

# Amplia Therapeutics

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Shareholder Update - July 2021

Amplia Therapeutics Limited



# Disclaimer

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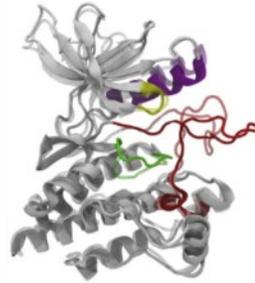


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# Focal Adhesion Kinase – one drug target, two applications



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

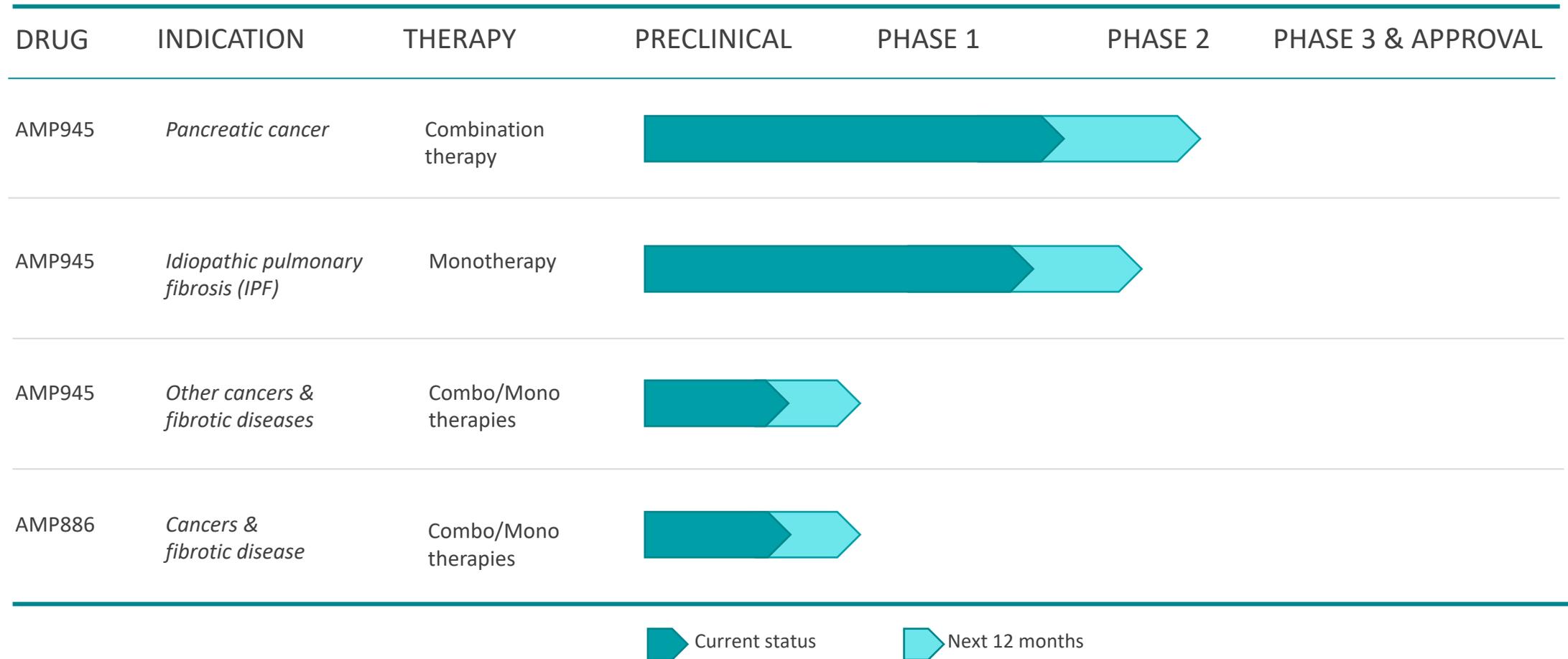
AMP945 was awarded Orphan Drug Designation by the US FDA for use in treating Pancreatic Cancer in March 2020

## **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

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- 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 presentation slide with the following elements:

- Logos:** Ampla Therapeutics (top left) and Garvan Institute of Medical Research (top right).
- Diagram:** A 3D brain model with orange and blue vessels (left).
- Graph:** A line graph titled "Tumour Growth" showing "Tumour Volume (mm<sup>3</sup>)" on the y-axis (0 to 400) and "Days Treatment" on the x-axis (0 to 6). Two series are shown: "Vehicle" (orange line with circles) and "AMP945" (teal line with squares). Error bars are included for each data point.
- Video Player:** A bottom control bar with play, volume, and progress indicators (34:49 / 56:21), and a small inset video of a presenter.

Days Treatment	Vehicle (mm <sup>3</sup> )	AMP945 (mm <sup>3</sup> )
0	~20	~20
1	~80	~40
2	~110	~60
3	~130	~80
4	~170	~90
5	~210	~100
6	~250	~110

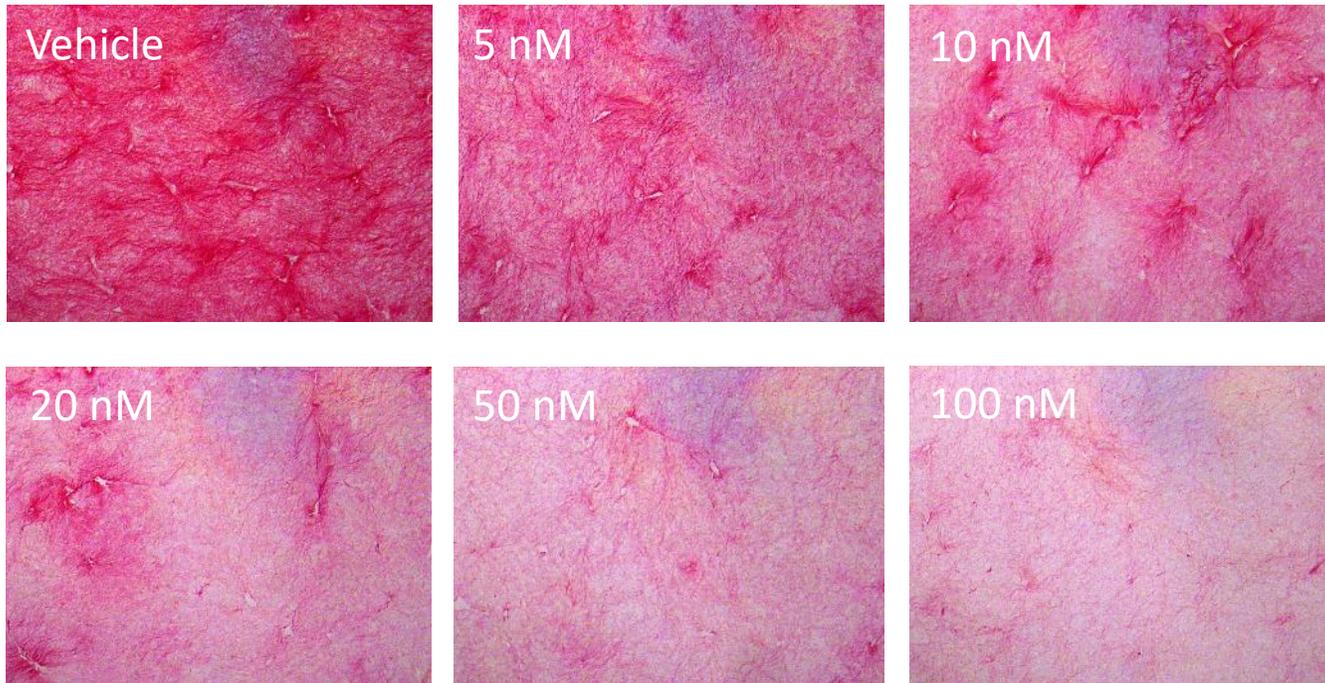
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# Preclinical Data

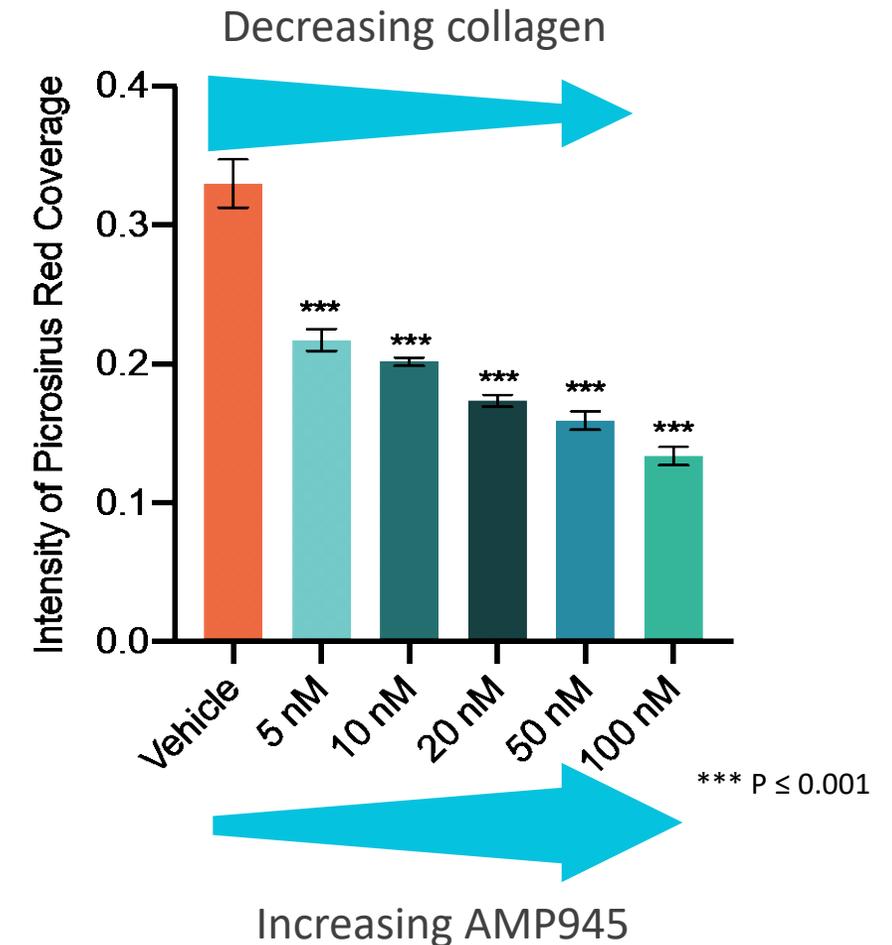
# AMP945 inhibits deposition of collagen



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

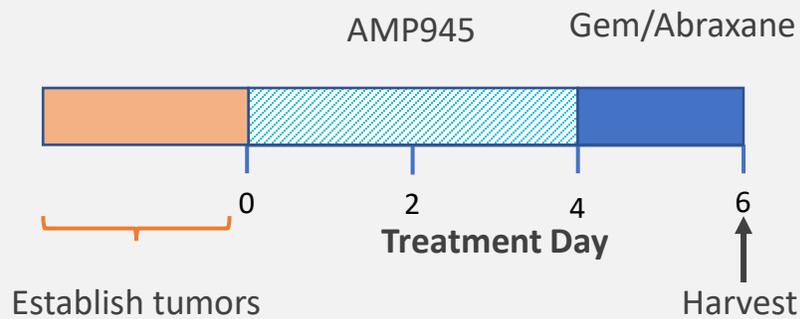


Studies conducted in the laboratory of Professor Paul Timpson (Garvan)

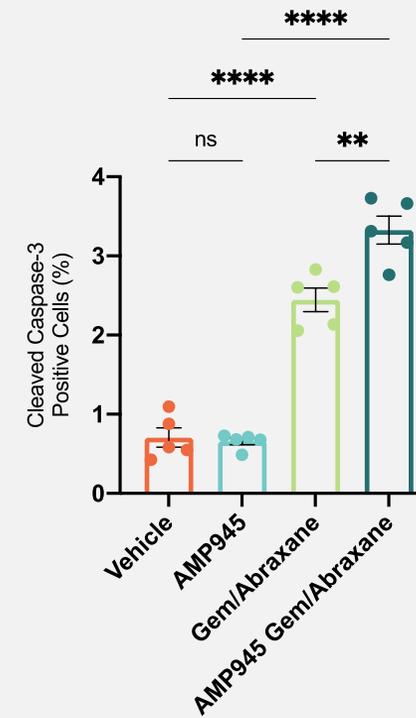
# AMP945 has positive impact on key tumour markers



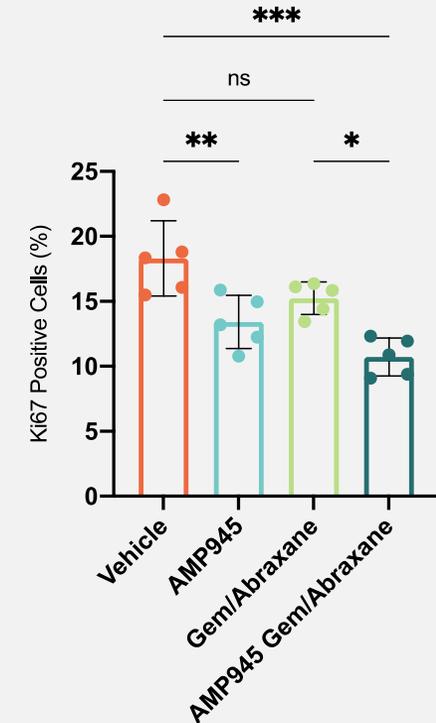
AMP945 priming strategy – pretreatment to make tumours more responsive to standard of care



Marker of cell death increases (Caspase 3)



Marker of cell proliferation decreases (Ki67)



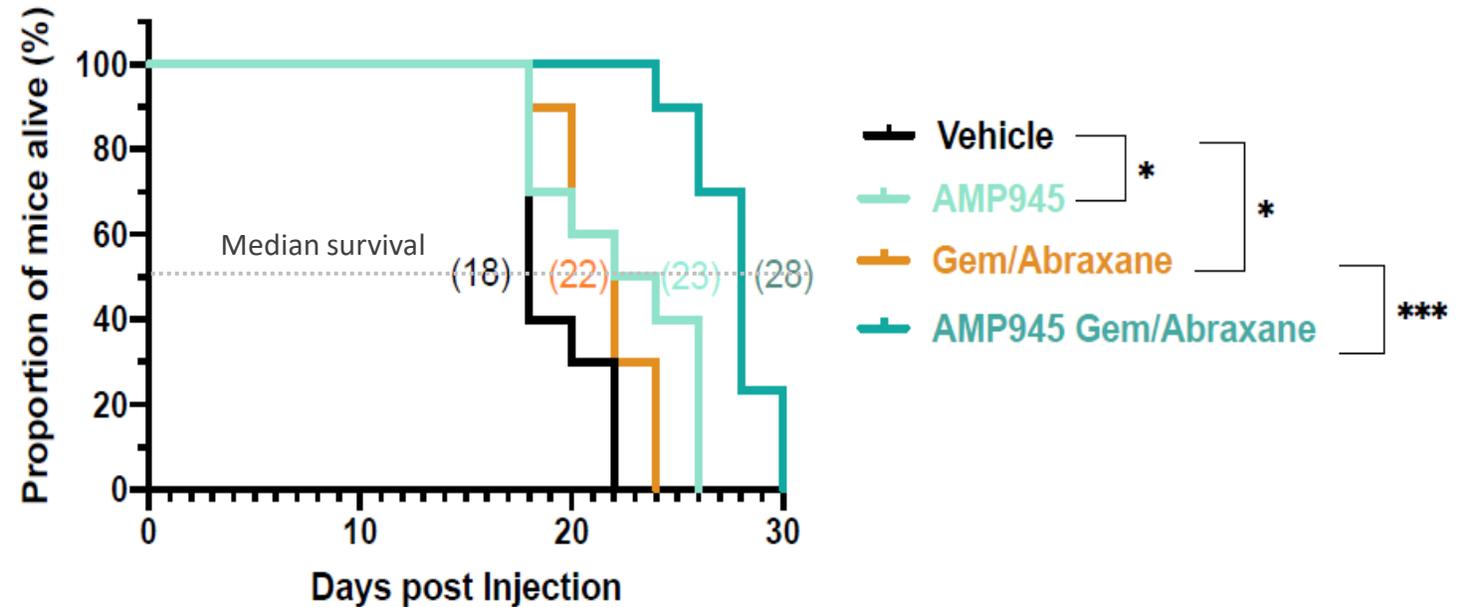
\* P ≤ 0.05 \*\* P ≤ 0.01 \*\*\* P ≤ 0.001 \*\*\*\* P ≤ 0.0001

# 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

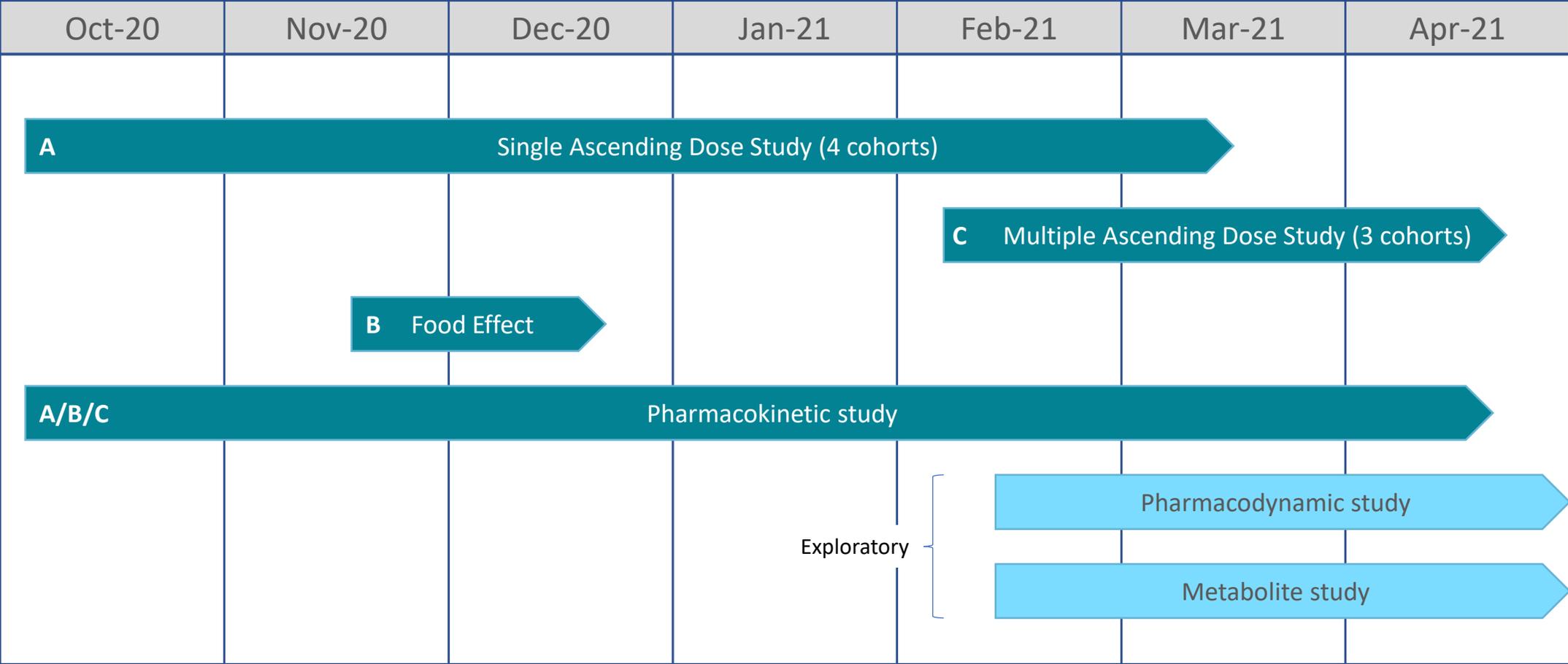


*"A 25% improvement in survival in this model is very impressive and a level of improvement that we rarely see"*

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# Phase 1 Clinical Trial

# Phase 1 trial of AMP945 – design and execution

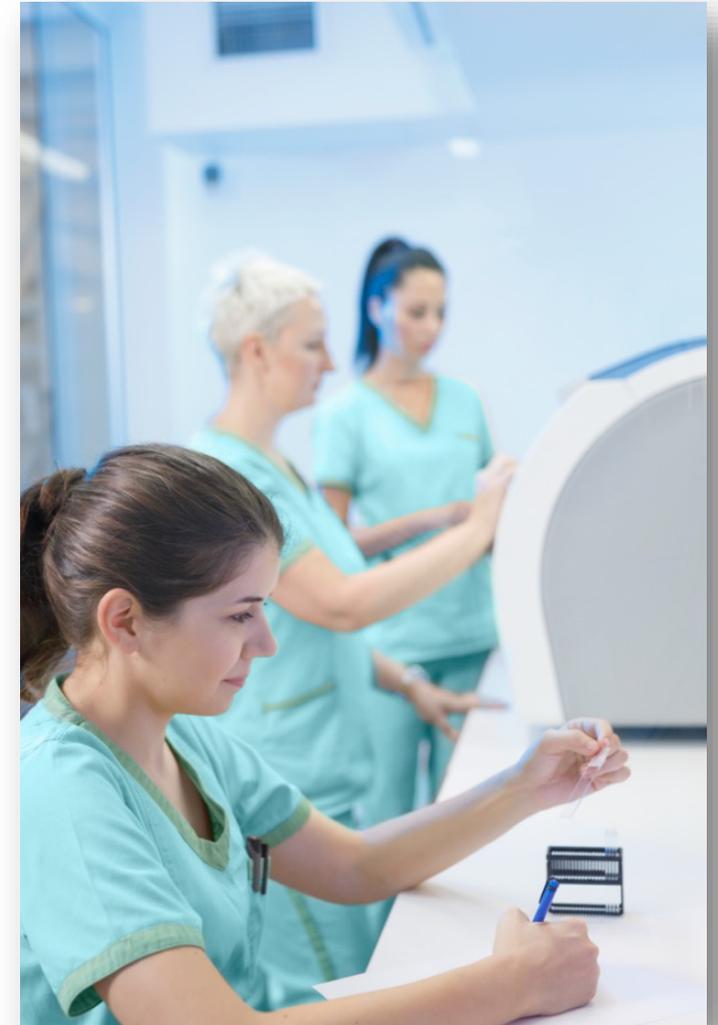


# Data from successful Phase 1 clinical trial of AMP945



## Data on AMP945 from Phase 1 clinical trial

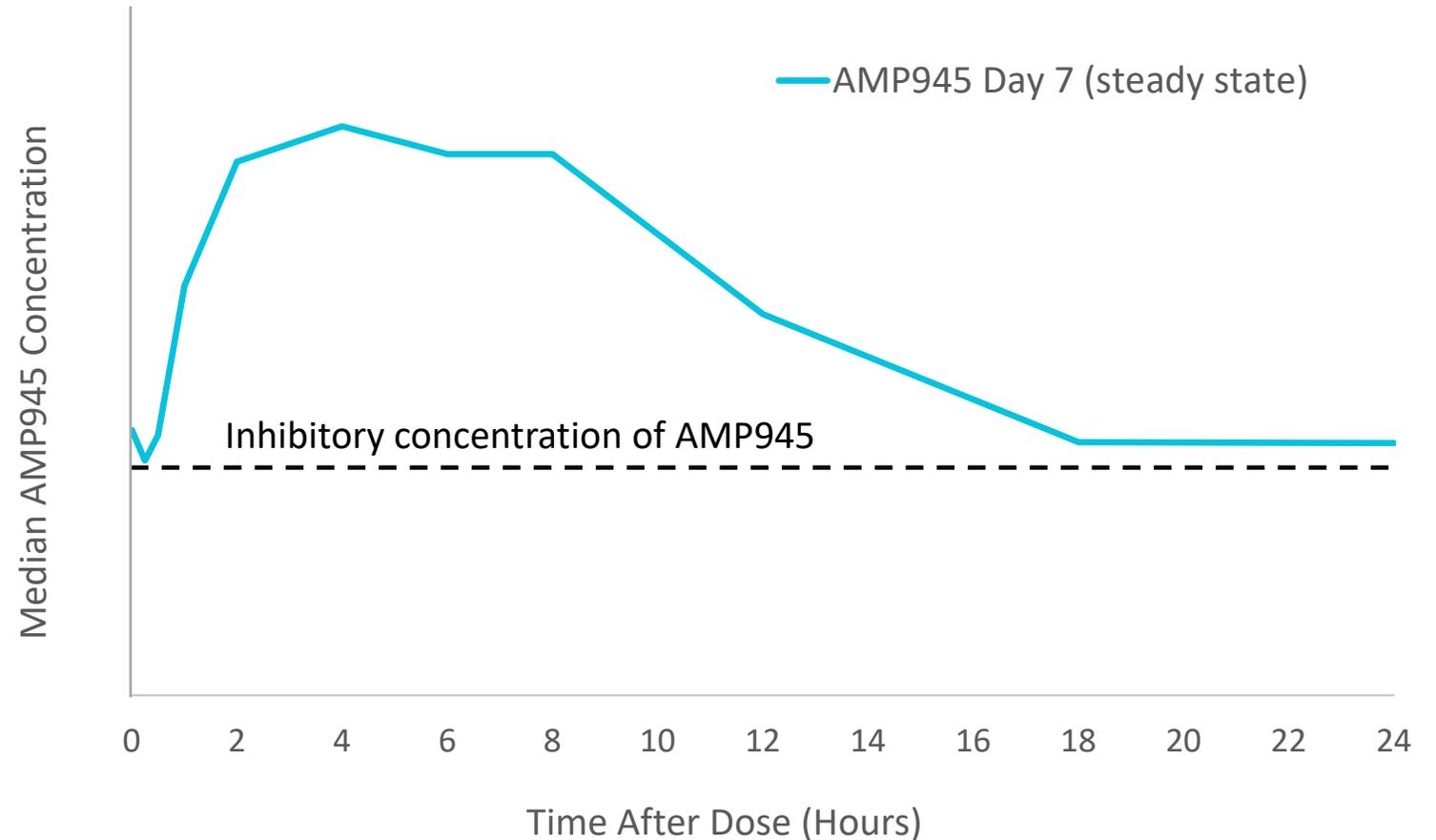
- Safe and well-tolerated at all doses tested:
  - Single ascending doses – up to 125mg
  - Multiple ascending dose (up to 100mg for 7 days)
- No serious adverse events (SAEs) or withdrawals and no identified safety trends
- Once-a-day oral dose supported by pharmacokinetics
- No detectable food effect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



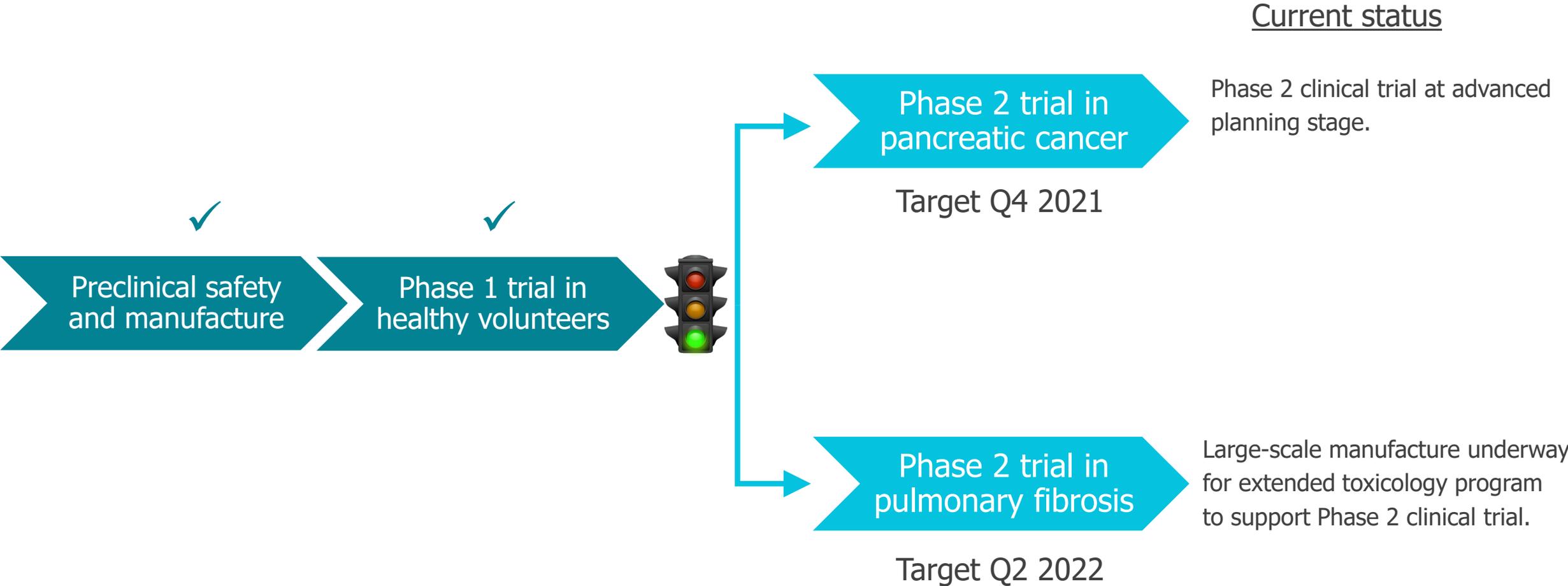
# Inhibitory concentration of AMP945 achieved



- 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



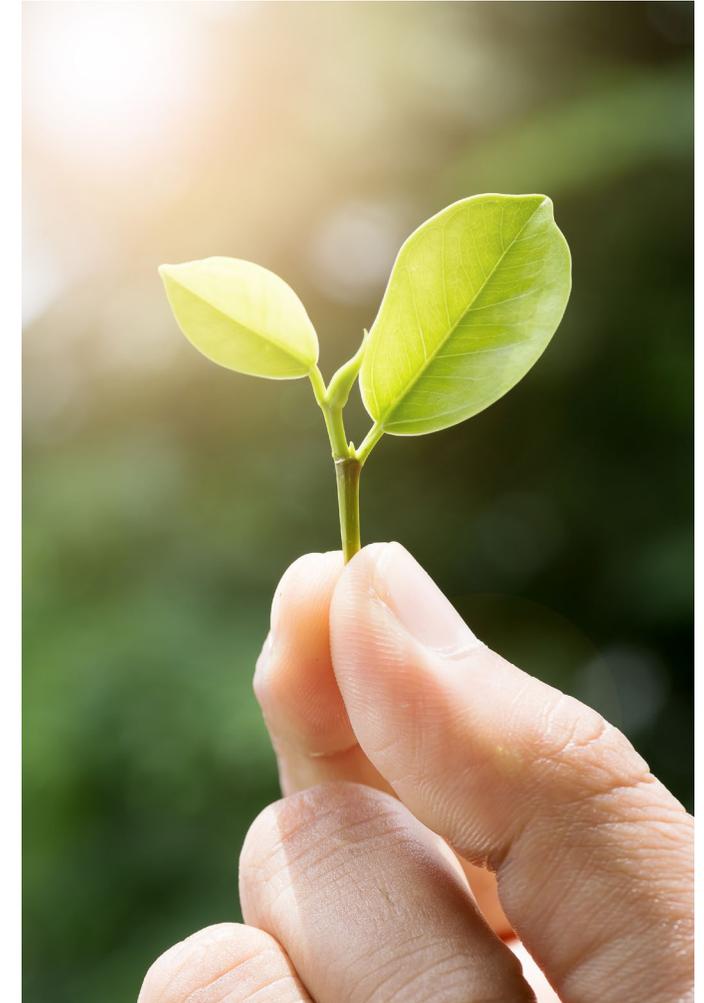
# Significance of Phase 1 results



# 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





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