MEDIA RELEASE

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Australian-made treatment for pancreatic cancer – clinical trial milestone

Medical researchers from Garvan Institute of Medical Research and Australian biotechnology company Amplia Therapeutics Ltd are today marking an important milestone in the clinical trial program for a world-first potential treatment for pancreatic cancer.

The ACCENT trial, a Phase 2 clinical trial for people with advanced pancreatic cancer, has now commenced in Australia. ACCENT will test the efficacy of a therapeutic known as AMP945, which targets a protein called Focal Adhesion Kinase (FAK), one of the factors that controls the formation of fibrotic tissue in the body (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 to protect them from the immune system, which can then hinder the ability for a drug to treat cancer.
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> AMP945 has been shown to act on FAK, offering the potential for it to both treat and prevent fibrotic diseases, as well as to potentially make cancers that were previously resistant to treatment responsive to drugs.

This milestone signals a significant achievement for collaborators in the Australian biotechnology sector and new hope for people with pancreatic cancer – a devastating illness with a five-year survival rate of just 5% or below 3% if the cancer has already metastasised.

AMP945 was invented in Australia, as part of the former Cancer Therapeutics Cooperative Research Centre. Its discovery and early development involved 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 the CSIRO.

Amplia Therapeutics (Amplia) is now working closely with leading medical research institute, Garvan Institute of Medical Research (Garvan) to guide AMP945 from lab development into patients.

"Reaching a Phase 2 Clinical Trial milestone for AMP945 represents an important achievement for Australia's medical research and biotechnology sector, signalling the translation of a novel therapy – discovered and developed by Australian scientists – into a tangible and potentially life-saving treatment for people fighting pancreatic cancer," said Amplia CEO and MD, Dr John Lambert.

"With collaboration in our DNA, Amplia is delighted to be working with the Garvan Institute's Professor Paul Timpson and his team, to refine and prepare this potential therapy for patients as part of our Phase 2 Clinical Trial program."

Garvan's Professor Paul Timpson connected with Amplia in 2019, identifying a common interest in the drug target, FAK. Professor Timpson's lab was undertaking ground-breaking research into how FAK impacts pancreatic cancer, while Amplia was establishing a clinical trial protocol for AMP945, with plans to test it in cancer patients. Ideal territory for a research partnership.

Garvan researchers have already shown that pre-treating or 'priming' pancreatic tumours with a FAK inhibitor alters the tumour environment in a way that may improve how effective chemotherapy is for pancreatic ductal adenocarcinoma, one of the most aggressive forms of pancreatic cancer. Now, this research is ready to be translated and tested as part of Amplia's ACCENT clinical trial in patients with advanced pancreatic cancer.

"In preclinical models, our team at Garvan has been able to enhance the response of pancreatic cancer to chemotherapy by reducing the stiffness and density of the connective tissue around the tumour known as the stroma. This research has paved the way towards the ACCENT Trial, which will assess whether these findings translate into a clinical benefit for patients," said Professor Paul Timpson, Head of the Invasion and Metastasis lab at Garvan.

"Partnerships such as this one, where our cutting-edge science meets the drug development expertise of companies like Amplia, is how new drugs transition from the laboratory to patients."

> Selected members of the press will be invited to meet with Garvan and Amplia to learn more about AMP945 – a potentially life-saving therapy – and to mark the commencement of the Phase 2 Clinical Trial program. Together with a former carer of someone with pancreatic cancer.

"We have spent considerable time and resources getting AMP945 to its current stage of development and it is with great anticipation that we now bring this potential drug to patients. We are also pleased to have approval to run the ACCENT trial with first-line pancreatic cancer patients, as we expect these patients to be most likely to benefit from this novel treatment approach," said Amplia CEO and Managing Director, Dr John Lambert.

AMP945 Phase 2 Clinical Trial Program

The AMP945 Phase 2 Clinical Trial is now recruiting people who have been diagnosed with advanced pancreatic cancer, specifically those patients who have inoperable pancreatic cancer or whose cancer has spread to other parts of the body. Patients will be initially recruited through treating doctors at hospitals in Melbourne and Sydney, and the trial is expected to expand to other countries as it progresses. In total, it is expected that the trial will recruit approximately 62 participants. **Details about the trial, including the participating sites, can be found at ampliatx.com/accent (media is encouraged to include this in the story to direct patient enquiries).**

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