

13 December 2019

ASX Announcement

CE Approval

PolyNovo is pleased to announce NovoSorb BTM has been granted a certificate of conformance (CE Mark) approval for sale throughout UK/Ireland and the European Union.

NovoSorb BTM has been approved for use in all full dermal loss procedures:

- Full thickness burns
- Trauma
- Reconstructive / wide excision surgery
- Revision of scar
- Venous leg Ulcers
- Diabetic foot ulcers
- Pressure injuries
- Any loss of dermis needing repair.

PolyNovo will now need to file documents with each European market, however this is a routine administrative function that will not delay sale and shipment.

PolyNovo has prepared the market in anticipation of this approval and we look forward to reporting sales success in the near term. We already have strong brand recognition and awareness of our clinical success through various international conferences, publications and peer to peer interactions.

PolyNovo displayed at the British Burn Association (BBA) meeting in Leeds in May, the European Burn Association meeting in Helsinki in September, BAPRAS plastic surgery meeting in Bournemouth in July, at the Harrogate Wound Conference in October and the BAPRAS plastic surgery meeting in Monaco this month. These conferences gave us the opportunity to discuss NovoSorb BTM with a wide range of surgeons, nurses and allied health staff from the many European countries. This market preparation means we anticipate reporting first sales in the near future.

PolyNovo has had a UK/Ireland salesperson for the past year to prepare for CE approval and we are currently recruiting a further two salespeople. There is considerable interest already from doctors in the National Health Service wanting to evaluate NovoSorb BTM as soon as possible.

We previously announced PMI as our distributor for the Germany, Austria and Switzerland. The PolyNovo marketing team have provided training, marketing resources and clinical support for the PMI team and have visited surgeons in the region. We will be supporting a launch event for PMI in Austria in January 2020. PMI have indicated they already have 14 hospitals ready to evaluate NovoSorb BTM.

PolyNovo CEO, Mr Paul Brennan said, *"This is watershed moment for PolyNovo. Our global regulatory approvals have expanded significantly with this certification. Our early preparedness in UK/Ireland and*

DACH should mean a shortened timeline to booking our first sale. We also believe CE approval will fast track regulatory approval in a number of other countries including several in South East Asia”.

PolyNovo Chairman, Mr David Williams said, “We are confident we will have early sales in the UK/Ireland and in Germany through PMI. We will now quickly expand our direct sales force in other parts of the EU.”

Further information,

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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

About PolyMedics®

Headquartered in Germany, PMI has become a market leader for biosynthetic epidermal skin substitutes. PMI is committed to offering the most innovative solutions to its burn and wound care customers. PolyMedics is the manufacturer and marketer of Suprathel wound dressing. Suprathel is an absorbable, microporous membrane and alloplastic skin substitute for the treatment of wounds, split-skin donor sites and burns. <http://www.polymedics.de>