PolyNovo Limited
ABN 96 083 866 862

2/320 Lorimer Street
Port Melbourne
VIC Australia 3207

P +61 (0) 3 8681 4050
F +61 (0) 3 8681 4099

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ASX Announcement

Results of NovoSorb® BTM CE Mark Burn Trial

PolyNovo is pleased to announce the results of the CE Mark Burn Study to assess the safety and performance of NovoSorb® Biodegradable Temporizing Matrix (BTM) in the treatment of patients with deep burn injuries. This trial was a prospective, multicentre, single-arm, open label, pre-market study conducted in Australia and France where NovoSorb® BTM was used as the investigational device.

This study is separate to the BARDA funded feasibility study, announced 16 March 2020.

The burn trial commenced in 2015 when a successful clinical trial was deemed essential for making an ARTG and CE Mark application. However, during the study's progress the Government introduced the Priority Review Designation pathway which gave PolyNovo the chance to gain regulatory approval via an alternative path. In August 2019 PolyNovo gained ARTG listing for NovoSorb BTM that included a burn indication. This was before the burn trial was complete. With the ARTG listing and supporting clinical data from around the world PolyNovo submitted for CE Mark approval still ahead of the trial completion. The Company achieved CE Mark approval on 13 December 2019 but continued with the burn trial.

Notwithstanding, the Company has an ARTG and CE burn indication, the trial is still valuable as a means of demonstrating and reinforcing, scientifically, the benefits that NovoSorb BTM offers. The trial provides robust clinical evidence supporting NovoSorb BTM use in full thickness burns and provide supporting evidence for reimbursement where required outside of the US e.g. in South Africa.

The 12-month clinical outcomes study recruited 30 patients with burns across five study sites in Australia and France:

- The Alfred Hospital, Melbourne, Australia
- Royal North Shore Hospital, Sydney, Australia
- Concord Hospital, Sydney, Australia
- Royal Brisbane and Women's Hospital, Brisbane, Australia and
- St Anne's Hospital, Toulon, France.

The study assessed the integration of BTM into the wound bed after application, wound healing after skin grafting and how the wounds healed over time. The safety of patients was also monitored throughout the study.

Of the 30 patients recruited, BTM was applied to 100 individual burn wounds and 22 patients completed the study. Four patients died due to serious adverse events not related to BTM and four patients were lost to follow-up before study completion.

The primary endpoint for this study was the percentage of split-thickness skin graft take (% SSG Take) over BTM within 7 to10 days after grafting as a proportion of the total amount of BTM applied.

The concept of “take” is commonly used in wound treatment outcome studies, where “take” describes the percentage of device or skin graft incorporated into the wound bed. Primary endpoint data was available for 26 patients, aged 18 to 70 years with deep dermal/full thickness burn injuries of mean size 47.5% total body surface area (TBSA) and a range of 25% to 70% TBSA.

The %SSG Take had a mean of 81.9% and a median of 88.6%. Independent statistical analysis compared the %SSG Take to a target value of 77% derived from results published in the literature for other dermal matrices. After transformation to allow for the non-normal distribution of the data, the mean %SSG Take over BTM was significantly greater than 77% ($p = 0.031$) thereby demonstrating superiority.
Wound closure was assessed at 7 to10 days after skin grafting and 3, 6 and 12 months after BTM application with mean values of 90.4%, 99.9%, 99.8% and 100.0%, respectively.

These results provide further clinical evidence supporting the role of BTM in providing temporary wound closure and reconstruction of a dermis for subsequent wound healing. The skin grafts used by the surgeons to provide final closure were considered largely incorporated into the new wound bed formed by BTM. There were high rates of early wound closure and the BTM-treated wounds remained robust as they continued to heal and mature.

The percentage of BTM take (% BTM Take) at the time of skin grafting as a proportion of the BTM implanted was one of the secondary endpoints. The results for the % BTM Take were a mean 88.6% and a median of 95.0%, demonstrating that there was effective integration of the BTM assessed at the time of sealing membrane removal and skin grafting.

No new risks were identified in this study. As may be expected in patients with severe burns, there were infections at both BTM and non-BTM treated wounds, being reported for 10 patients during BTM integration and 1 patient after skin grafting. Three patients with four serious device-related events (infections) were reported; all had treatment given and all resolved with successful skin grafts.

PolyNovo Chief Executive Officer, Paul Brennan, said*, “The results of this full thickness burn trial reinforce what surgeons across the world are reporting; That BTM is “robust”, a relatively simple product to use, performs extremely well in the most challenging of case applications and seems to be resilient even if there is an infection. This study supports our CE Mark claims and adds to the high level of data that clinicians request to support their decisions to make BTM their preferred choice of dermal matrix. Achieving a superior result to the benchmark is often demonstrated by our clinical and functional outcomes reported by surgeons and patients around the world.”*

PolyNovo Chairman, David Williams, said*, “While the burn trial was ultimately not needed for ARTG or CE approval, the excellent results, while expected, will strengthen our marketing to surgeons worldwide.”*

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

Further information:

Paul Brennan
Chief Executive Officer
Mobile +61 427 662 317

David Williams
Chairman
Mobile +61 414 383 593

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.polynovo.com.au