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ASX Announcement

US FDA feedback on Pivotal Protocol

PolyNovo has received formal feedback from the FDA on its Pivotal trial protocol, including a request for some additional information including a formalisation of the review points through the trial.

PolyNovo's Clinical team and the BARDA team are working through a response to the FDA. This may delay the commencement of the trial recruitment.

Managing Director, Paul Brennan said, "*The request for further information from the FDA is positive and will give the trial clarity and ensure robust outcome measurements. We have the ongoing support of our BARDA colleagues, and we will announce funding arrangements immediately the FDA approve the IDE.*"

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

Further information:

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BARDA information

This project is being funded in part with federal funds from the U.S. Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under contract number HHSO100201500021C_ModP00006 For more information on BARDA go to www.phe.gov/barda.

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.

PolyNovo's NovoSorb® based BTM offers significant advantages compared with the current standard of care in its ability to generate a neo-dermis. BTM is scalable in production, robust yet easy to handle and apply, delivers outstanding cosmetic and functional outcomes. BTM provides a temporary scaffold allowing a new full dermis to be generated and then biodegrades leaving the patient's own tissue fully repaired.

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.polynovo.com

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