgeons who participated in the trial will be able to access ReCell®, for their patients who require grafting, but whose injuries do not meet the criteria for Compassionate Use. Further, the surgeons will record the treatment in compliance with the approval trial protocols, which will contribute to the body of clinical data being amassed around Avita's regenerative medical approach.

'It is heartening that more US burns patients will now be able to receive our unique treatment approach during the pre-approval period,' said Andy Quick, Senior VP of Clinical Development. 'But it is also important that those surgeons who had adopted ReCell® into their practice will now be able to again deploy the device and further see its effectiveness, beyond what they have seen to date.'

Adam Kelliher, Avita CEO, said the approval was a positive step within the context of Avita's plans to enter the US healthcare market, the world's largest.

'It is a very positive step that the FDA have decided that we comply with the guiding criteria for Continued Access, under which eligible devices must be assessed as safe, effective and meeting a real public need', Kelliher said. 'At the same time my team remains on track to meet our stated objectives and achieve US market approval.'

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ABOUT AVITA MEDICAL LIMITED

Avita Medical develops and distributes regenerative products for the treatment of a broad range of wounds, scars and skin defects. Avita's patented and proprietary collection and application technology provides innovative treatment solutions derived from a patient's own skin. The Company's regenerative product portfolio includes ReCell® for burns & plastic reconstructive procedures, ReGenerCell® for chronic wounds and ReNovaCell® of restoration of pigmentation and cosmesis. ReCell®, ReGenerCell® and ReNovaCell® are patented, CE-marked for Europe. 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 use, and a pivotal U.S. trial is well underway aimed at securing FDA approval.

To learn more, visit www.avitamedical.com.

AVITA'S REGENERATIVE TECHNOLOGY AND RES™

Avita Medical's unique proprietary technology enables a clinician to rapidly create, at the point of care in approximately 30 minutes, Regenerative Epithelial Suspension (RES™) using a small sample of the patient's skin. RES™ is an autologous suspension comprising the cells and wound healing factors necessary to regenerate natural, healthy skin. RES™ has a broad range of applications and can be used to restart healing in unresponsive wounds, to repair burns using less donor skin yet with improved functional and aesthetic outcomes, and to restore pigmentation and improve cosmesis of damaged skin.

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