

AVITA MEDICAL RECEIVES FDA APPROVAL TO INITIATE STUDY OF ITS *RECELL*[®] *SPRAY-ON-SKIN*[™] FOR COSMETIC INDICATIONS

- **FDA APPROVAL TO CONDUCT FEASIBILITY STUDY ON HYPERTROPHIC DYSPIGMENTED SCARS**
- **STUDY TO BE CONDUCTED AT UP TO 4 US CENTRES**
- **EXPANDS INDICATIONS FOR RECELL TO INCLUDE COSMETIC TREATMENTS**

Australia, 25 August 2011,—**Avita Medical Ltd.** (ASX: **AVH**), the regenerative medicine company, today announced that the United States Food and Drug Administration (FDA) has approved the Company's investigational device exemption (IDE) feasibility study for the use of **ReCell[®] Spray-On-Skin[™]** in the treatment of hypertrophic dyspigmented scars: i.e., raised and/or discoloured scars.

The approved FDA protocol permits the Company to treat 20 patients with pre-existing scars at up to four U.S. study sites. The treated scars will be assessed for healing and pain on a weekly basis during the initial four weeks post-treatment; at weeks 12 and 24 the treatment site will be assessed for healing and aesthetic outcomes by both the patient and the surgeon.

"We are pleased that the FDA has approved our request to study expanded indications for ReCell," said **Dr. William Dolphin, Avita Medical's CEO**. "We believe that ReCell offers the potential to deliver significant benefits over currently available options in the treatment of acute and chronic wounds and skin defects. This study will allow us to demonstrate the use of ReCell in the corrective treatment of existing scars with application to the very large cosmetic markets."

The ReCell Scar feasibility study is primarily designed to assess the effectiveness of using ReCell for the treatment of existing scars in a single treatment session, measured as time-to-healing and aesthetic outcomes, compared to the current standard of care which involves dermabrasion of the existing scar and often requires multiple sessions.

Data obtained from this feasibility study will be used to design a larger, statistically powered pivotal clinical investigation. Once the 12-week follow-up with the 20th patient is completed, Avita will submit the feasibility data to the FDA and will seek FDA approval for the pivotal trial protocol.

Avita Medical is currently conducting an FDA-approved study for the use of ReCell in the treatment of acute burn wounds.

ABOUT RECELL[®] SPRAY-ON SKIN[™]

The company's lead product, ReCell[®] Spray-On Skin, has been designed for use in a wide variety of burns, plastic, reconstructive and cosmetic procedures. ReCell allows in-theater preparation of a spray-on suspension consisting of cells derived from a small (2x2cm), thin (0.15-0.20mm) biopsy of a patient's own skin that is sufficient to cover an area up to 80 times the size of the biopsy. The ReCell suspension contains basal keratinocytes, melanocytes, fibroblasts and Langerhans cells. The metabolically responsive epithelial cells migrate across the wound surface, leading to regeneration of skin of normal color and texture. ReCell requires only a minimal donor site and is immediately available as a cell-based spray at the patient's bedside.

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 U.S. ReCell[®] is an investigational device limited by federal law to investigational use.

ABOUT AVITA MEDICAL LTD.

Avita Medical ASX:AVH (www.avitamedical.com) is a publicly listed medical technology company that develops and distributes regenerative and tissue-engineered products for the treatment of a broad range of wounds, scars and skin defects. Using patented and proprietary tissue-culture, collection and application technology, the company is able to provide innovative treatment solutions derived from a patient's own skin.

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