PolyNovo Limited
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29 September 2015

PolyNovo awarded BARDA contract for clinical burn trials

- US$8.2M contract award for base period
- 10 patient clinical trial for PolyNovo's Biodegradable Temporising Matrix (BTM) for Full Thickness Burns conducted at 4 US based Burn Centres
- Additional funding of US$18M for at BARDA's discretion upon successful completion of base period milestones for a further 150 patient trial
- Successful completion of the BARDA contract results in a fully funded PMA pathway for the FDA valued at circa US$26M

The US based Biomedical Advanced Research and Development Authority (BARDA) is a division of the US Dept. of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response has agreed to fund a clinical research program for PolyNovo's Biodegradable Temporising Matrix (BTM).

BARDA supports advanced research, development, and procurement of medical countermeasures against American security threats and against a broad array of public health threats. Many mass casualties result in burn injuries which have long treatment and rehabilitation pathways imposing significant resource demands on the health system. Full thickness dermal repair is the ultimate goal of all burns treatment.

PolyNovo's NovoSorb™ based BTM offers significant advantages compared with the current standard of care in its ability to generate a neodermis. 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. PolyNovo provides BARDA an opportunity to explore, through rigorous clinical testing, the delivery of a new approach to mass burn management whilst improving the healed outcomes. With this contract BARDA will fund US-based preclinical studies, regulatory activities, manufacturing, testing and a feasibility trial with 10 patients at 4 major burns centres in the US.

The base period contract budget is US$8.2M on a reimbursement for activity basis. This non-dilutive funding will enable PolyNovo to begin Food & Drug Administration (FDA) Pre-Market Approval (PMA) pathway in the US. PPD, a leading global contract research organization (CRO), has been selected to conduct the feasibility trial. BARDA selected PPD in 2014 as a contractor for the Medical Countermeasure Clinical Studies Network (MCM CSN) to design and conduct clinical studies needed to develop medical countermeasures for public health emergencies.

At the conclusion of the base period BARDA has the right to grant an option to conduct a pivotal trial of a further 150 patients. This second trial is required to achieve a FDA PMA for the use of our BTM in full thickness burns.

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Chief Executive Officer, Paul Brennan said, "*This is a very exciting step towards achieving a PMA approval. We will work closely with BARDA and the FDA to prove our BTM has the capability to treat a large number of burns victims in the event of a disaster. Being a fully synthetic product our capacity to quickly provide large volumes of product in response to a disaster makes our product attractive in emergencies and acute medical treatment".*

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BARDA Statement:

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For more information on BARDA go to www.phe.gov/barda