Avita Medical Announces First Patient Enrolment in US Pivotal Study of ReCell® for the Treatment of Burns

Australia, 28 January 2015 — Avita Medical Ltd. (ASX: AVH), a regenerative medicine company specializing in the treatment of wounds and skin defects, announced today that the first patient has been enrolled in the Company's Pivotal Phase III burn trial for ReCell®.

The FDA-approved study is designed to confirm the safety and effectiveness of ReCell® in patients requiring skin grafts due to burn injuries. The use of ReCell® in combination with mesh grafting reflects a clinical development strategy intended to support mainstream adoption of ReCell® for all burn surgeries. In total, thirty subjects will be recruited into the trial so that complete follow-up data from 25 subjects can be evaluated after accounting for some attrition. Each subject serves as their own control, with a portion of their injury randomly allocated to receive skin grafting (control) and a similar portion of their injury randomly allocated to receive ReCell® treatment in combination with meshed skin grafting that is further expanded than the control. Co-primary effectiveness endpoints will compare (1) donor site to treatment area expansion ratios and (2) incidence of complete closure eight assessed 8 weeks after treatment by personnel blinded to the treatment received. It is hypothesized that the use of ReCell® will show a comparable (non-inferior) incidence of complete closure but with a superior expansion of donor skin. For patients, this means a larger burn injury is successfully treated with a smaller donor site. Also, it is important to note that donor site pain associated with burn surgery is a chief concern of burn patients. Secondary endpoints will be evaluated after 24 weeks, and are hypothesized to demonstrate subject preference for the outcome of ReCell® treatment vs. control, as well as superiority of the subjects' and blinded assessor rating of scar outcomes.

"Today's announcement marks a significant achievement for the Company as this program represents a definitive pathway to US market approval, and also provides important substantiation for the positioning of the use of ReCell® in a clinically and economically meaningful way all over the world," commented Andrew Quick, Avita's VP of Research & Technology.

A successful trial will yield data demonstrating the use of ReCell® for achieving primary wound closure with a reduced requirement for donor skin harvesting along with improved functional and aesthetic outcomes. The use of less donor skin results in achieving primary closure in fewer surgical procedures and a corresponding decreased length of hospital stay and less pain management. The advantage of improved functional and aesthetic outcomes is largely self-evident, but also provides a positive economic impact in terms of reduced requirements for reconstructive (scar) surgery and an earlier return for patients to a normal, productive life. In addition to supporting a PMA application for FDA approval to market ReCell® for burns in the US, the study data will be important for supporting commercialization efforts, particularly in the UK, with NICE looking for a high standard of supplemental research for their medical technology assessment of ReCell®.

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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