

ASX RELEASE

16th December 2021

Amplia Provides Updated Investor Presentation

Amplia Therapeutics Limited (ASX: ATX) (“Amplia” or the “Company”) today released a new investor presentation (attached) which outlines the Company’s technology, plans for growth during 2022 and reviews some key events of 2021.

The presentation provides the following:

- An overview of the Company’s technology and targeted therapeutic indications;
- Key value drivers, company objectives and timelines for 2022; and
- A summary of key events that occurred during 2021.

This ASX announcement was approved and authorised for release by the CEO of Amplia Therapeutics.

- End -

For Further Information

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About Amplia Therapeutics Limited

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

Amplia Therapeutics Growth plans for 2022 and 2021 Year In Review

December 2021

Amplia Therapeutics Limited



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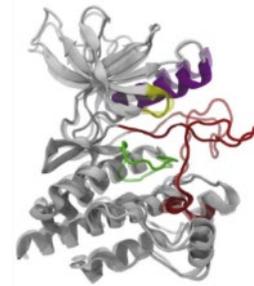
This presentation contains forward-looking statements which can be identified by the use of words such as “may”, “should”, “will”, “expect”, “anticipate”, “believe”, “estimate”, “intend”, “scheduled” or “continue” or similar expressions. Any forward-looking statements contained in this presentation are subject to significant risks, uncertainties, assumptions, contingencies and other factors (many of which are outside the control of, and unknown to Amplia, and its officers, employees, agents or associates), which may cause the actual results or performance to be materially different from any future result so performed, expressed or implied by such forward-looking statements.

There can be no assurance or guarantee that actual outcomes will not differ materially from these statements. The data and results pertaining to clinical subjects used in this presentation are illustrative of medical conditions and outcomes associated with potential applications of Amplia’s acquired product pipeline. Actual results from clinical trials may vary from those shown.

Company & Technology Snapshot



Why is FAK a good target for drug development?



Focal Adhesion Kinase (FAK)

Indication

FIBROTIC DISEASES

SOLID CANCERS

Opportunities

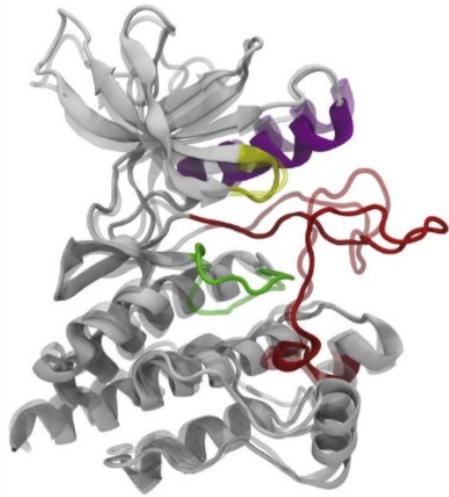
Monotherapy

- Lung fibrosis
- Liver fibrosis (NASH)
- Renal fibrosis
- Wound healing

Combination Therapy

- Pancreatic cancer
- Ovarian cancer
- Breast cancer
- Hepatocellular carcinoma
- Melanoma
- Gastric cancer
- Lung cancer

Targeting cancer's defence mechanisms



Focal Adhesion Kinase (FAK)

Fibrosis
FAK helps establish and maintain the dense, fibrotic tissue around cancers
Immune response
FAK triggers the release of signaling molecules (cytokines) which suppress the immune system
Cell migration
FAK regulates cell migration that is involved in the formation of secondary cancers (metastases)



FAK is involved in many cancer defence mechanisms that reduce the effectiveness of cancer drugs

Increased FAK activity is found in many, difficult-to-treat, solid cancers

Elevated levels of FAK in cancers are associated with poor outcomes



Amplia is investigating the use of FAK inhibitors (FAKi's) to disrupt cancer defence mechanisms, making them more responsive to cancer drugs

**Remove the shield.
Deliver the blow.**

Amplia's target indications



Pancreatic Cancer

- 60,000 new diagnoses and 48,000 deaths from pancreatic cancer in the US each year
- Difficult-to-treat cancer that is often surrounded by a protective, fibrotic stromal layer
- Less than 20% of patients eligible for surgery – chemo main treatment
- Few new therapies approved and most patients treated with cytotoxic chemotherapy drugs

AMP945 was awarded Orphan Drug Designation by the US FDA for use in treating Pancreatic Cancer in March 2020

* [American Cancer Society](#), 2021

Idiopathic Pulmonary Fibrosis (IPF)

- Affects 130,000 in the US and ~3M people worldwide
- Devastating, progressive disease caused by the build up of fibrotic tissue in the lungs
- Only two drugs approved which slow progression but are unable to stop the disease
- With treatment, median survival time is 3-5 years

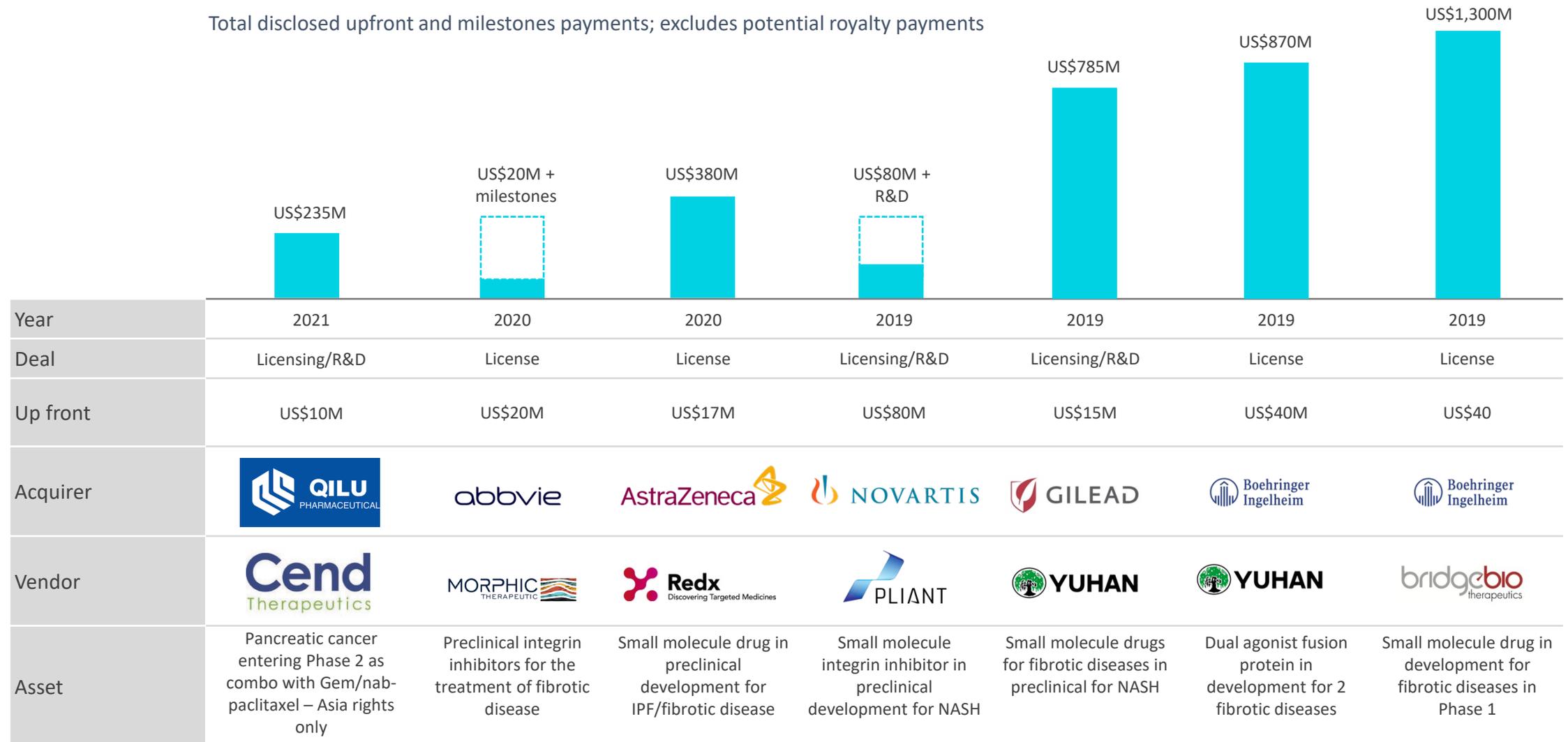
AMP945 was awarded Orphan Drug Designation by the US FDA for use in treating Idiopathic Lung Fibrosis in May 2020

** [The American Journal of Managed Care](#), 2021

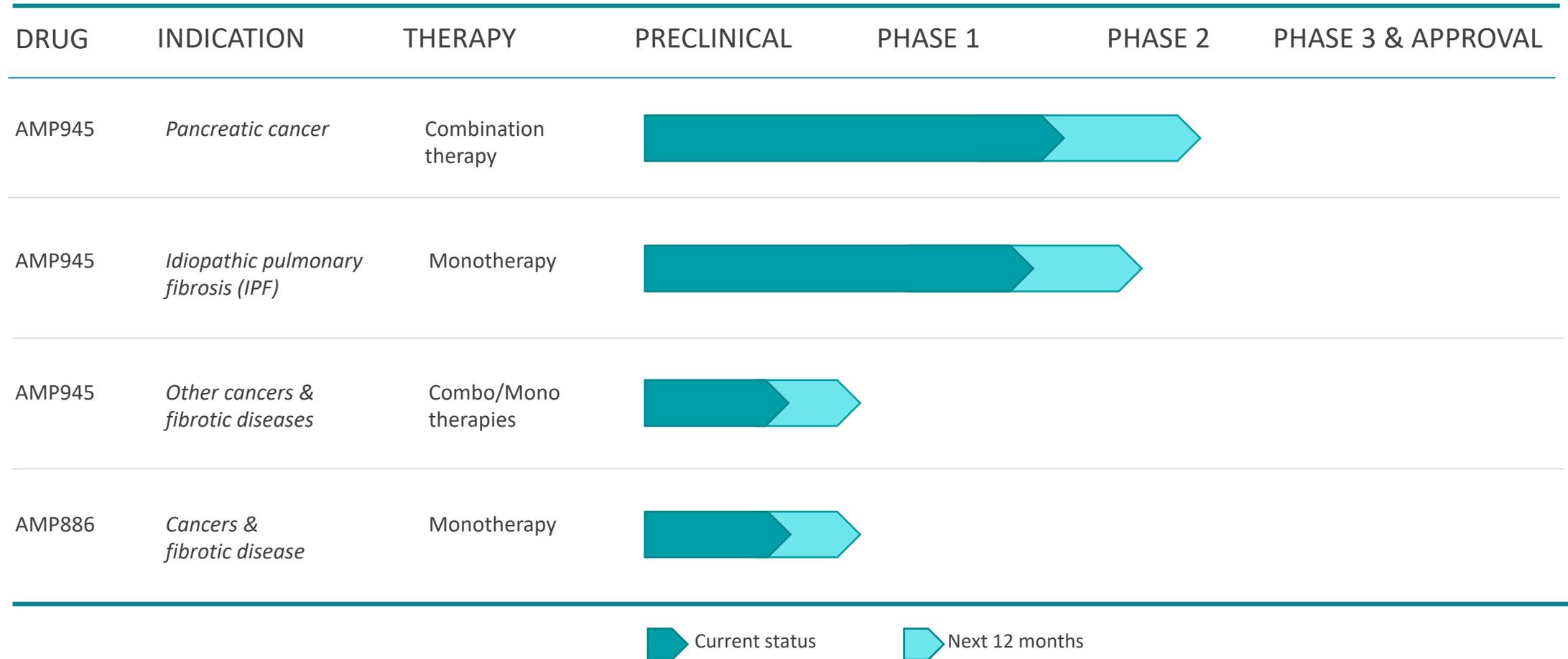
Recent deals for anti-fibrotic and pancreatic cancer drugs



Total disclosed upfront and milestones payments; excludes potential royalty payments



Amplia's pipeline



Amplia's Growth Plans for 2022

Key objectives for 2022



Recruit patients in two Phase 2 trials of AMP945

Pancreatic cancer
Pulmonary fibrosis → Report early results

Expand pipeline by progression of AMP886 into early development

Continue to build momentum by hitting key development and corporate milestones



Phase 2 trials planned in 2022



- **Phase 2 pancreatic cancer clinical trial**
 - Protocol and design work completed
 - Funded through recent capital raise
 - Drug manufacture nearing completion
 - Dosing expected to commence in Q1 CY2022



- **Phase 2 pulmonary fibrosis clinical trial**
 - Vendors, designs and schedules for preliminary toxicology locked in
 - Clinical design work is at an advanced stage
 - Recruitment to commence in H2 CY2022

Clinical schedule



Activity	CY2021		CY2022				CY2023				CY2024			
	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Pancreatic Cancer														
HREC Filing		◆												
Pre-IND			◆											
Patient Recruitment														
Interim Analysis														
Pulmonary Fibrosis														
Toxicology														
Patient Recruitment														

Decision Point

HREC: Human Research Ethics Committee
 IND: Investigational New Drug

Performance track record



"Amplia's team has built a solid track record for delivery against our key objectives. We expect this to continue in 2022 as we progress AMP945 into Phase 2 trials." Dr John Lambert, Amplia CEO.

Major achievements in 2021

- Completed successful Phase 1 trial of AMP945 supporting progression into Phase 2 trials in two indications
- Phase 2 trial design work led to inclusion of first-line patients in final trial design
- New preclinical data further supporting Amplia's approach in cancer and fibrosis
- Capital requirements in place to advance plans
 - Stage 1 of pancreatic cancer trial
 - Preliminary work for pulmonary fibrosis trial



Corporate & Company Milestones in 2021

Human capital



Expansion of team, capabilities and experience reflecting the growth and maturation of Amplia

- Jane Bell appointed as Independent Director in April 2021:
 - 30 years experience as banking and finance lawyer
 - Extensive experience as a Director on health and medical research Boards
- Expansion of executive management team:
 - Internal headcount expanded over the course of 2021
 - Additional capabilities in clinical trial development and program management
- José Iglesias M.D. appointed as Clinical Advisor in October 2021:
 - >30yrs pharmaceutical industry experience, primarily in developing oncology drugs
 - Responsible for development of Abraxane® as standard of care for pancreatic cancer
- Hamish George appointed as Chief Financial Officer for Amplia in October 2021



Financial capital



Secured investment and accessed additional funding sources to support initiation of Phase 2 program

- Strong support from investors resulting in \$16.2 million in new capital in two rounds:
 - \$3.8 million raised in May 2021 via Share Placement
 - \$12.4 million raised in December 2021 via Share Placement and underwritten Entitlement Offer
- Continued to build base of experienced institutional investors on Amplia's register
 - Substantial institutional investors*
 - Platinum Investment Management (17.5%)
 - Blueflag Holdings (7.0%)
 - Acorn Capital (6.5%)
- Access additional, non-dilutive funding available through the R&D Tax Incentive Scheme
 - \$1.1 million received in October for R&D expenditure incurred during FY21
 - \$2.1 million rebate for FY22 accessed via the Victorian Government's Cash Flow Loan Initiative



Clinical Development Milestones in 2021

Completed Phase 1 trial of AMP945 in May 2021



- **Trial execution:**

- Commenced in October 2020 - completed May 2021
- Recruited 56 healthy volunteers aged 18 - 65
- Single site in Melbourne, Australia

- **Summary of Outcomes**

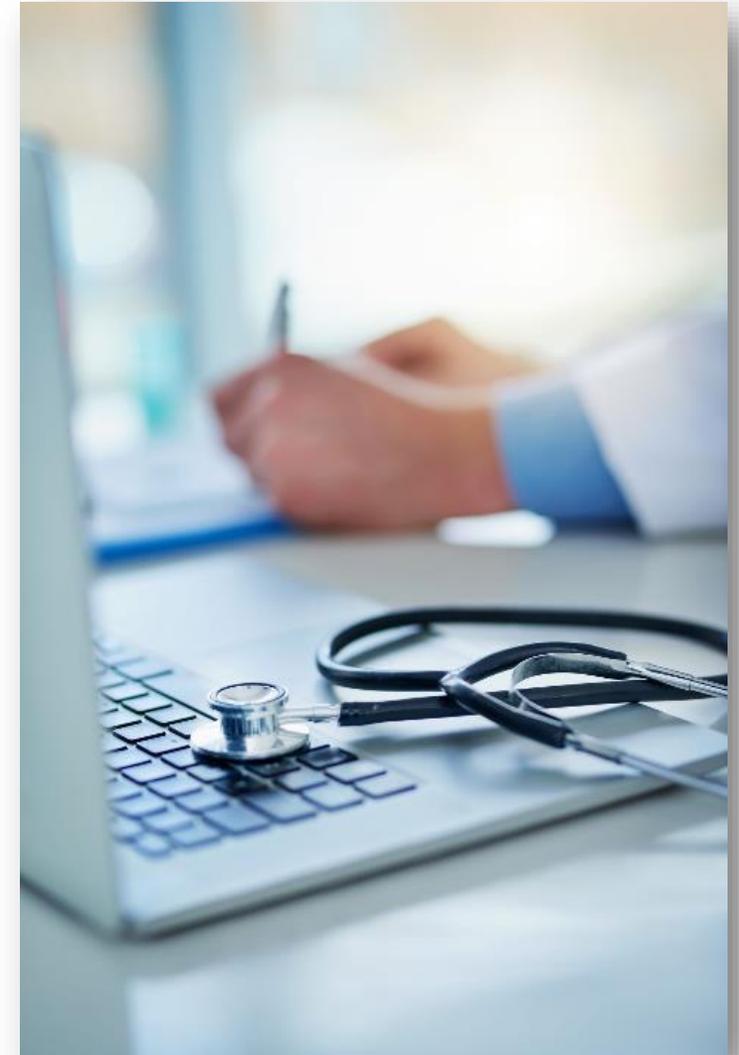
- Safe and well-tolerated at all doses tested
- Inhibition of FAK demonstrated in skin biopsies taken from participants
- No serious adverse events (SAEs) or withdrawals and no identified safety trends
- Once-a-day oral dose supported by pharmacokinetics
 - Predictable dose/exposure relationship
 - No food effect
- Low risk of interaction with other drugs in combination therapy



Significance of data from Phase 1 clinical trial



- **Inhibition of FAK in skin biopsies confirms target engagement**
 - AMP945 inhibits human FAK in human volunteers
 - 'Target engagement' is a prerequisite for clinical efficacy
- **AMP945's safety profile supports dosing in patients**
 - Pancreatic cancer patients in combination with chemotherapy
 - Idiopathic pulmonary fibrosis (IPF) patients
- **AMP945 can be dosed orally, once daily**
 - Once-a-day oral administration delivers therapeutically relevant levels of AMP945 in the bloodstream
 - Patients can self-administer capsules of AMP945, supporting both oncology and longer-term once-daily dosing for chronic fibrotic disease



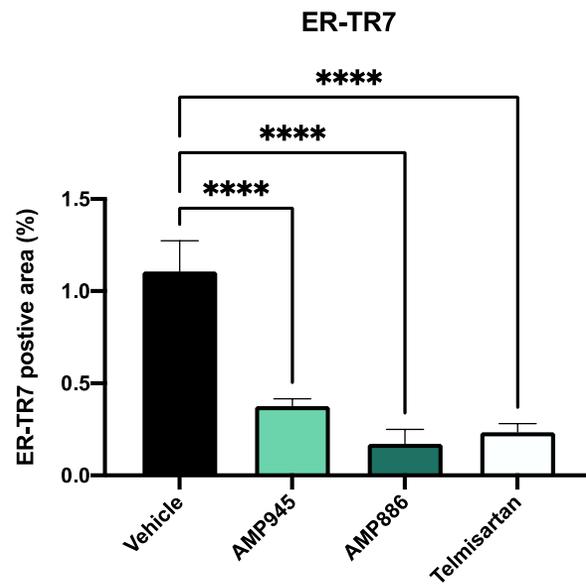
Research Achievements & Developments in 2021



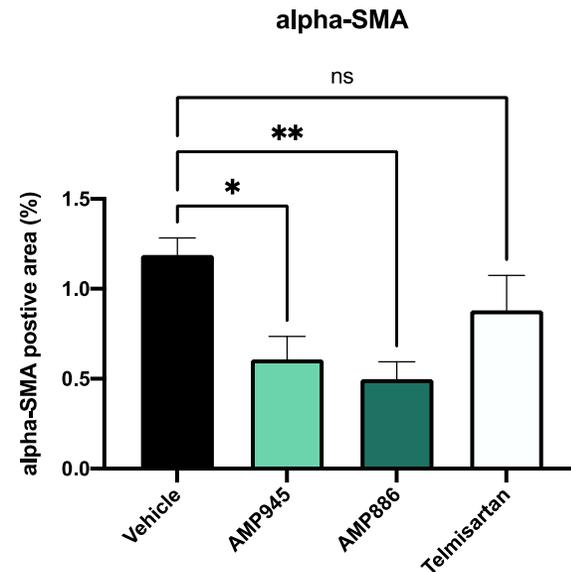
Amplia's FAK inhibitors reduce key disease markers in liver fibrosis model



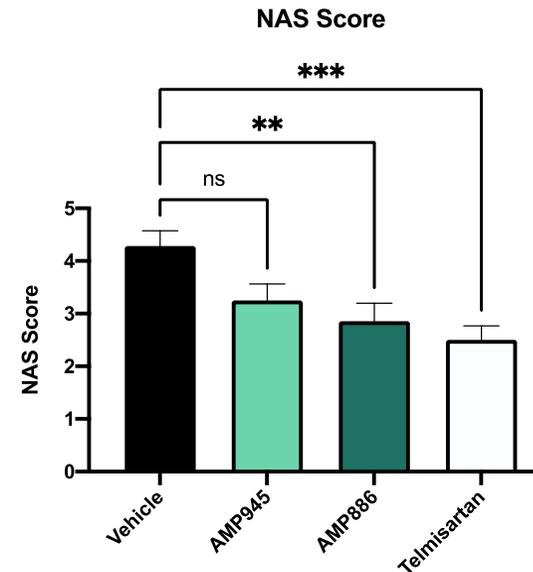
Fibroblast marker



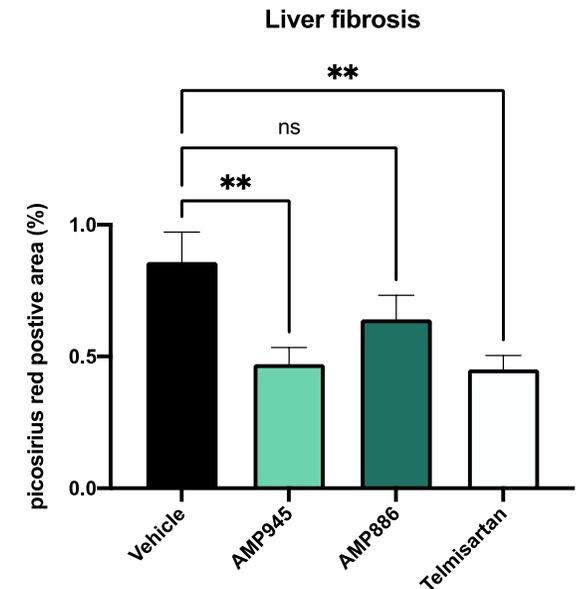
Fibroblast activation



NASH symptoms



Fibrosis



ns Not significant
* P ≤ 0.05
** P ≤ 0.01
*** P ≤ 0.001
**** P ≤ 0.0001

Formalised collaboration with the Garvan Institute



- **Garvan and Amplia collaboration agreement signed June 2021:**
 - Work program seeks to expand on therapeutic opportunities for AMP945
 - Collaboration builds on existing knowledge and taps clinician network
- **Collaboration has already shown that:**
 - AMP945 improves efficacy of chemotherapy in animal models of pancreatic cancer
 - Underlying biology consistent with enhanced survival effect



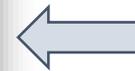
Garvan data supports rationale for Phase 2 trial



[Murphy, Kendelle J., Reed, Daniel A., et al., *Science Advances*, 7 \(2021\), eabh0363.](#)

- Recent publications highlight potential synergy of FAK inhibition with current standards of care

Key findings



- Priming with FAK inhibitor before treatment with gemcitabine/Abraxane®
 - Increases survival in KPC pancreatic cancer model
 - Reduces metastasis
- FAK inhibition synergises with Abraxane®



Journal of Experimental & Clinical Cancer Research

RESEARCH

Open Access

Focal adhesion kinase inhibition synergizes with nab-paclitaxel to target pancreatic ductal adenocarcinoma



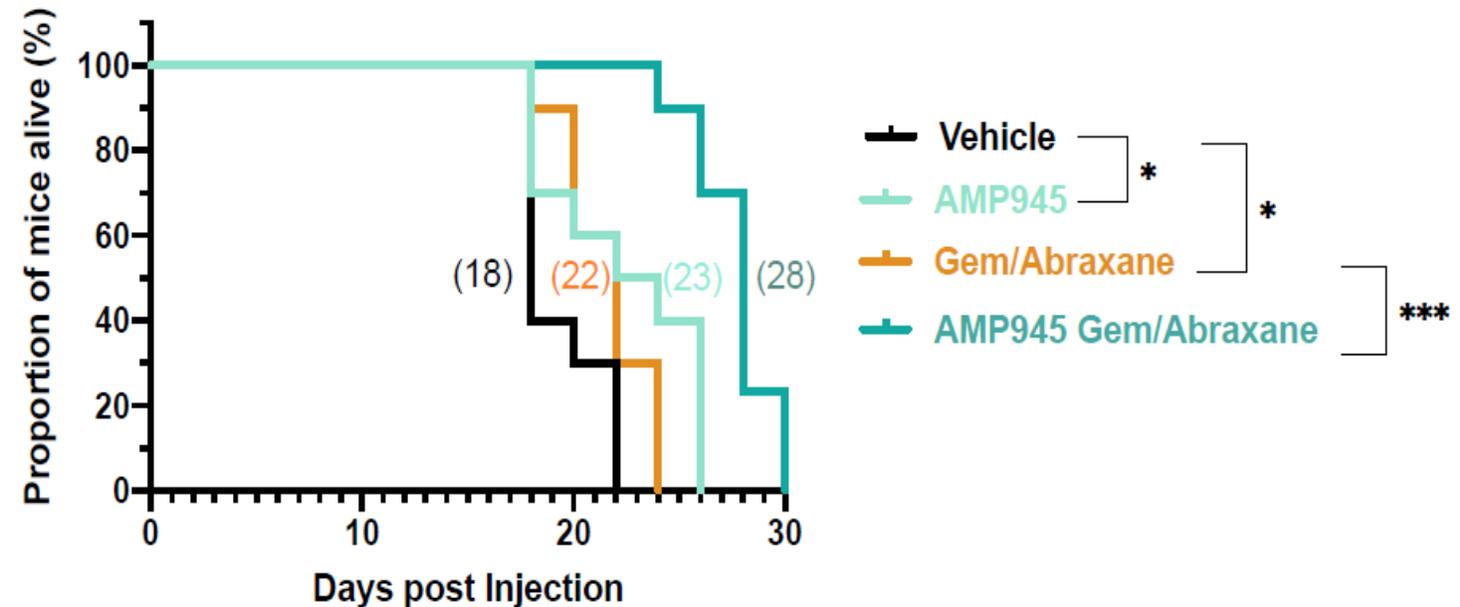
[Le Large, T. Y. S., Bijlsma, M. F., et al., *Journal of Experimental & Clinical Cancer Research*, 40 \(2021\), 91.](#)

AMP945 improves survival in pancreatic cancer model



Survival in the KPC mouse model of pancreatic cancer

- 25% improvement in survival when added to standard of care ($p \leq 0.001$)
- KPC* is a highly aggressive animal model of human pancreatic cancer
- Demonstrates pharmaceutical activity of AMP945 translates into survival benefit



"A 25% improvement in survival in this model is very impressive and a level of improvement that we rarely see"

PROFESSOR PAUL TIMPSON

* Niknafs, N. et al., 2019. *Nature Communications*, 10: 5435.

Summary of growth plans for 2022



- Over the last 18-months, Amplia has progressed from a pre-clinical stage company to being a Phase 2-ready company
- In 2022, Amplia will continue to build on its track record for delivery
- Key value drivers for the company will be
 - Initiation of two Phase 2 clinical trials and reporting early results
 - Progression of AMP886 into new therapeutic opportunities
- The Phase 2 pancreatic cancer trial
 - Is supported by preclinical and clinical datasets
 - Is fully designed and scoped out
 - Is funded by recent capital raising





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