ASX | News Release

Avita Medical Announces U.S. FDA Doubles Patient Numbers Permitted for Compassionate Use of ReCell®

Compassionate Use Cases Presented at TERMIS World Congress

Northridge, CA and Cambridge, United Kingdom, 5 October 2015 – Avita Medical Ltd. (ASX: AVH), (OTCQX: AVMXY), a regenerative medicine company specializing in the treatment of wounds and skin defects, today announced approval from the U.S. Food and Drug Administration (FDA) for the expansion of its Compassionate Use Investigational Device Exemption (IDE) program for ReCell®.

The IDE supplement allows Avita Medical to continue clinical evaluation of ReCell® on twice as many patients as originally permitted under the IDE, now allowing for ReCell® treatment of a total of 24 patients who have insufficient healthy skin available for standard skin grafting of their injury. Investigational use of ReCell® in these patients may be granted in cases where the treating physician believes that there is no suitable treatment alternative. The IDE also allows the application of ReCell® beyond burns and to larger, more serious defects than those previously studied in the U.S.

"Approval from the FDA for doubling the number of compassionate use cases is not only a significant achievement for Avita as we continue our pivotal U.S. trial of ReCell® in burns, it provides an alternative treatment option for patients with no other skin-healing option," Adam Kelliher, CEO of Avita Medical, commented. "The ability to achieve definitive closure of extensive injuries in this patient population can have a life-saving impact."

The FDA approved the initial IDE for up to 12 subjects with life-threatening wounds in April 2014. Under the original IDE, 12 compassionate use cases using ReCell® have been conducted with success at several leading institutions, including Wake Forest Baptist Medical Center, Maricopa Medical Center, Walter Reed National Military Medical Center and MedStar Washington Hospital Center.

Individual case results have been presented to the international medical community at various professional meetings this year and last year, such as the Southern Region Burn Conference, the 17th Biennial Congress of the International Society for Burn Injuries, the 47th Annual Meeting of the American Burn Association, Avita's Skin Regeneration Symposium, and the Military Health System Research Symposium.

Most recently, long-term results from two early compassionate use cases were presented at the 2015 4th Tissue Engineering and Regenerative Medicine International Society World Congress (TERMIS) World Congress, held last month in Boston, MA.

In the presentation at the TERMIS World Congress, surgeons from Walter Reed National Military Medical Center presented two complex trauma cases approved for compassionate use of ReCell®, and compared results to two similar cases not using ReCell®. The cases involved massive reconstruction using dermal regenerative templates, and the patients had little available healthy skin to graft their defects closed. Their findings indicated that using ReCell® in these cases allowed for a greater skin graft expansion, thereby limiting donor site morbidity and decreasing donor site burden by 65%. Further, they showed a decreased time to complete healing of 50% relative to skin grafting without ReCell® and achieved outcomes with matching pigmentation.

ABOUT RECELL® AND RES™

ReCell® is Avita Medical's unique proprietary technology that enables a clinician to rapidly create, at 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.

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 lead product, ReCell®, is used in the treatment of a wide variety of burns, plastic, reconstructive and cosmetic procedures. ReCell® is patented, CE-marked for Europe, 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. A pivotal U.S. trial is underway, with patient enrollment completion anticipated by the end of 2015. To learn more, visit www.avitamedical.com.

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FOR FURTHER INFORMATION

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