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ASX Announcement

PolyNovo U.S. Pivotal Trial – Clinical Study Report Finalised & PMA Submission Timeline Updated

- The Clinical Study Report for PolyNovo's U.S. pivotal randomised controlled trial has been finalised.
- Following updated FDA guidance effective from February 2026, the Company has proactively refined its PMA submission plan, including the sequencing of key manufacturing and validation activities.
- Certain activities originally planned post-submission will be included to strengthen the submission package, and align with updated regulatory expectations and PolyNovo's quality standards.
- The PMA submission is now expected before the end of calendar 2026.
- The revised timing does not impact current sales or clinical use of NovoSorb® products.

PolyNovo Limited ("**PolyNovo**" or the "**Company**"), a leading medical technology company transforming the management of complex wounds, provides an update on its U.S. pivotal randomised controlled trial (**RCT**) of NovoSorb® BTM and associated Premarket Approval (**PMA**) submission.

The pivotal RCT, funded by the Biomedical Advanced Research and Development Authority (**BARDA**), is designed to support an on-label indication for NovoSorb® BTM in full thickness burns in the United States.

The Clinical Study Report (**CSR**) has now been finalised based on 12-month patient follow-up data, which supports proceeding with the PMA submission.

In February 2026, updated FDA guidance relating to quality management system (**QMS**) information in PMA submissions came into effect. In response, PolyNovo undertook a comprehensive review of its submission plan, including the scope and sequencing of manufacturing and validation activities.

As a result of this review, certain activities originally planned post-submission will be included in the submission. This refinement is intended to strengthen the overall submission package, enhance inspection readiness, and align with evolving FDA expectations. The revised timeline gives the Company an opportunity to include the eighteen-month follow-up data into the final submission package. As the 18-month follow-up data is a prerequisite for the granting of the PMA, the associated FDA review timeline remains unchanged.

Consistent with this quality-focused approach, and following the recent appointment of Chief Quality & Regulatory Affairs Officer, Allison Myers, the Company has prioritised the completion, validation and documentation of key manufacturing and supplier processes to support a robust and review-ready submission. Accordingly, the Company now expects to submit its full PMA application before the end of calendar 2026.

PolyNovo notes that this adjustment to the submission timeline has no material impact on current revenue or sales. NovoSorb® products continue to be used by clinicians in accordance with existing approvals, and demand remains strong.

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PolyNovo CEO Bruce Peatey said:

"We are pleased to have reached this important milestone with the completion of the Clinical Study Report and acknowledge the significant effort of our clinical, quality and operational teams in getting us here.

We have taken a disciplined approach to ensure that every element of our PMA submission meets both current FDA expectations and our own quality standards. While this has resulted in an adjustment to timing, we believe it strengthens our submission and positions PolyNovo for long-term success in the U.S. Importantly, this has no impact on our existing commercial operations. Demand for NovoSorb® remains strong, and we continue to support clinicians and patients while progressing toward PMA submission."

This announcement has been authorised for release by PNV's Board of Directors.

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About PolyNovo®

PolyNovo (ASX: PNV) is a leading medical technology company transforming the management of complex wounds. Headquartered in Melbourne, Australia, it has international operations in the United States, United Kingdom, India, Hong Kong and Singapore and several other markets supported by distributor partners.

The proprietary NovoSorb® polymer is addressing significant unmet needs in wound care, as evidenced by its clinical adoption and patient outcomes, and the Company is leveraging the technology platform to develop new products and markets.

Achievements to date, including continued revenue growth, profitability, numerous clearances and registrations, as well as market leadership in several geographies, provide a strong foundation for continued growth.

For more information see polynovo.com

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