

2 October 2023

ASX Announcement

BARDA increases funding US\$10 million

PolyNovo is pleased to announce that it has received additional funding of \$US10 million from the Biomedical Advanced Research and Development Authority (“BARDA”) for the Pivotal Trial program of NovoSorb® BTM. This increases the total funding commitment from BARDA to \$US25 million. The contract is a cost-plus monthly reimbursement arrangement. PolyNovo will continue to contribute to the trial through the provision of product, employee resources and infrastructure support.

The NovoSorb® BTM Pivotal Trial is gathering data on the effectiveness of NovoSorb® BTM for treating full thickness burns. Successful completion of this trial will enable PolyNovo to file a PMA application for use in full thickness burns and may lead to BARDA buying NovoSorb® BTM for disaster management.

NovoSorb BTM is already indicated for full thickness burns outside of the U.S. and has the CE Mark for the EU market, including an indication for use in full thickness burns, other surgical wounds, and reconstruction procedures.

PolyNovo’s BARDA contract, funded by the U.S. Department of Health and Human Services (Office of the Assistant Secretary for Preparedness and Response), commenced 28 September 2015. The first patient was enrolled in September 2021, with patients currently being recruited from 22 U.S. burn centres and 1 site in Canada. An additional 5 U.S. sites, 4 Canadian sites and 3 Indian sites are in the process of being enrolled to participate in the trial.

To date, 71 patients have been enrolled out of a target 120. Recruitment is expected to be completed in FY24.

Director of Clinical Operations, John Cockwill said, *“Our partnership with BARDA over the past decade has been extraordinary. Together, we have pioneered innovation in the medical device industry, pushing boundaries and saving many lives. It’s been a journey of dedication, collaboration, and the relentless pursuit of excellence. Our shared vision has driven technological advancements but has also made for a profound impact on healthcare worldwide.”*

Chairman, David Williams said *“BARDA and PolyNovo have a clear end game to bring our technology to as many patients as possible. It is an honour for us to know that our technology will play an important part in the US preparedness for mass disasters.”*

Chief Executive Officer, Swami Raote said “*BARDA has been partnering with us and the FDA on this program in the most collegial way. We appreciate their consistent engagement and guidance in helping us construct, navigate, and execute a complex, large-scale multi-centre trial to secure FDA approval for our life saving and life changing technology.*”

This announcement has been authorised by PolyNovo Company Secretary Jan-Marcel Gielen.

Further information:

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About PolyNovo®

PolyNovo is a disruptive medical device company, focused on Advanced Wound Care that designs, develops, and manufactures dermal regeneration solutions (NovoSorb BTM, NovoSorb MTX) using its patented NovoSorb biodegradable polymer technology. Our development program covers Breast Sling, Hernia, and Orthopaedic applications. For further information see polynovo.com

About NovoSorb®

NovoSorb® BTM is a dermal scaffold for the regeneration of the dermis when lost through 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.

Reach

PolyNovo supplies approximately 638 hospitals directly in Australia, Hong Kong, India, Ireland, the Middle East, New Zealand, Singapore, the United Kingdom, and the United States. Other countries, such as Canada, Germany, France and Spain are serviced by a distributor.