

In a rare achievement for the Australian biotechnology industry, a new potential cancer therapy developed in Australia has entered clinical trials in Melbourne. The drug invented by scientists in Cancer Therapeutics CRC will be taken into the first phase of clinical testing by Melbourne-based ASX-listed biotechnology company Amplia Therapeutics. If the clinical trials prove successful, this important discovery could be used to treat pancreatic cancer – the disease that led to the death of the prominent US Supreme Court Justice Ruth Bader Ginsburg in September this year.

The therapeutic, known as AMP945, was invented, and has now entered into its first clinical trial, in Australia. A team led by Cancer Therapeutics CRC, involving scientists from Monash Institute of Pharmaceutical Sciences, Peter MacCallum Cancer Centre, St Vincent’s Institute of Medical Research, the Walter and Eliza Hall Institute of Medical Research and Australia’s national science agency, CSIRO, created AMP945 and Amplia Therapeutics has subsequently guided AMP945 from lab development into clinical trials. It has been commented that Australian research often struggles to progress from laboratory discoveries into commercial products and outcomes, despite punching well above its weight in early stage medical research. The Cancer Therapeutics CRC has been a shining example of the strength of collaborative research in overcoming this gap. Two drug programs that were developed in the Cancer Therapeutics CRC have already been licensed to multinational pharmaceutical companies (Merck, Sharpe & Dohme and Pfizer) in 2016 and 2018 in deals with a headline value of close to US\$1 billion.

Lisa Dube, Acting CEO of Cancer Therapeutics CRC commented: “We are very excited that this is the first Cancer Therapeutics CRC drug to enter into human trials, especially as it was created in Melbourne and will move to clinical trials in Melbourne. This is a wonderful outcome for the local drug discovery community and is testament to the high quality of researchers within our network”.

The trial, which began in Melbourne on 8 October, will test for safety in 64 healthy volunteers. Data from the trial is due in the first half of 2021 and is expected to support phase 2 clinical trials in patients with hard to treat cancers and fibrotic diseases, including pancreatic cancer and idiopathic pulmonary fibrosis. Due to its promising preclinical data, Amplia has already been awarded Orphan Drug Designations for both these diseases by the US Food and Drug Administration, which entitles Amplia to ongoing assistance and reduced fees from the regulator.

Dr John Lambert, CEO of Amplia Therapeutics commented “Pharma companies work for years to find new drugs for unmet medical needs and the team at the Cancer Therapeutics CRC deserve enormous credit for their discovery of AMP945. Amplia’s role is now to steer AMP945 through the stages of clinical development and we are delighted to start this journey here in Australia. This is the next big step on the path that we hope will one day see AMP945 approved for use by the patients who need it.”

AMP945 targets a protein called Focal Adhesion Kinase, or FAK, that controls the formation of fibrotic tissue in the body, in a process called fibrosis. Fibrosis is important for providing both structural integrity to many organs in the body, and in healing after injury. However, when fibrosis is uncontrolled, it can result in a build-up of stiff scar tissue that can prevent organs in the body from functioning properly, causing disease. Many cancers also form a fibrotic tissue shield in order to protect them from the immune system, this can also hinder the drug's ability to treat the cancer. AMP945 has been shown, in preclinical testing, to act on FAK potentially enabling it to both treat and prevent fibrotic diseases, as well as make cancers that were previously resistant to treatment responsive to drugs.

Pancreatic cancer is one of the 10 most diagnosed cancers in Australia in both men and women and has one of the lowest survival rates out of all cancer types. Todd Harper, CEO of Cancer Council Victoria said research into cancers with such low survival rates, such as pancreatic, is vital to give patients hope. "Sadly, pancreatic cancer has a five-year survival rate of just 10.7%. It is only through research that we will find targeted and effective new treatments to save lives."

Contact Details

John Lambert

CEO and Managing Director, Amplia Therapeutics

john@ampliatx.com

0409 525 259

Lisa Dube

Acting CEO, Cancer Therapeutics CRC

lisa@cancercrc.com

0432 362 075



About Amplia Therapeutics

Amplia Therapeutics Limited is an Australian pharmaceutical company (ASX:ATX) advancing a pipeline of Focal Adhesion Kinase (FAK) inhibitors for cancer and fibrosis. FAK is an increasingly important target in the field of cancer therapy and Amplia has a particular development focus in fibrotic cancers such as pancreatic and ovarian cancer. FAK also plays a significant role in a number of chronic fibrotic diseases, such as idiopathic pulmonary fibrosis (IPF).



About Cancer Therapeutics CRC

Cancer Therapeutics CRC is an oncology focused small molecule drug discovery and early development biotechnology group, established under the Australian government's Cooperative Research Centre Program. Cancer Therapeutics CRC's unique partnership model leverages the capabilities and expertise of its Industry Participants with several of Australia's pre-eminent Medical Research Institutes and Universities. The CRC Participants are the Children's Cancer Institute, CSIRO, Griffith University, Melbourne Health, Monash University, National Cancer Centre Singapore, Peter MacCallum Cancer Centre, Walter & Eliza Hall Institute of Medical Research, Clinical Genomics, SYNthesis Research, CTxONE, Cancer Trials Australia, Medicines Development for Global Health Limited, Cancer Council of Victoria, Syneos Health and the Victorian Comprehensive Cancer Centre.



Australian Government

Department of Industry,
Innovation and Science

Business

Cooperative Research
Centres Program

About the CRC Program

The Federal Government's Cooperative Research Centres Program was designed to foster collaborative research programs between academia and industry partners in order to solve industry-identified issues. Australia's network of CRCs operates across all sectors of Australia's economy and society. Further information about the CRC Program is available at www.business.gov.au