

**ASX RELEASE**

**28 July 2021**

## **QUARTERLY ACTIVITIES AND CASH FLOW REPORTS**

**Melbourne, Australia:** Amplia Therapeutics Limited (ASX: ATX), (“Amplia” or the “Company”), a company developing new approaches for the treatment for cancer and fibrosis, is pleased to announce further progress across its small molecule, focal adhesion kinase (FAK) inhibitor program and the release of its Appendix 4C Cash Flow Report (attached) for the quarter ending 30 June 2021.

### **Key Highlights from the Quarter**

- Completed dosing in the Phase 1 clinical trial of AMP945 in healthy volunteers;
- Finalised and executed Collaboration Agreement with the Garvan Institute of Medical Research;
- Preclinical data shows AMP945 confers 27% survival benefit in challenging animal model of pancreatic cancer;
- Raised A\$3.8M to prepare for initiation of Phase 2 clinical program for AMP945.

Amplia’s CEO and Managing Director, Dr John Lambert, commented that “The progress Amplia has made during this quarter has put the Company in a strong position for its next stage of clinical development. The results from our successful Phase 1 clinical trial announced last week have confirmed that AMP945 has a profile which makes it very suitable for advancing into Phase 2 clinical trials in both patients with pancreatic cancer and idiopathic lung fibrosis (IPF). Our Collaboration Agreement with the Garvan announced last quarter was finalised and the collaboration has already provided valuable data validating our strategy to add AMP945 into existing standard-of-care therapies to enhance the currently poor response experienced by patients with pancreatic cancer. Amplia is very appreciative of the support it received from new and existing shareholders, with \$3.8M of new capital raised during the quarter that will enable the Company to prepare for the launch of its Phase 2 clinical program later this year”.

### **Operations update**

During the quarter, Amplia completed dosing in its Phase 1 clinical trial of AMP945 in healthy volunteer and has recently received the final data. The trial achieved its Primary Endpoints by demonstrating that AMP945 is safe and well-tolerated at the doses tested when it is administered as a single oral dose or as repeated, daily oral doses over seven days. Furthermore, oral administration was able to achieve the levels of AMP945 in the bloodstream that are required to inhibit the drugs intended target, FAK, and the pharmacokinetic data supports once daily, oral dosing of AMP945. These data are extremely pleasing and fully support advancing AMP945 into Phase 2 clinical trials for both pancreatic cancer and IPF.

The plans for a Phase 2 clinical trial of AMP945 in patients with pancreatic cancer are well advanced and the Company expects to finalise the design of this trial during the current Quarter. Amplia has engaged a range of clinicians, regulatory and biostatistics consultants and other experts to assist with this process and is incorporating their advice into the design of this trial. In parallel, Amplia has commenced the scale-up manufacture of AMP945 and longer-term animal toxicology studies required

to support a Phase 2 clinical trial of AMP945 in patients with IPF which is currently scheduled to start in mid-2022.

In June, Amplia finalised the commercial terms and executed its Research Collaboration Agreement with the Garvan Institute of Medical Research (the “Garvan”) in Sydney. This collaboration provides the Company with access to the Garvan’s research strength in FAK biology and its extensive clinical research network. Amplia has been working with Professor Paul Timpson, a world-renowned expert in FAK biology, from the Garvan for over two years and appointed him to the Company’s Scientific Advisory Board in February 2020.

During the quarter, Amplia reported preclinical data generated by Professor Timpson’s laboratory as part of the Company’s collaboration with the Garvan. In June, the company reported that these changes were associated with a statistically significant, 27% improvement in survival in a highly aggressive animal model of pancreatic cancer (the KPC mouse model). These results provide further support and validation of the scientific rationale for incorporating FAK inhibitors into treatment regimens for pancreatic cancer and indicate that they have the potential to have a positive impact on the clinical outcomes for these patients.

#### **Financial update**

Amplia finished the June 2021 quarter with cash of \$4,081,000. During the quarter, the Company used \$1,344,000 in operating activities, with \$993,000 being used for research and development that was primarily focused on close-out of the Phase 1 clinical trial of AMP945.

Having completed recruitment in the Phase 1 clinical trial, research and development expenditure is forecast to decrease in the coming quarter.

#### **Payments to Related Entities**

In Section 6.1 of the Appendix 4C lodged for this quarter, the Company discloses payments to related parties of \$131,000. These payments reflect salary, superannuation and a short-term incentive paid to the CEO/Managing Director in line with Dr Lambert’s employment contract.

#### **Outlook and future activities**

Amplia’s primary focus will be on preparing for Phase 2 clinical trials of AMP945. This will involve working with the Company’s clinical advisors to further refine clinical study designs, fully scoping the studies and preparing for regulatory and ethics committee submissions required to allow initiation of Phase 2 studies. In addition, the Company will continue its parallel program of non-clinical studies for AMP945 and AMP886 in order to expand the Company’s data set supporting the potential utility of AMP945 and AMP886 in other therapeutic areas of commercial potential.

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

- End -

#### **For Further Information**

Dr. John Lambert  
CEO and Managing Director  
[john@ampliatx.com](mailto:john@ampliatx.com)  
[www.ampliatx.com](http://www.ampliatx.com)

#### **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).

## Appendix 4C

### Quarterly cash flow report for entities subject to Listing Rule 4.7B

**Name of entity**

Amplia Therapeutics Limited

**ABN**

16 165 160 841

**Quarter ended ("current quarter")**

30 June 2021

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (3 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers		
1.2 Payments for		
(a) research and development	<993>	<993>
(b) product manufacturing and operating costs		
(c) advertising and marketing		
(d) leased assets		
(e) staff costs	<249>	<249>
(f) administration and corporate costs	<105>	<105>
1.3 Dividends received (see note 3)		
1.4 Interest received	-	-
1.5 Interest and other costs of finance paid		
1.6 Income taxes paid		
1.7 Government grants and tax incentives	-	-
1.8 Other (provide details if material)		
Intellectual property costs & licence fees	<11>	<11>
Miscellaneous	14	14
<b>1.9 Net cash from / (used in) operating activities</b>	<b>&lt;1,344&gt;</b>	<b>&lt;1,344&gt;</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire or for:		
(a) entities		
(b) businesses		
(c) property, plant and equipment	<4>	<4>
(d) investments		

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
(e) intellectual property		
(f) other non-current assets		
2.2 Proceeds from disposal of:		
(a) entities		
(b) businesses		
(c) property, plant and equipment		
(d) investments		
(e) intellectual property		
(f) other non-current assets		
2.3 Cash flows from loans to other entities		
2.4 Dividends received (see note 3)		
2.5 Other (provide details if material)		
<b>2.6 Net cash from / (used in) investing activities</b>	<b>&lt;4&gt;</b>	<b>&lt;4&gt;</b>

<b>3. Cash flows from financing activities</b>		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)	3,814	3,814
3.2 Proceeds from issue of convertible debt securities		
3.3 Proceeds from exercise of options	39	39
3.4 Transaction costs related to issues of equity securities or convertible debt securities	<272>	<272>
3.5 Proceeds from borrowings		
3.6 Repayment of borrowings		
3.7 Transaction costs related to loans and borrowings		
3.8 Dividends paid		
3.9 Other (provide details if material)		
<b>3.10 Net cash from / (used in) financing activities</b>	<b>3,581</b>	<b>3,581</b>

<b>4. Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1 Cash and cash equivalents at beginning of period	1,848	1,848
4.2 Net cash from / (used in) operating activities (item 1.9 above)	<1,344>	<1,344>

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (3 months) \$A'000</b>
4.3	Net cash from / (used in) investing activities (item 2.6 above)	<4>	<4>
4.4	Net cash from / (used in) financing activities (item 3.10 above)	3,581	3,581
4.5	Effect of movement in exchange rates on cash held	-	-
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>4,081</b>	<b>4,081</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1	Bank balances	136	103
5.2	Call deposits	3,945	1,745
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>4,081</b>	<b>1,848</b>

<b>6.</b>	<b>Payments to related parties of the entity and their associates</b>	<b>Current quarter \$A'000</b>
6.1	Aggregate amount of payments to related parties and their associates included in item 1	131
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<i>Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.</i>		

## Quarterly cash flow report for entities subject to Listing Rule 4.7B

<b>7. Financing facilities</b>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
<i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i>		
<i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>		
7.1 Loan facilities		
7.2 Credit standby arrangements		
7.3 Other (please specify)		
<b>7.4 Total financing facilities</b>	-	-
<b>7.5 Unused financing facilities available at quarter end</b>		-
7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.		

<b>8. Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (item 1.9)	<1,344>
8.2 Cash and cash equivalents at quarter end (item 4.6)	4,081
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	4,081
<b>8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	3.04
<i>Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.</i>	
8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:	
8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?	
Answer:	
8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?	
Answer:	
8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?	
Answer:	
<i>Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.</i>	

## Compliance statement

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Date: 28 July 2021

Authorised by: The Audit Committee  
(Name of body or officer authorising release – see note 4)

## Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.

# Amplia Therapeutics

---

Shareholder Update - July 2021

Amplia Therapeutics Limited



# Disclaimer

---

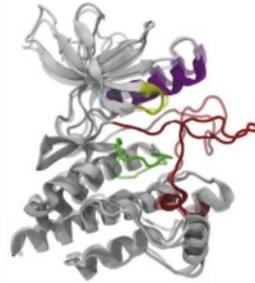


The information contained in the presentation is not intended to be an offer for subscription, invitation or recommendation with respect to shares of Amplia Therapeutics Limited (“Amplia”) in any jurisdiction. No representation or warranty, express or implied, is made in relation to the accuracy or completeness of the information contained in this document or opinions expressed in the course of this presentation. The information contained in this presentation is subject to change without notification.

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.

# Focal Adhesion Kinase – one drug target, two applications



Focal Adhesion Kinase (FAK)

## Indication

### FIBROTIC DISEASES

### SOLID CANCERS

## Biology

- Collagen accumulation
- Collagen crosslinking
- Fibronectin production

- Cell migration and metastasis
- Collagen accumulation
- Local regulation of immune response

## Opportunities

### Monotherapy

- Lung fibrosis
- Liver fibrosis

### Combination Therapy

- Pancreatic cancer
- Ovarian cancer

# Amplia's target indications



## **Pancreatic Cancer**

- 60,000 new diagnosis and 48,000 deaths from pancreatic cancer in the US each year
- Difficult-to-treat cancer that is often detected late and surrounded by a protective, fibrotic layer
- Less than 20% patients eligible for surgery – chemo main treatment
- Median survival time for patients with advanced disease is 8-9 months

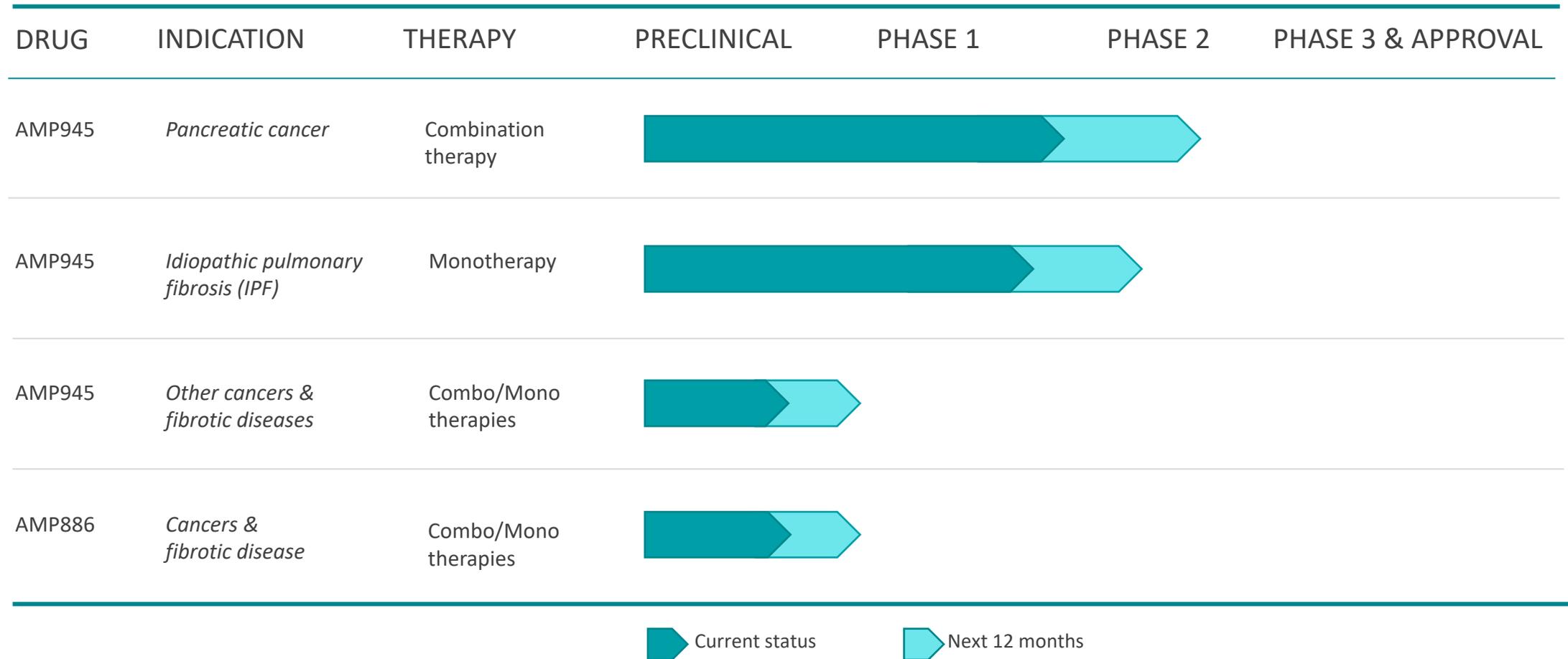
AMP945 was awarded Orphan Drug Designation by the US FDA for use in treating Pancreatic Cancer in March 2020

## **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
- Median survival time is 3-5 years with current treatments

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

# Amplia's pipeline



# Amplia – highlights from the June 2021 quarter

---



- Finalised and executed Collaboration Agreement with the Garvan Institute for Medical Research in Sydney
- Preclinical data supports advancing AMP945 in Phase 2 clinical trials in patients with pancreatic cancer:
  - Inhibits formation of new fibrotic tissues
  - 27% survival benefit in aggressive model of pancreatic cancer
- Completion of successful Phase 1 clinical trial of AMP945 in healthy volunteers
  - On time and on budget
- Raised \$3.8M to support preparation for initiation of Phase 2 clinical programs in pancreatic cancer and pulmonary fibrosis

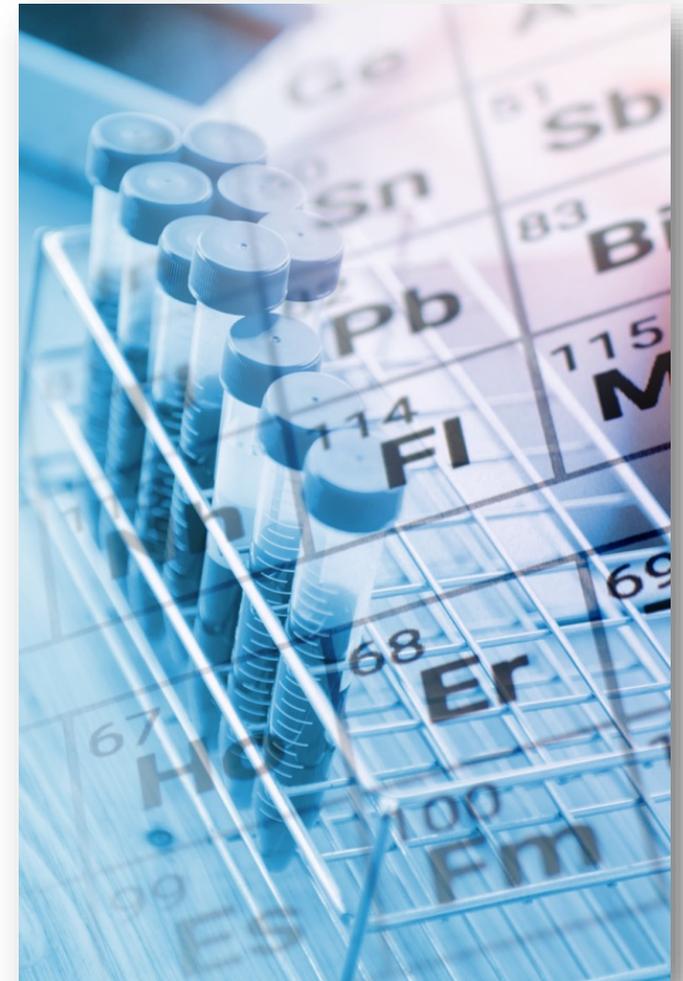


# Garvan Collaboration

# Amplia's collaboration with the Garvan Institute



- Garvan and Amplia collaboration agreement signed June 2021:
  - Prof. Timpson's group studying FAK in pancreatic cancer for >6 years
  - Professor Timpson joined Amplia's Scientific Advisory Board in Feb 2020
  - Collaboration builds on existing knowledge and taps clinician network
- Collaboration has already provided valuable data showing that AMP945:
  - Inhibits deposition and maturation of collagen that forms fibrotic tissue
  - Improves survival in an aggressive animal model of pancreatic cancer by 27% in combination with standard chemotherapies
- Further studies planned or underway



# Garvan collaboration



- Amplia receives
  - Access to Garvan know-how
  - First right to arising IP
- Garvan receives
  - Research funding
  - Translational opportunities for science
- Amplia collaboration promoted in Garvan's June Seminar *The Power of Personalized Medicine*

The screenshot shows a video player displaying a slide from a presentation. The slide features the Ampla Therapeutics logo at the top left and the Garvan Institute of Medical Research logo at the top right. Below the logos, there is a 3D diagram of a brain with a network of orange and blue vessels. To the right of the diagram is a line graph titled "Tumour Growth". The graph plots "Tumour Volume (mm<sup>3</sup>)" on the y-axis (ranging from 0 to 400) against "Days Treatment" on the x-axis (ranging from 0 to 6). Two data series are shown: "Vehicle" (orange line with circles) and "AMP945" (teal line with circles). Both series show an increase in tumour volume over time, but the AMP945 group shows a significantly lower volume compared to the Vehicle group at all time points after day 0. Error bars are present for each data point.

Days Treatment	Vehicle (mm <sup>3</sup> )	AMP945 (mm <sup>3</sup> )
0	~40	~40
1	~80	~50
2	~110	~70
3	~130	~80
4	~170	~90
5	~210	~100
6	~250	~110

At the bottom of the video player, there is a progress bar showing 34:49 / 56:21, a play button, a volume icon, and various control icons. A small inset video in the bottom right corner shows a person speaking.

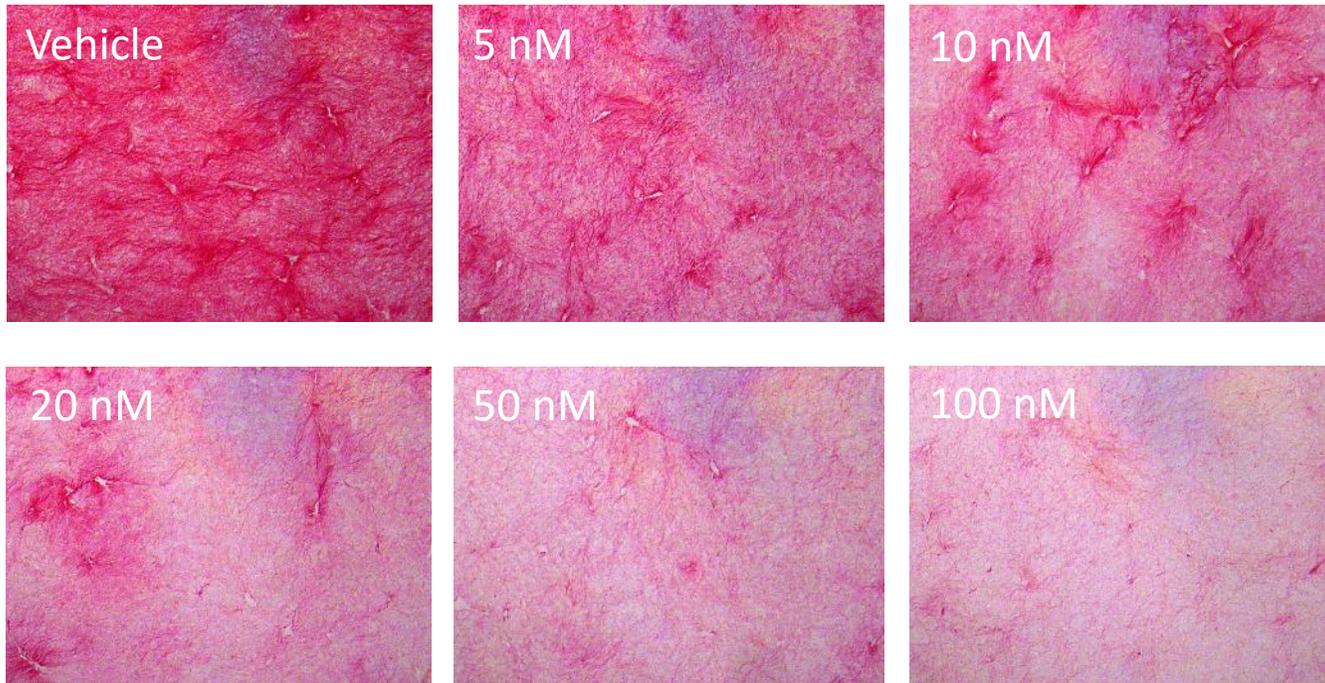
---

# Preclinical Data

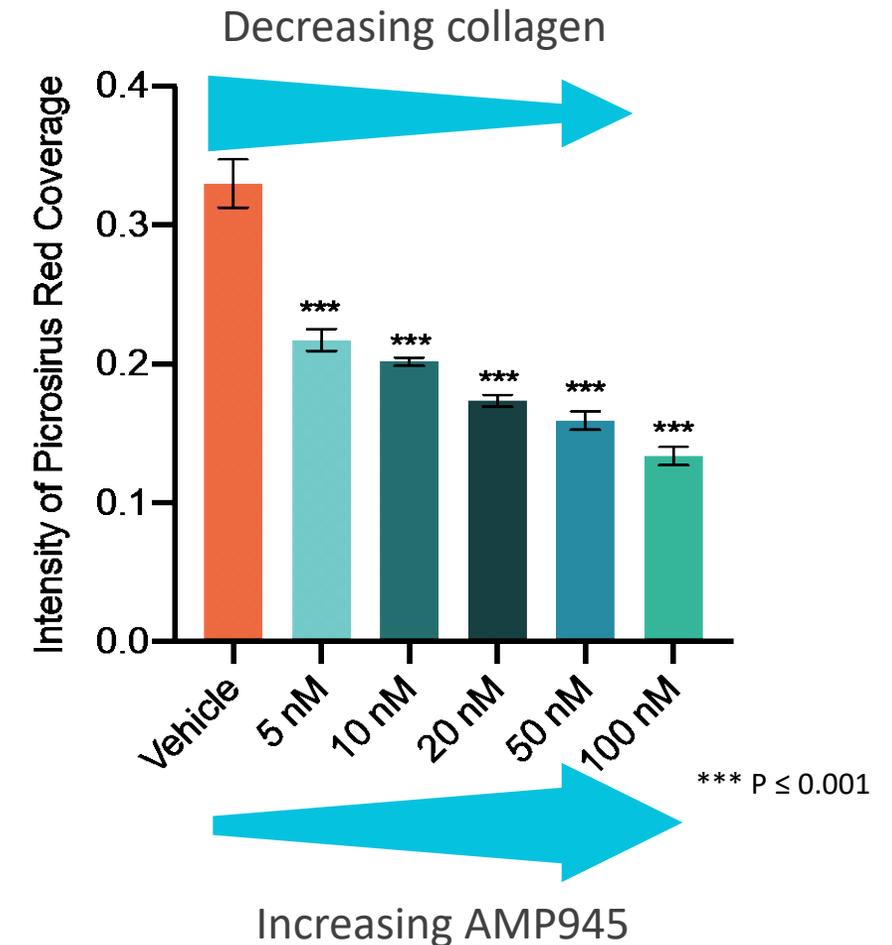
# AMP945 inhibits deposition of collagen



Picosirius red staining for total collagen



- Fibroblasts lay down new collagen
- Collagen is a key component of fibrotic tissue
- AMP945 inhibits fibroblasts, causing less new collagen to be deposited

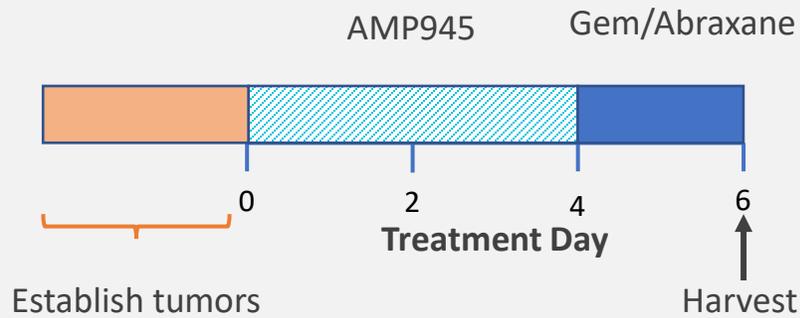


Studies conducted in the laboratory of Professor Paul Timpson (Garvan)

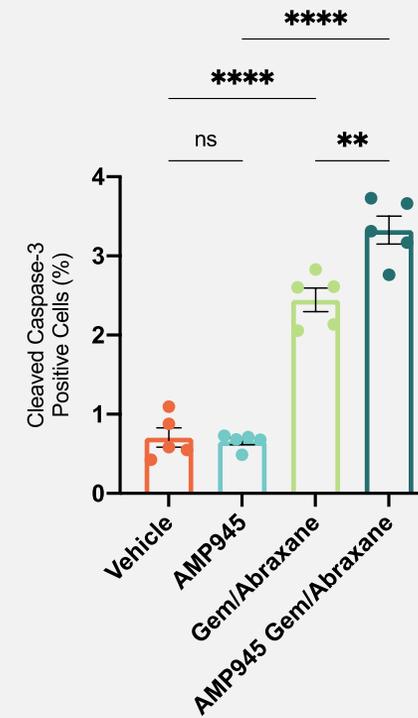
# AMP945 has positive impact on key tumour markers



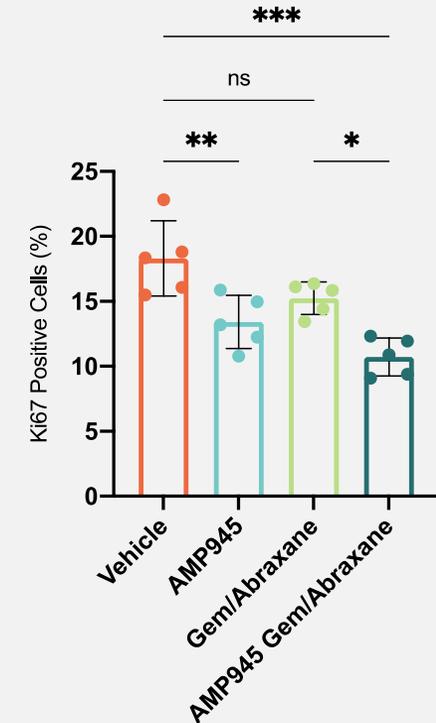
**AMP945 priming strategy – pretreatment to make tumours more responsive to standard of care**



**Marker of cell death increases (Caspase 3)**



**Marker of cell proliferation decreases (Ki67)**



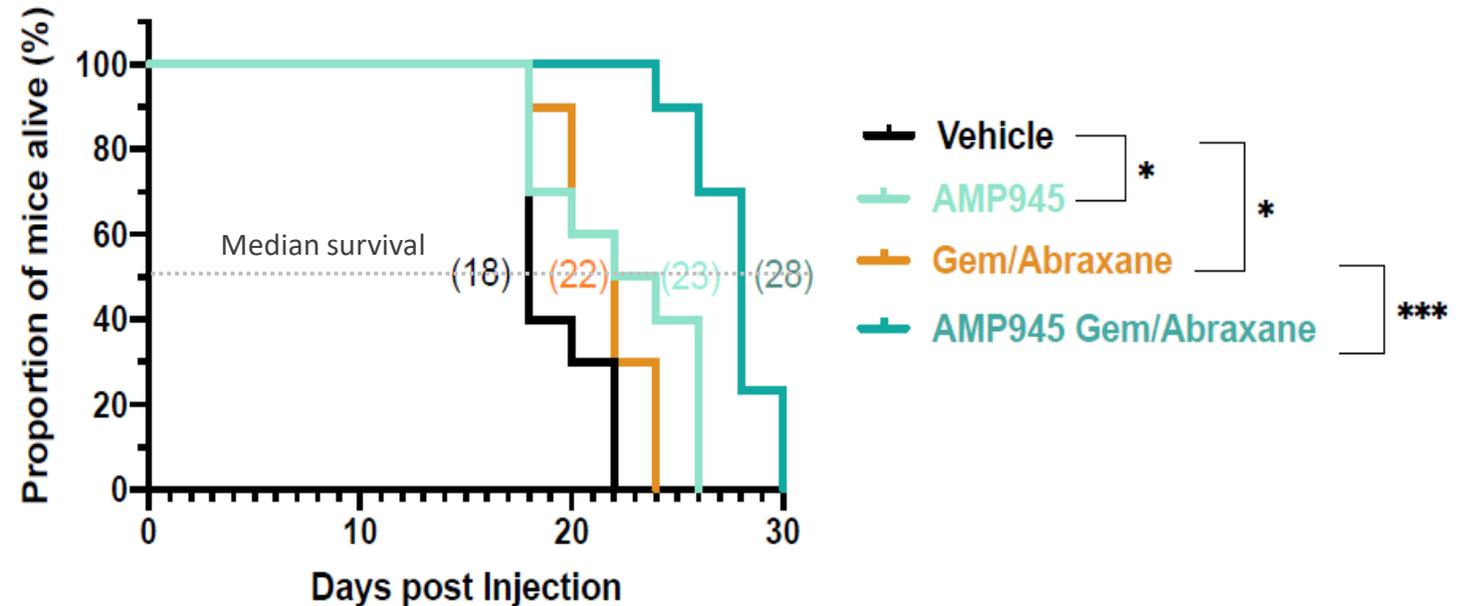
\* P ≤ 0.05    \*\* P ≤ 0.01    \*\*\* P ≤ 0.001    \*\*\*\* P ≤ 0.0001

# AMP945 improves survival in pancreatic cancer model



## Survival in the KPC mouse model of pancreatic cancer

- 25% improvement in median 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

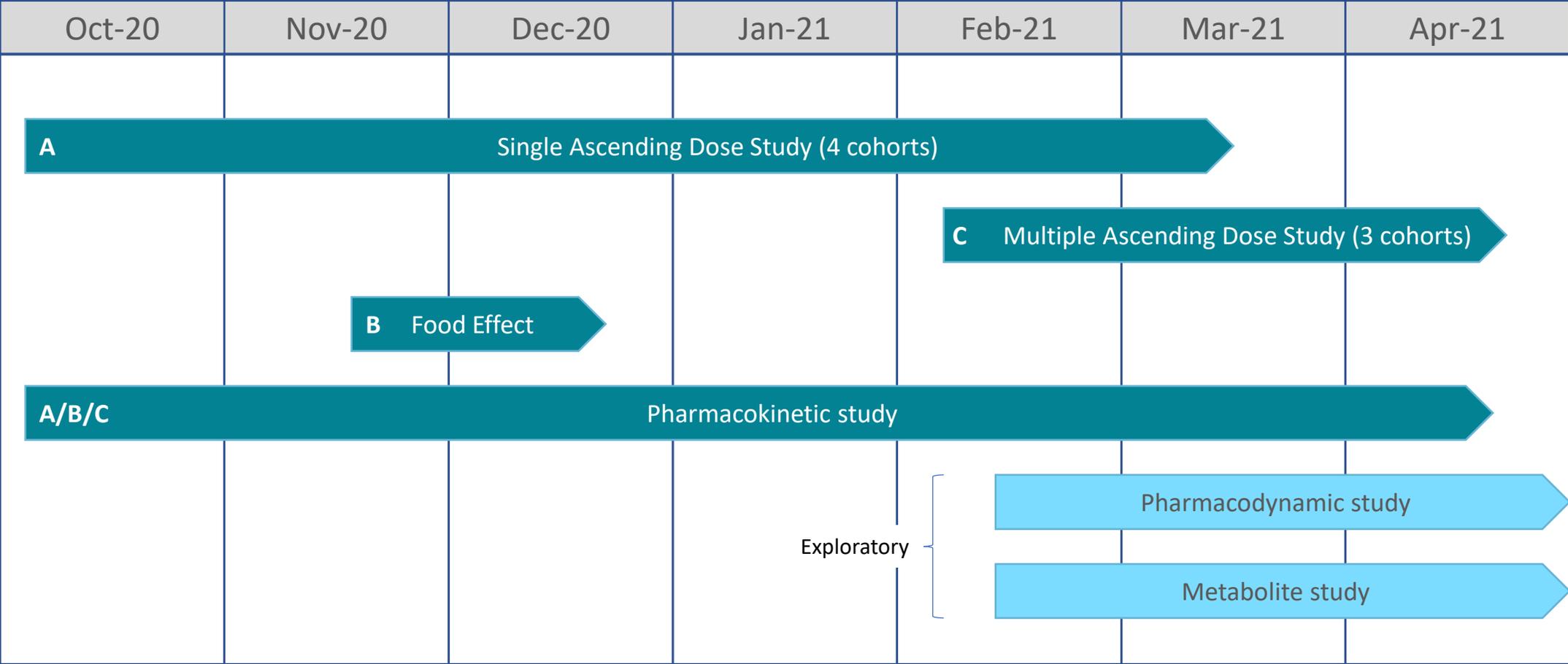


*"A 25% improvement in survival in this model is very impressive and a level of improvement that we rarely see"*

---

# Phase 1 Clinical Trial

# Phase 1 trial of AMP945 – design and execution

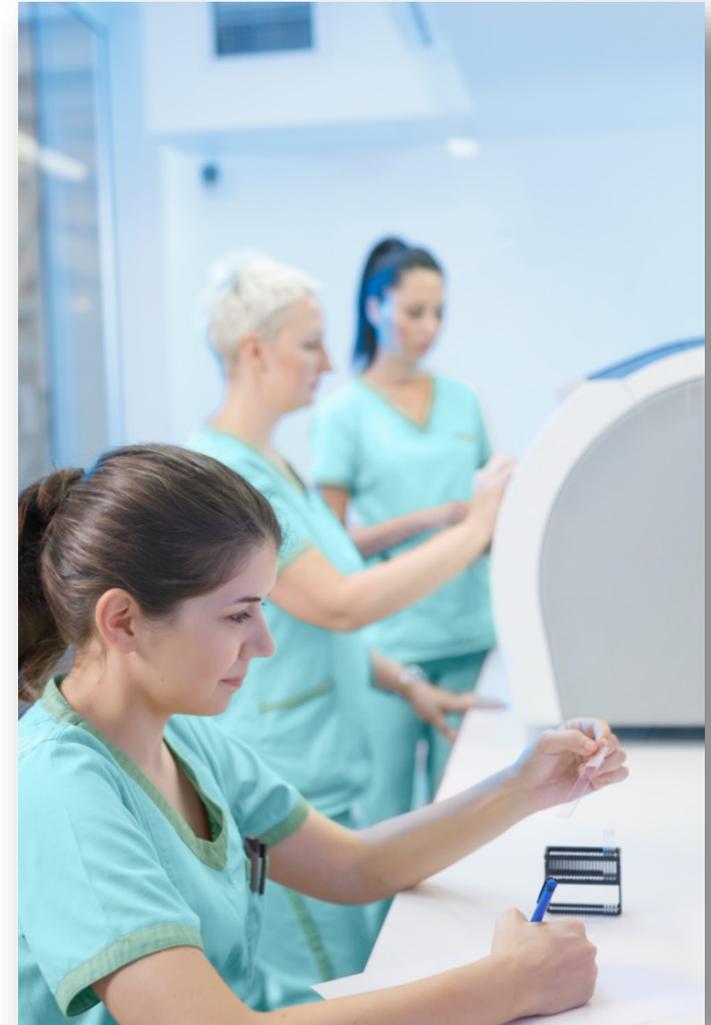


# Data from successful Phase 1 clinical trial of AMP945



## Data on AMP945 from Phase 1 clinical trial

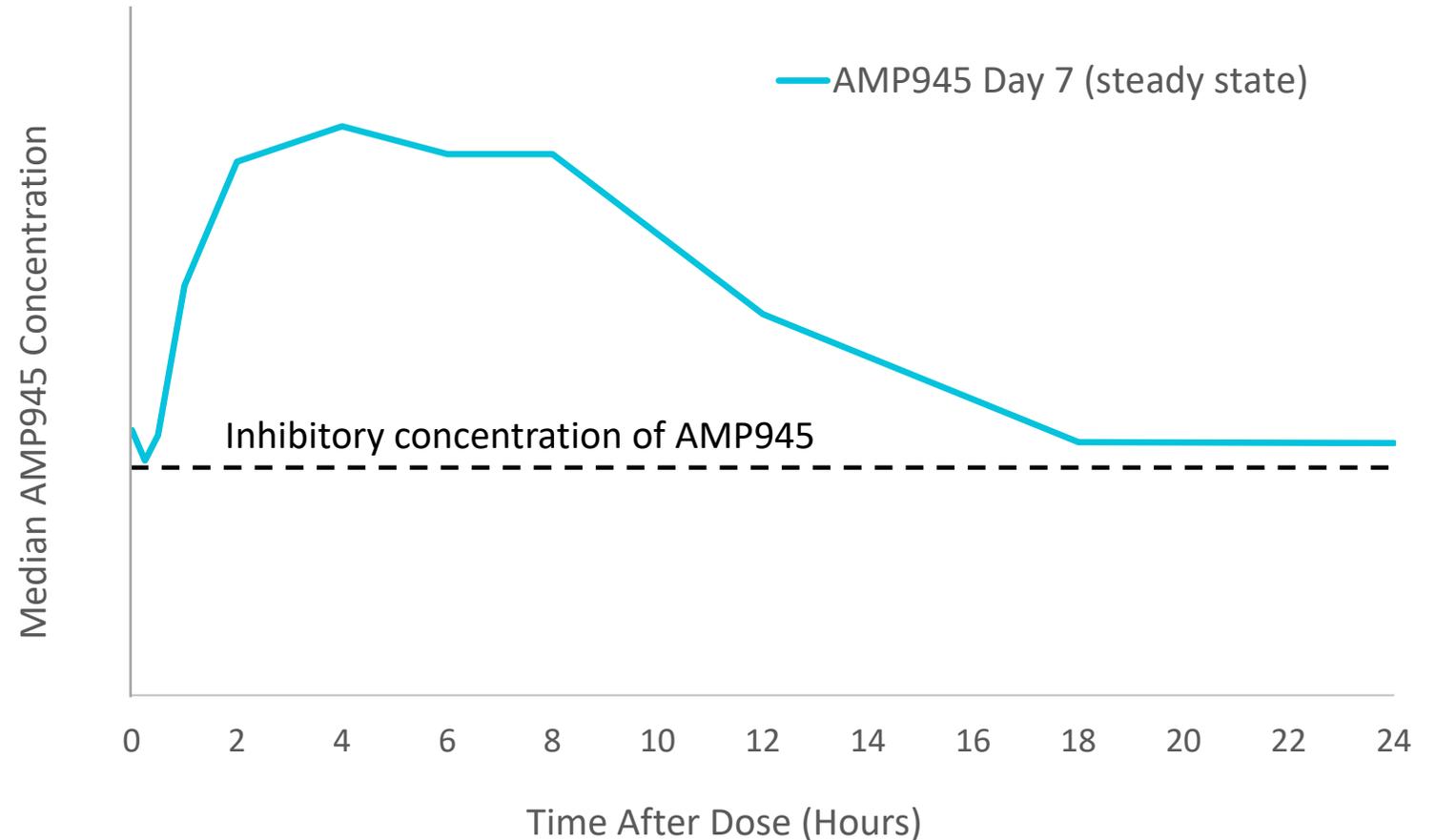
- Safe and well-tolerated at all doses tested:
  - Single ascending doses – up to 125mg
  - Multiple ascending dose (up to 100mg for 7 days)
- No serious adverse events (SAEs) or withdrawals and no identified safety trends
- Once-a-day oral dose supported by pharmacokinetics
- No detectable food effect – simplifies dosing
- Achieved blood levels of AMP945 sufficient to inhibit FAK



# Inhibitory concentration of AMP945 achieved



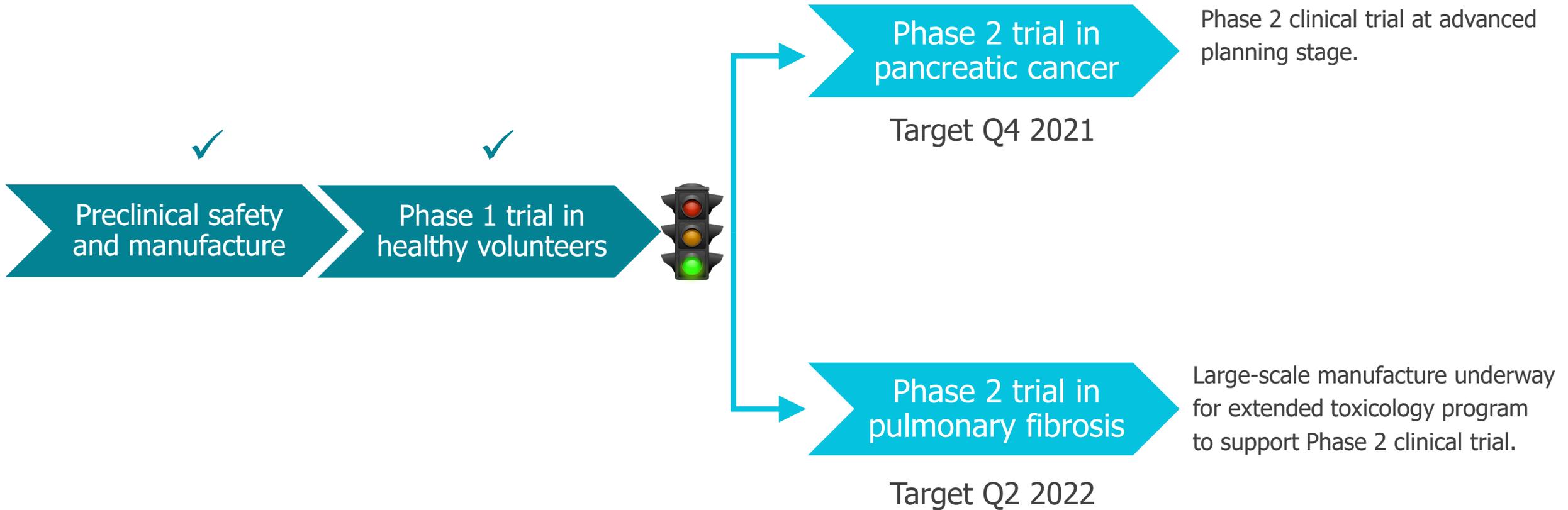
- Concentrations of AMP945 that inhibit FAK were rapidly achieved in the blood of human volunteers
- These levels were maintained in the steady state concentrations achieved following oral administration of AMP945 once daily for seven days



# Significance of Phase 1 results



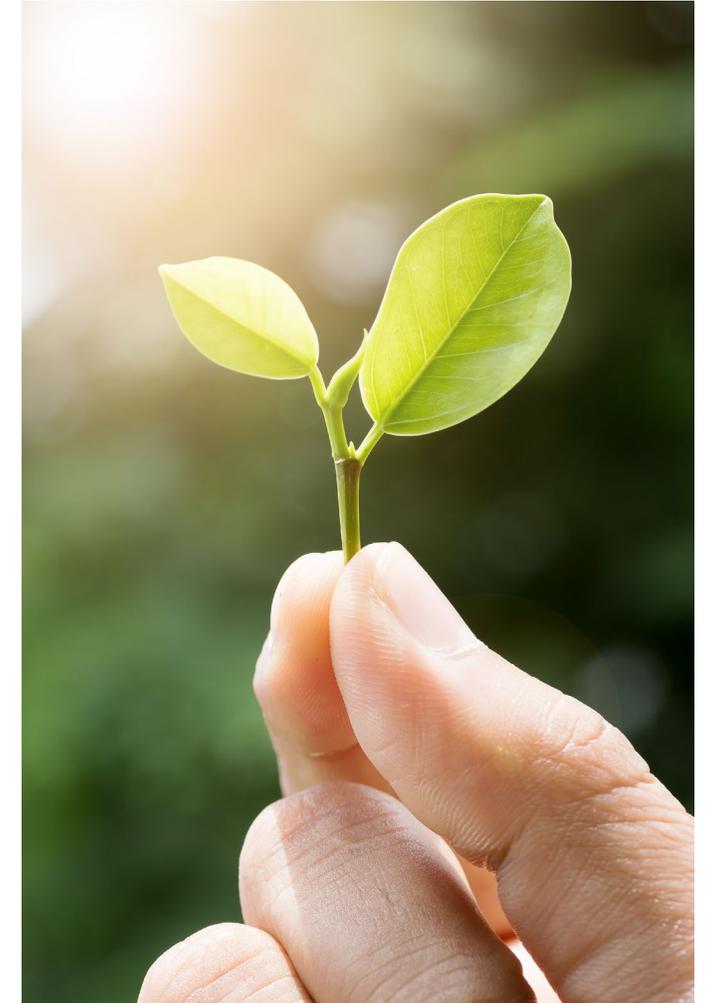
## Current status



# Raised \$3.8M to support preparation for Phase 2



- In May 2021, Amplia successfully completed a \$3.8M capital raising at \$0.23 / share
  - Total of 16.6M new shares issued
  - New institutional shareholder: Acorn Capital
  - Supported by existing institutional shareholders: Platinum and Blueflag
- New capital allows Amplia to plan and prepare its Phase 2 program for AMP945
  - Design and refine clinical trial to test AMP945 in combination with existing treatments in pancreatic cancer patients
    - Could AMP945 augment the activity of current treatment?
  - Commence preparations for Phase 2 studies
    - Prepare for IND Q1 2022
    - Manufacture of AMP945 for further clinical trials and toxicology studies
    - Longer duration animal toxicology studies to support chronic dosing in fibrosis patients



# Summary



## Outcomes for the quarter

- Phase 1 completion
  - Successful implementation of clinical strategy so-far
  - Opens up opportunities in cancer and fibrosis
- Garvan Collaboration
  - Supports current plans
  - Prospects for further opportunities

## Coming Up

- Disclosure of pancreatic cancer trial design
- Regulatory interactions
- Updates on non-clinical studies at Garvan and elsewhere





[ampliatx.com](http://ampliatx.com)