

**MEDIA RELEASE – UNDER EMBARGO UNTIL 11:00AM AEDT THURSDAY 26TH OCTOBER 2017**

## **Australian-first manufacturing and hands-on training facility to produce medical products for early stage human clinical trials receives funding from MTPConnect’s Project Fund Program**

**Thursday, 26 October 2017** -: MTPConnect - the Medical Technologies and Pharmaceuticals Industry Growth Centre today announced it will provide \$500,000 to establish a clinical manufacturing and training facility over two years, with proposed matched funding coming from the Translational Research Institute (TRI) and Vaxxas.

“With the benefit of MTPConnect funding, this project will establish a medtech and pharmaceutical manufacturing training hub that enables external parties the opportunity of hands-on training, using state-of-the-art facilities and equipment,” said Charles Ross, Head of Clinical Operations and Supply at Vaxxas.

“Additionally, the project will establish a “turn-key” early stage clinical product manufacturing facility, at the Translational Research Institute (TRI) in Brisbane, which can be used for a wide-range of clean to sterile medical device, biotechnology and pharmaceutical products.”

Access to cleanroom manufacturing facilities and personnel for the manufacture of early stage clinical trial material is very limited in Australia and this is considered a missed opportunity. This project aims to address this gap by establishing a manufacturing and training facility that can provide a smooth translation of investigational medical products from research through to early human clinical trial supply.

“We will begin by upgrading the existing clinical manufacturing cleanroom facility located at the TRI to a standard of current Good Manufacturing Practice (cGMP) to allow for the manufacture of early stage clinical trial product for Phase I and Phase II studies,” said Michelle Richards, TRI Director of Building Operations

“The facility will be upgraded to maximise manufacturing flexibility allowing for the manufacture of aseptic products such as injectables; assembly of medical devices; combination products such as drugs and devices; nanoparticle systems; sterile liquid filling; diagnostics; and a wide range of biologics requiring different containment levels.”

The next stage is to develop a road map for users via links to the contract analytical laboratory Eurofins AMS so environmental and product testing can be outsourced; specialist consultant PharmOut to provide cGMP, validation and quality consulting; and access to the TRI Clinical Research Facility.

“The road map will leverage off our existing Quality Management System (QMS) for manufacture of clinical product and would give access to experienced, trained personnel from within both Vaxxas and the TRI,” said Charles Ross.

The project will also address the barrier of a lack of trained staff that understand cGMP manufacturing processes and Quality Management Systems. External parties from all over Australia will have the opportunity to learn in a fully operational state-of-the-art small scale GMP production facility. TRI and other university researchers will have access to training to provide industry experience and provide a pool of trained staff available for casual employment as cleanroom operators.

MTPConnect's Project Fund Program is a competitive, dollar-for-dollar matched funding program investing in big, bold ideas to improve the productivity, competitiveness and innovative capacity of Australia's medical technology, biotechnology and pharmaceutical sector. MTPConnect is supported by the Australian Government's Industry Growth Centres Initiative.

This year, MTPConnect has selected 20 national MTP projects to receive \$7.385 million in funding over two years with proposed matched funding of \$15.2million coming from the sector. Sue MacLeman, CEO of MTPConnect, said, "MTPConnect is focused on harnessing Australia's world-class research to seize more commercialisation opportunities and accelerate growth. As part of our mission, we are funding big, bold ideas that will deliver results on a national scale, have sector-wide impact, and are aligned with the Sector Growth Priorities we have identified in our 10-year Sector Competitiveness Plan."

For more information on MTPConnect's Project Fund Program and the successful applicants, visit: [www.mtpconnect.org.au/2017projects](http://www.mtpconnect.org.au/2017projects)

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#### **About MTPConnect**

MTPConnect was formed as an industry-led independent not-for-profit organisation in November 2015 as part of the federal government's Industry Growth Centres Initiative to accelerate the rate of growth of the MTP sector to achieve greater commercialisation and establish Australia as an Asia-Pacific hub for MTP companies.

The MTPConnect Head Office is located at the New Horizons Building at Monash University, co-located with CSIRO and industry. There are also key hubs at the University of Sydney's Institute of Biomedical Engineering and Technology and the Medical Device Research Institute at Flinders University at Tonsley in Adelaide.

#### **Media inquiries:**

##### **TRI clinical manufacturing and training hub**

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