



23 August 2021

ASX Announcement

Hernia product update

PolyNovo is pleased provide an update on our hernia device and path to market. Syntrel® is our new novel hernia device composed of NovoSorb® foam that is ultrasonically welded to a new NovoSorb film to create a 100 percent bioabsorbable hernia repair device. The film provides strength to the repaired hernia whilst the foam promotes native tissue regeneration within the foam scaffold.

PolyNovo has commenced a pre-clinical study in the US to demonstrate bio-absorption rates, biocompatibility, toxicology profile, and efficacy in hernia repair. This study will provide progressive data at three-month intervals. PolyNovo is assisted by two external regulatory consultants and advice from the US FDA, to ensure we have sufficient data to submit a strong dossier supporting hernia applications. Data generated from this study will also support future product filings that utilise the NovoSorb technology.

Unlike the film used on NovoSorb BTM, which requires delamination, the NovoSorb film and NovoSorb foam are designed to be absorbed in the body. The Syntrel device will provide reinforcement to the hernia repair site, allowing for optimal tissue regeneration. The resorbable NovoSorb film was originally developed to provide sufficient long-term mechanical strength for Syntrel, but will also be deployed in a portfolio of other hernia repair devices, as well as future product applications including breast reconstruction, sports medicine, and other clinical applications where mechanical strength is a key requirement.

Syntrel product for the trials and beyond is being manufactured at our Port Melbourne facility.

We anticipate filing the Syntrel dossier with the US FDA for a 510(k) submission in circa March 2023 and gaining approval to sell in the US by August 2023.

Managing Director of PolyNovo, Paul Brennan said, “Development of Syntrel means *we now have a new polymer and film formulation, film extrusion, production capacity, and developed ultrasonic welding as new technology skillsets within the business. Combined with the pre-clinical study data these new skillsets will allow us to quickly develop an exciting range of other new devices.*”

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

Further information:

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