

Edition 01: July 2023

# INVESTOR NEWSLETTER

For personal use only

**02** Note from CEO and MD, Dr Chris Burns

**03** ACCENT Clinical Trial Update

**04** FOLFIRINOX Data

**05** What's in a name? Meet Narmafotinib

**05** Wound healing with CSIRO

**06** Media Update | Amplifying ATX

  
AMPLIA  
THERAPEUTICS

# Note from Dr Chris Burns

## ATX CEO and MD

Since transitioning from a Board role to commence as Amplia Therapeutics' CEO and MD in December 2022, I have been inspired by the focus and energy underpinning the team during an important period of clinical and commercial growth.

Amplia is entering a transformational chapter for an Australian-made biotechnology company. We have at our core a lead program which was the result of excellent science from the team at the Cancer Therapeutics CRC. Since licensing the drug, we have undertaken collaborative research with some of the world's best translational scientists and laboratories, to explore the potential of the drug in preclinical, and now clinical, studies.

**The results of this work to date, are truly exciting.**

Our lead Phase 2 clinical program for AMP945 is now actively recruiting people who have been diagnosed with advanced pancreatic cancer, across three states in Australia.

In addition, we recently disclosed new preclinical data from an animal model of pancreatic cancer, showing that AMP945 in combination with the FOLFIRINOX chemotherapy regime, significantly prolongs survival. This data, from our close collaborators at the Garvan Institute in Sydney, was reported at the recent American Society of Clinical Oncology meeting held in June in Chicago, USA.

Amplia is also pleased to be collaborating with CSIRO - via grant funding from the Federal Government's Innovation Connections scheme - to help develop formulations of our FAK inhibitors for application directly to wounds that may aid healing and reduce scarring.

As we celebrate these achievements and others, I encourage you to stay engaged with our Company on [LinkedIn](#) and [Twitter](#), which includes regular updates from our Company and other broader industry headlines too. You will also hear from us via a bi-annual newsletter wrap-up - welcome to this, our first edition.

**Thank you for your ongoing support. We look forward to sharing more positive news with you in the coming months.**

**Dr Christopher Burns**  
CEO & MD





# ACCENT Clinical Trial gains momentum

**Amplia's Phase 1b/2a clinical trial for people with advanced pancreatic cancer commenced in Australia in August 2022 – the ACCENT trial – and is now recruiting across sites in Brisbane, Sydney and Melbourne, Australia.**

ACCENT is testing the efficacy of Amplia's lead therapeutic, AMP945, which targets a protein called Focal Adhesion Kinase (FAK), in combination with the two standard-of-care therapies for advanced pancreatic cancer, gemcitabine and nab-paclitaxel (Abraxane®).

The trial is a single-arm open-label study conducted in two stages. The first, Phase 1b stage of the trial, is to select an optimal dose of AMP945 by assessing the safety, tolerability, pharmacokinetics, pharmacodynamics and preliminary efficacy of AMP945 when dosed in combination with gemcitabine and nab-paclitaxel in first-line patients with advanced pancreatic cancer. The second, Phase 2a stage of the trial is designed to perform an assessment of the optimal dose of AMP945 (selected in the Phase 1b stage) in combination with gemcitabine and nab-paclitaxel.

**By inhibiting the FAK protein with our drug we believe we deliver a critical 'one-two' blow to the cancer: firstly, as FAK is overexpressed and over-active in pancreatic cancer cells, inhibition of FAK should limit the cells' ability to proliferate and migrate; and secondly, FAK inhibition should block the formation of fibrotic tissue around the tumour allowing for greater penetration and activity of concomitantly administered chemotherapeutic drugs.**

Patient recruitment is continuing and we are currently dosing patients in our third cohort in the Phase 1b dose-escalation stage of the trial.

To date we have dosed 12 patients, 2 of whom are still undergoing their first cycle of treatment. Importantly, the 10 patients who have been dosed with drug for the first full cycle of treatment (28 days), in consultation with their oncologist, elected to stay on the drug. As noted in previous ASX announcements, the drug has appeared safe and well tolerated for the first two dose cohorts and we are currently collecting safety data for cohort three. The dose escalation phase of the study is not powered for efficacy readouts; however, we have been encouraged by the data to date and will report on this further once a dose for the Phase 2a stage of the trial has been identified.

*"Recruiting to a Phase 2 clinical trial represents an exciting milestone for AMP945 and Australia's medical research and biotechnology sector at large. We are in the midst of translating a novel therapy – discovered and developed by Australian scientists – into a tangible and potentially impactful treatment for people fighting pancreatic cancer,"* said Amplia CEO and MD, Dr Chris Burns.

## Recruiting NOW

The AMP945 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, Sydney, and Brisbane.

**Learn more: [ampliatx.com/accent](https://ampliatx.com/accent)**

# FOLFIRINOX Data

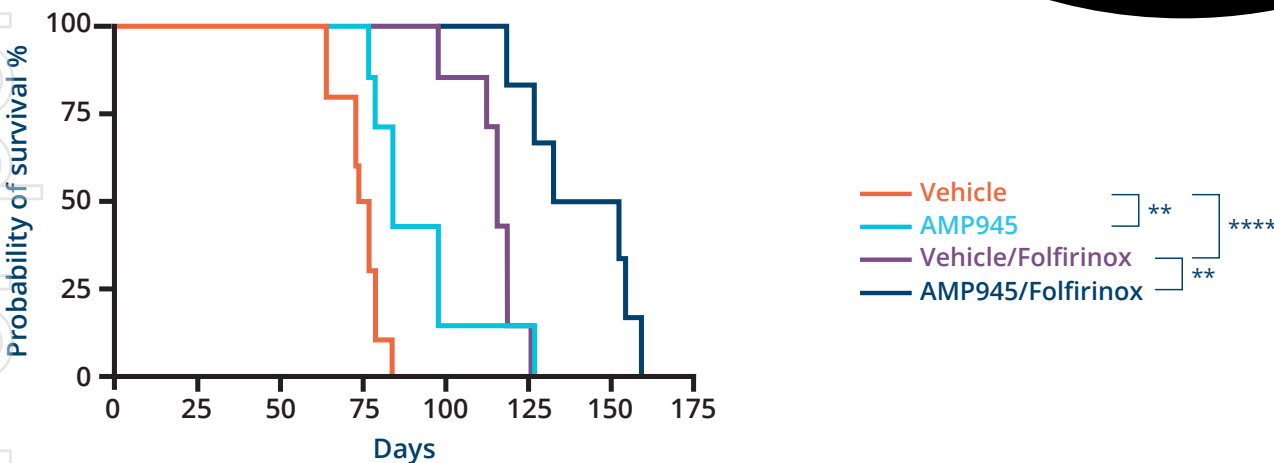
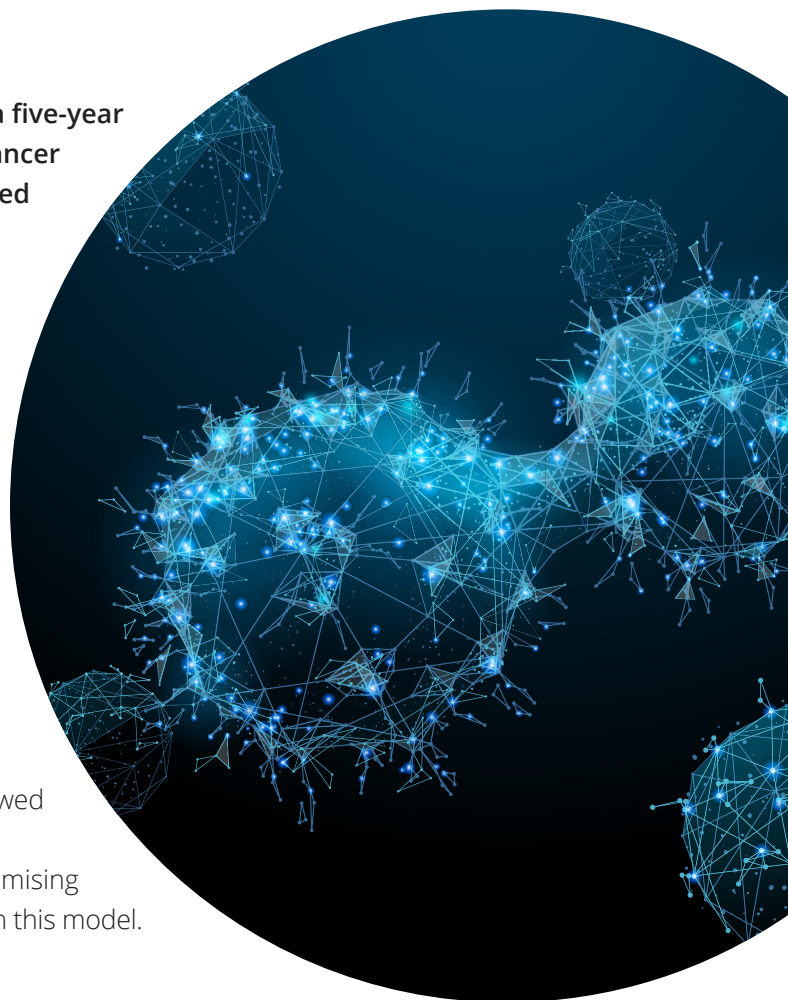
## Further hope in the fight against pancreatic cancer

Pancreatic cancer is a truly devastating illness with a five-year survival rate of just over 10%, and below 3% if the cancer has already metastasised. Amplia is resolutely focused on leading targeted medical research to improve available treatments.

Recently, the team shared good news - new preclinical data showing the efficacy of its highly selective FAK inhibitor AMP945 in an animal model of pancreatic cancer, when used in combination with FOLFIRINOX treatment.

FOLFIRINOX, a combination of four chemotherapies, is a widely-used treatment for pancreatic cancer in the US, Canada and most European countries.

The study, conducted in the laboratory of Prof. Paul Timpson at the Garvan Institute of Medical Research in Sydney, found that AMP945 in addition to FOLFIRINOX in a mouse model of pancreatic cancer showed a statistically significant increase in survival compared to those treated with FOLFIRINOX alone – a particularly promising outcome given the aggressiveness of the cancer growth in this model.



**In light of this data, Amplia has filed a patent application to cover the use of FAK inhibitors, and particularly AMP945, in combination with FOLFIRINOX and related chemotherapy regimes in the treatment of cancer.**

# Meet narmafotinib

**What's in a name? For Amplia's lead FAK inhibitor AMP945, plenty.**

The Company recently announced that AMP945 has been granted the International Nonproprietary Name (INN) of 'narmafotinib'.

The process of assigning a name to a drug compound involves an extensive review procedure prior to approval. This review considers similarity to existing drug names, ease of pronunciation across multiple languages, language review for accidental meaning, and finally a period for parties to voice objections regarding the proposed name.

Approval of the name narmafotinib signals to potential partners and collaborators that Amplia is leading a long-term clinical program, with promising clinical and commercial prospects. **A good name, with good news.**



## Wound healing with CSIRO



Australia's national science agency, CSIRO, is highly regarded for leading the way for innovation, science and technology.

Amplia is now pleased to be collaborating with CSIRO - via grant funding from Innovation Connections - to develop formulations of its FAK inhibitors for topical application.

Amplia will work with researchers at CSIRO to help develop formulations that could be applied topically to wounds and burns which may aid healing and reduce scarring.

There is growing evidence that inhibition of FAK in the skin may accelerate wound healing and limit scar formation, so this is an important opportunity for collaborative learning and innovation.

With the global wound healing market estimated to be in excess US\$20b, this body of work could also be very good news for ATX investors in future. **Stay tuned.**

[Click here](#) to read the Company's full ASX announcement.

# Amplifying ATX in the media

## Media highlights from the year to date

### Yakup Newspaper - Korea

Amplia COO, Dr Rhiannon Jones, recently attended BIO KOREA - one of Asia's largest partnering conferences for the global biotech industry.

As part of the Global Victoria and AusTrade delegation, she gained insight into South Korea's life science ecosystem, together with opportunities for research collaborations, business partnerships, clinical trial attraction and commercialisation.

Rhiannon was interviewed by Yakup Newspaper, which covers pharmaceutical industry news in Korea. As part of a Q&A, she commented on the prospect for conducting clinical trials in Korea:

*"Conducting a phase 2 clinical study in Australia and Korea is a very attractive prospect for us. Korean hospitals are highly respected sites for clinical research, with world-class standards and infrastructure, good recruitment rates for pancreatic cancer trials, coupled with engaged and enthusiastic investigators. We also share a common standard of care, which differs to that in the US and some European countries."*

[Link to Yakup article](#)

### Brisbane ACCENT Trial Launch - ABC

Amplia CEO and MD, Dr Chris Burns, spoke with Craig Zonca and Loretta Ryan on ABC Radio's Brisbane Breakfast program to discuss QLD recruitment for Amplia's ACCENT trial, and how patients can get involved. The story was also covered by ABC online.

[Click here to read the ABC story online](#)



### The Courier Mail

The Courier Mail Health Reporter, Jackie Sinnerton, published an article titled "New hope for advanced pancreatic cancer patients in clinical trials" - featuring pancreatic cancer patient and passionate advocate for medical research, Judi Adams.

[Click here to read the story](#)



### Channel 9 News

The ACCENT trial was featured on Channel 9 News in Brisbane. The segment featured clinical trial investigator, Dr Warren Joubert, as well as an interview with pancreatic cancer patient, Judi Adams.

Dr Joubert said: *"In cancers where we have limited options, we're always on the lookout for new treatments that will advance and move the needle in terms of what drugs we have available to us."*

[Click here to watch the TV story](#)

