



11 September 2020

ASX Announcement

US FDA feedback on Pivotal Protocol

PolyNovo has received further formal feedback from the FDA on our Pivotal trial protocol. The US FDA has made some suggestions to improve the rigour of the trial with some design and administrative changes. PolyNovo's Clinical team and the BARDA team are working on FDA recommendations and to incorporate these changes over the coming weeks.

Managing Director, Paul Brennan said, *"This discussion on aspects of the trial management processes does not have any impact on our US sales or momentum with NovoSorb BTM."*

For further information please contact:

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

About NovoSorb®

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 programmable bio-resorption profile. NovoSorb® BTM is a dermal scaffold for the regeneration of the dermis when lost through extensive surgery or burn.

About PolyNovo®

PolyNovo is an Australian-based medical device company that designs, develops and manufactures dermal regeneration solutions (NovoSorb® BTM) using its patented NovoSorb® biodegradable polymer technology. Our development program covers Breast Sling, Hernia, and Orthopaedic applications. For further information and market presentations see www.polyново.com



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