Avita Medical Provides NICE Guidance Recommendation Update

Australia, 13 November 2014 — Avita Medical Ltd. (ASX: AVH), a regenerative medicine company specializing in the treatment of wounds and skin defects, today announced the United Kingdom's National Institute for Health and Care Excellence (NICE) has issued guidance around the use of ReCell® Spray-on Skin® for the treatment of skin loss, scarring and depigmentation after a burn injury. While NICE commented that ReCell demonstrates potential to improve healing of acute burns, more evidence is required before a formal recommendation can be granted.

NICE provides national, evidence-based guidance and advice to improve the quality of health and social services in the United Kingdom. It serves as an advisory agency to the National Healthcare System (NHS), and is not statutory like the pharmaceutical guidance given by the European Medicines Agency (EMA) nor is it reimbursement as commonly understood in many other countries. Medical technologies, such as ReCell, can apply for a NICE guidance recommendation, and may receive one of three types of guidance, positive, negative or insufficient evidence to provide a recommendation. Receipt of a positive guidance recommendation often streamlines the purchase and procurement process of such medical technologies in NHS hospitals but it is not a prerequisite for procurement as demonstrated by the various NHS hospitals already using ReCell. This fact was reiterated by NICE in the press release it issued regarding its decision, "It's essential to note that these recommendations for further research don't mean that these promising technologies should not be used, as it's important that more data can be generated to help inform further considerations on their clinical utility. NICE will update both pieces of guidance if and when substantive new evidence becomes available."

Avita's NICE guidance application for ReCell was initially reviewed by the Agency's Medical Technologies Advisory Committee (MTAC) in November of 2013. The Committee requested further evidence of ReCell's efficacy in the treatment of acute large full-thickness or deep partial-thickness burn injuries, which was in part produced by the External Assessment Centre. Subsequent to this the Company provided newly collected and analysed data in May of 2014. MTAC reviewed the additional evidence in September, and determined that ReCell is a "promising technology with potential to improve healing in acute burns, especially for patients with burns that need skin grafting." However, the Committee cited insufficient evidence when they attempted to determine the most appropriate patient population for the ReCell Spray-on Skin system.

In evaluating ReCell, MTAC stated that it received expert clinical advice that ReCell's use may be most beneficial in the treatment of large area full-thickness or deep partial-thickness burns requiring skin grafting. The Committee also acknowledged that all of the medical professionals interviewed who had used ReCell when treating their skin graft patients, not only experienced benefit during the healing process, but found the immediate availability of the cells produced was an advantage over cultured cells which required a two week waiting period and are available only through a limited number of facilities. The committee also highlighted the potential application of ReCell on skin graft donor sites to reduce healing time and allow further grafts to be taken earlier from the same site in the treatment of very large burns.

MTAC found the expert advice from the Company's clinical and academic collaborators so informative that in the press release regarding its decision the Committee stated, "The guidance recommendations for further research means that NICE will now explore the development of appropriate further evidence, in collaboration with the technology sponsor and with clinical and academic partners."

The Company's self-evaluation both of the clinical evidence and the specific areas of clinical practice where ReCell best fits with contemporary burn care aligns with many of the key points of the NICE guidance, as evidenced by recent changes implemented to the US Burn study, the planned introduction of a higher capacity device for treatment of larger burn injuries, and strategic commercial re-positioning of the product for complementary use in patients requiring grafting. While the long-term approach still is for the paradigm-shifting use of ReCell without grafting for early intervention and better scar outcomes for partial-thickness injuries, in the short term the Company will pursue the complementary use of ReCell as a softer, more incremental transition in burn care, focusing on the clinical benefits of using less skin for grafting procedures.

"We appreciate MTAC's conclusion at this time that ReCell is a promising platform technology and recognize the necessity of the organization's stringent recommendation process. Avita is pleased to provide further evidence to aid the Committee in their determination of which patient population is best served by ReCell. The treatment of more patients with large-area full-thickness or deep partial-thickness burns requiring skin grafting in our US Clinical burns trial will give rise to key evidence for MTAC's evaluation," commented Tim Rooney, Avita Medical's Chief Executive Officer.

ABOUT AVITA MEDICAL LIMITED

Avita Medical (http://www.avitamedical.com/) develops and distributes regenerative products for the treatment of a broad range of wounds, scars and skin defects. Avita's patented and proprietary tissue-culture, collection and application technology provides innovative treatment solutions derived from a patient's own skin. The Company's lead product, ReCell® Spray-On Skin®, is used in a wide variety of burns, plastic, reconstructive and cosmetic procedures. ReCell is patented, CE-marked for Europe, TGA-registered in Australia, and SFDA-cleared in China. ReCell is not available for sale in the United States; in the United States, ReCell is an investigational device limited by federal law to investigational use. A Phase III FDA trial is in process.

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