

10 August 2022

## ASX Announcement

# First Patient enrolled in Clinical Trial of NovoSorb® SynPath Treatment for Diabetic Foot Ulcers

PolyNovo announces that the first patient has been enrolled in its Randomised Controlled Trial (RCT) evaluating the clinical safety and efficacy of NovoSorb® SynPath for the treatment of chronic diabetic foot ulcers (DFU's).

SynPath is designed to promote organised healing by providing a porous network of biodegradable synthetic polymers which act as a template to support the proliferation of vital cells involved in tissue repair. Chronic wounds advance quickly and, if not treated promptly may necessitate amputation.

The randomised control trial (RCT) on 138 subjects focuses on the use of SynPath to treat chronic diabetic foot ulcers. Given the number of people with Diabetes and the number of DFU patients, recruitment is anticipated to be completed by April 2023. The trial is being conducted over eight sites in the US including The Center for Clinical Research Inc., San Francisco, California and Barry University, Miami, Florida. The primary efficacy endpoint is to measure the percentage of ulcers fully healed at 12 weeks.

Diabetic foot ulcers affect more than 300,000 Americans annually and account for more than US\$9 billion in annual expenditures. Globally, the diabetic foot ulcer addressable market was valued at \$US 7.03 billion in 2019 and is projected to reach \$US 11.05 billion by 2027.

Chief Executive Officer, Mr. Swami Raote said *"We are thrilled to have initiated our trial utilising NovoSorb SynPath for the treatment of chronic diabetic foot ulcers. This critical milestone has us on the road to help more patients with non-healing chronic wounds and to further investigate the benefits of our novel technology for these wound types. SynPath is leveraging our successes in the acute care setting with NovoSorb BTM and allows us to expand our offering to the outpatient setting for clinicians dedicated to changing the lives of their patients."*

Chairman, David Williams said *"Many surgeons are already successfully using BTM for the treatment of DFUs, but the time has come for a specific product to treat DFUs and venous leg ulcers. The trial will provide valuable data for surgeons and importantly, also put us on the path to reimbursement."*

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. 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 Orthopedic applications. For further information and market presentations see [www.polynovo.com](http://www.polynovo.com)

## **About NovoSorb®**

NovoSorb® is a novel range of bio-resorbable polymers that can be produced in many formats including, film, fiber, 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.