23 November 2026

ASX Announcement

NovoSorb® BTM Achieves Pivotal Trial Endpoints, PMA Submitted

- PolyNovo has submitted its Premarket Approval (**PMA**) application to the U.S. Food and Drug Administration (**FDA**) for NovoSorb® BTM in the treatment of full-thickness burns.
- The PMA submission includes data from PolyNovo's Biomedical Advanced Research and Development Authority (**BARDA**) sponsored U.S. pivotal randomised controlled trial of 120 patients.
- The trial demonstrated that NovoSorb® BTM achieved adjusted mean wound closure of 94.9% compared with 87.3% for standard of care (**SOC**) four weeks after skin grafting.
- If granted, a PMA would allow PolyNovo to actively market NovoSorb® BTM for full-thickness burns in the United States and could support expanded reimbursement and market access opportunities.

PolyNovo Limited (ASX: PNV) ("**PolyNovo**" or the "**Company**") is pleased to announce it has submitted its PMA application to the FDA for NovoSorb® BTM in the management of full-thickness burns, ahead of its previously committed end-of-calendar-year timeline.

The application includes the final Clinical Study Report (**CSR**) from PolyNovo's BARDA sponsored U.S. pivotal randomised controlled trial, 18-month patient follow-up data, and supporting manufacturing and quality information.

Trial Findings

The trial met its primary effectiveness endpoint, demonstrating that NovoSorb® BTM was non-inferior to SOC.

NovoSorb® BTM achieved an adjusted mean wound closure of 94.9% compared with 87.3% for SOC four weeks after skin grafting, representing a treatment difference of +7.6 percentage points.

For the primary composite safety endpoint, NovoSorb® BTM recorded an event rate of 18.1%, compared with 21.6% for SOC, with the results supporting the safety profile of NovoSorb® BTM and showing no evidence of increased safety risk.

Full study results will be presented at the American Burn Association Annual Meeting in Chicago in April 2027, with a peer-reviewed publication to follow.

Expanding the U.S. Market Opportunity

NovoSorb® BTM has already achieved significant adoption in the U.S. without an on-label indication for full-thickness burns, with commercial sales of A$89.9m in FY26.

The PMA would allow PolyNovo to:

- support broader adoption in U.S. burns with Level 1 randomised clinical evidence;
- actively market NovoSorb® BTM for full-thickness burns in the United States; and
- pursue expanded reimbursement and market access opportunities internationally.

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Preparation for potential approval and launch is underway, including market access, pricing and commercial readiness.

The FDA will now conduct its acceptance and filing review, followed, if accepted for filing, by substantive review of the application. The review may include requests for additional information and clinical and manufacturing inspections. PolyNovo does not anticipate that further pivotal clinical trials will be required to support the PMA application.

The PMA submission has no impact on current sales or clinical use of NovoSorb® products under existing FDA clearances.

PolyNovo CEO Bruce Peatey said:

"This study is one of the largest controlled evaluations in the burns space undertaken to date and the culmination of many years of clinical research. It represents a major milestone for PolyNovo, and I want to thank our team, the trial investigators, the patients who participated, and BARDA for its support.

NovoSorb® BTM has built a strong position in the United States. This submission is an important step forward, and we're already preparing for the opportunities that approval could bring. We're increasing our investment in clinical evidence generation, marketing and reimbursement expertise to support further adoption of NovoSorb® BTM and expand its use across more indications.

Our team is excited about the potential to help more patients with complex injuries regain function and get back to their lives."

This project 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 (BARDA), under contract number HHSO100201500021C. BARDA is investing in the program to advance medical countermeasures that may be used during mass casualty incidents such as a nuclear detonation.

This announcement has been authorised for release by PNV Company Secretary, Amy Demediuk.

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Appendix 1: Summary of U.S. Pivotal Randomised Controlled Trial

Trial identification	CP-003 – A Pivotal Study to Assess the Safety and Effectiveness of NovoSorb® BTM in the Treatment of Severe Burn Skin Injuries (NCT04090424)
Study objective	To evaluate the safety and effectiveness of NovoSorb® BTM compared with SOC in patients with deep dermal and full-thickness thermal burns.
Study design	Multicentre, randomised controlled trial conducted under a U.S. FDA Investigational Device Exemption (IDE).
Sponsor	PolyNovo North America LLC.
Clinical sites	34 investigative sites were activated: 30 U.S. sites, 1 Canadian site, and 3 Indian sites. Of the 34 activated sites, 26 enrolled at least 1 subject. .
Patient population	Adults aged 18–75 years with burns affecting 3–60% of total body surface area (TBSA).
Patient enrolment	127 patients enrolled; 120 randomised and treated.
Randomisation	Patients randomised 2:1 to NovoSorb® BTM or SOC.
Treatment	NovoSorb® BTM or SOC applied before split-thickness skin grafting (SSG).
Control group	SOC treatments included a dermal matrix containing cross-linked bovine collagen and chondroitin-6-sulfate or cadaveric allograft.
Trial period	September 2021 to May 2026
Primary effectiveness endpoint	The study was designed as a non-inferiority study, with the primary effectiveness endpoint assessing mean percentage wound closure for NovoSorb® BTM compared with SOC. The pre-specified non-inferiority margin was 15 percentage points. The total percent wound closure calculated for each randomised subject based on an Independent Panel assessment of study lesions four weeks after split-thickness skin grafting.
Effectiveness results	At four weeks after grafting, mean wound closure was 94.86% for NovoSorb® BTM compared with 87.34% for SOC, a difference of 7.52 percentage points in favour of NovoSorb® BTM (95.18% CI: 0.24 to 14.81). The lower bound of the confidence interval was above the study's pre-specified non-inferiority margin of -15 percentage points (one-sided P<0.0001), meaning NovoSorb® BTM met the study's primary effectiveness objective and demonstrated non-inferiority to SOC. NovoSorb® BTM achieved adjusted mean wound closure of 94.9%, compared with 87.3% for SOC. NovoSorb® BTM met the primary effectiveness endpoint, with the lower bound of the confidence interval exceeding the pre-specified non-inferiority threshold of -15 percentage points.
Primary safety endpoint	The primary safety endpoint is a composite of device (NovoSorb® BTM group)-/treatment (SOC group)-related mortality, skin graft loss requiring re-operation and device (NovoSorb® BTM group)-/treatment (SOC group)-related AEs requiring re-operation.
Safety results	NovoSorb® BTM recorded an event rate of 18.1%, compared with 21.6% for SOC. The primary safety composite occurred in 15 of 83 participants (18.1%) in the NovoSorb® BTM group and 8 of 37 (21.6%) in the SOC group (risk difference, -3.5 percentage points; 95% CI, -21.4 to 11.3; P=0.6487).