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NovoSorb® BTM

4 September 2024

ASX Announcement

Pivotal Trial Recruitment Complete

PolyNovo Limited (**PolyNovo** or **Company**) is pleased to announce that all 120 patients have been enrolled in the complex randomised controlled trial comparing NovoSorb BTM to standard of care for third degree, full thickness burns (**Pivotal Clinical Trial**). As an outcome of the Company meeting 120 enrolments, the patient-enrolment component of the Pivotal Clinical Trial is now complete. The trial is funded by the Biomedical Advanced Research and Development Authority (**BARDA**), part of the Administration for Strategic Preparedness and Response within the U.S. Department of the Health and Human Services.

The Company has initiated discussions with the U.S. Food and Drug Administration (**FDA**) to align on timing of the premarket approval (**PMA**) filing for an on-label indication supporting the use of NovoSorb BTM in full thickness burns. Granting of a PMA approval by the FDA would bring the U.S. market in line with other markets where this indication is already approved by regulators.

Chief Medical Officer, Dr Joseph Amaral said: “We are incredibly grateful to the patients and their families who volunteered for this study, and to the investigators who participated in it. We could not have achieved this milestone without their commitment to enhancing scientific knowledge and improving patient care.”

Chief Executive Officer, Swami Raote said: “We are extremely grateful to our decade-plus long partnership with BARDA and their financial support and guidance through all stages of our clinical trial and FDA interactions.”

Chairman, David Williams said: “Although we still await the final results of the trial, this is a critically important milestone for us in the U.S.”

This announcement has been authorised by PolyNovo General Counsel & Company Secretary, Lior Harel.

About PolyNovo®

PolyNovo is a disruptive ASX 200 medical technology company, based out of Melbourne, Australia. Its products simplify management of acute complex wounds, redefining healing with meaningfully differentiated patient outcomes across multiple wound etiologies. After treating 50,000+ patients across 41 countries, the company is investing for growth via new products, indications, and markets. For more information see polynovo.com

About NovoSorb®

NovoSorb BTM is a dermal scaffold for the regeneration of the dermis when lost through extensive surgery, trauma or burn. NovoSorb is a novel range of bio-resorbable polymers that can be produced in many formats including film, fibre, foam, and coatings. NovoSorb's unique properties provide excellent biocompatibility, control over physical properties, and a programmable bio-resorption profile.

About the Pivotal Trial

The pivotal clinical trial study is a multi-center, randomised, fixed, group sequential design to compare the safety and effectiveness of NovoSorb BTM to the standard of care (SOC) in patients with severe full thickness burn injuries. 120 patients with 3% to 60% Total Body Surface Area (TBSA) deep dermal or full-thickness thermal burns, recruited through 24 U.S. burn centres, and 3 sites in India, were randomised to receive either NovoSorb BTM or SOC treatment. The primary endpoint for the trial is to compare the total percent wound closure in the NovoSorb BTM and the SOC treatment groups. This trial has been supported in whole or in part with federal funds from the U.S. Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority, under contract HHSO100201500021C.