

**ASX RELEASE**

**1 February 2022**

**Amplia Investor Presentation - February 2022**

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

This ASX announcement was approved and authorised for release by the CEO 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).



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

# Investor Presentation

February 2022



# 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.



## Section One

# Company and Technology Snapshot

Amplia is a clinical-stage company developing small molecule inhibitors of Focal Adhesion Kinase (FAK) for the treatment of cancer and fibrotic diseases.

Next Page



# Company Snapshot



SHARES | 194m



MARKET CAP | \$31m



CASH | \$16.2m

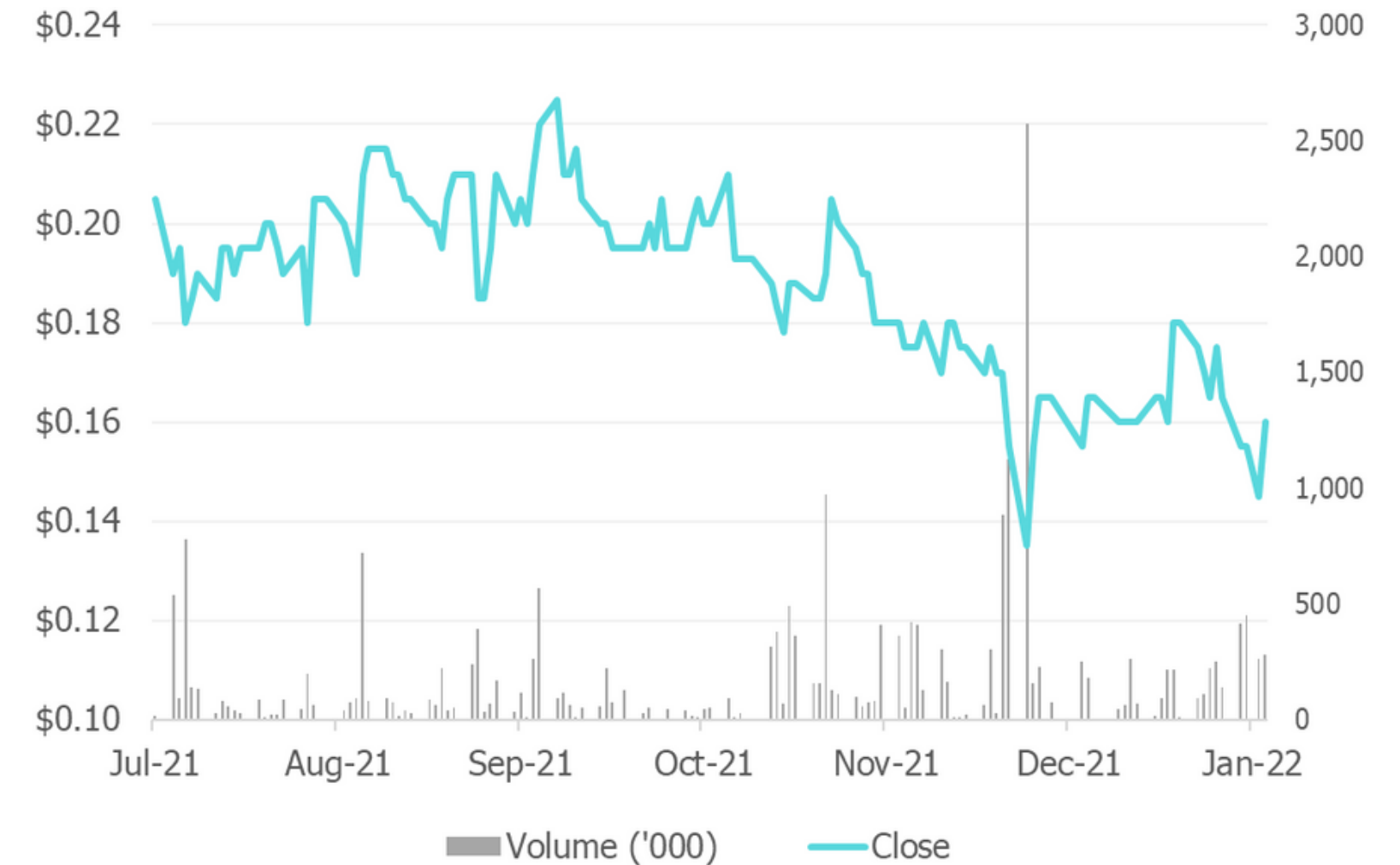


LAST QUARTER BURN | \$0.94m



INSTITUTIONS |  
Platinum Inv. Management 17.5%;  
Blueflag Holdings 7.0%;  
Acorn Capital 6.5%.

## ATX Price and volume – 6 months to 28 Jan 2022



PRICE | \$0.16  
12-MONTH HIGH | \$0.35  
AV DAILY VOLUME | 169k

# Amplia Board



**Warwick Tong**  
MB, ChB, MPP, GAICD  
Non-Executive Independent  
Director & Chair



**John Lambert**  
PhD, GAICD  
Managing Director & CEO



**Jane Bell**  
LLM, LLB, BEc  
Non-Executive  
Independent Director



**Robert Peach**  
PhD  
Non-Executive  
Independent Director



**Chris Burns**  
PhD, FRSC, GAICD  
Non-Executive  
Independent Director

GSK (NZ, London,  
Singapore)

ex-CEO & Director of  
Cancer Therapeutics CRC  
(Melbourne)

Biota Pharmaceuticals  
Medicines Development  
for Global Health

Deputy Chair, Monash  
Health

Administrative Appeals  
Tribunal, Member

NED UCA Funds  
Management 2014-2021

Co-founder Receptos  
(acquired by Celgene for  
\$7.8B in 2015)

Apoptos, Biogen Idec,  
IDEC, Bristol Myers Squibb

Pfizer (UK), Ambri (Head of  
Chemistry), University of  
Sydney

Cytopia (Head Medicinal  
Chemistry, Research  
Director)

# Investment Highlights



Two Phase 2 clinical trials of lead asset AMP945 scheduled to start in 2022.

- First results expected mid-2023 with early data reports likely beforehand



Fully funded to achieve major value inflections

- Initial efficacy assessment in pancreatic cancer trial
- Regulatory approval to start pulmonary fibrosis trial



AMP945 has completed a Phase 1 clinical trial

- Excellent safety, tolerability and pharmacokinetic profile
- Engages with intended target

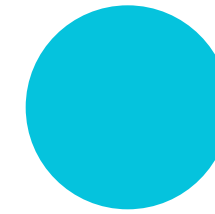


Highly experienced management team, Board and advisor network

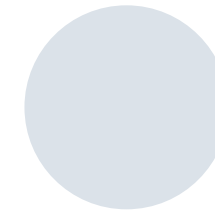


Solid track record in delivery against timelines and budgets

# Amplia's Pipeline



Current Status



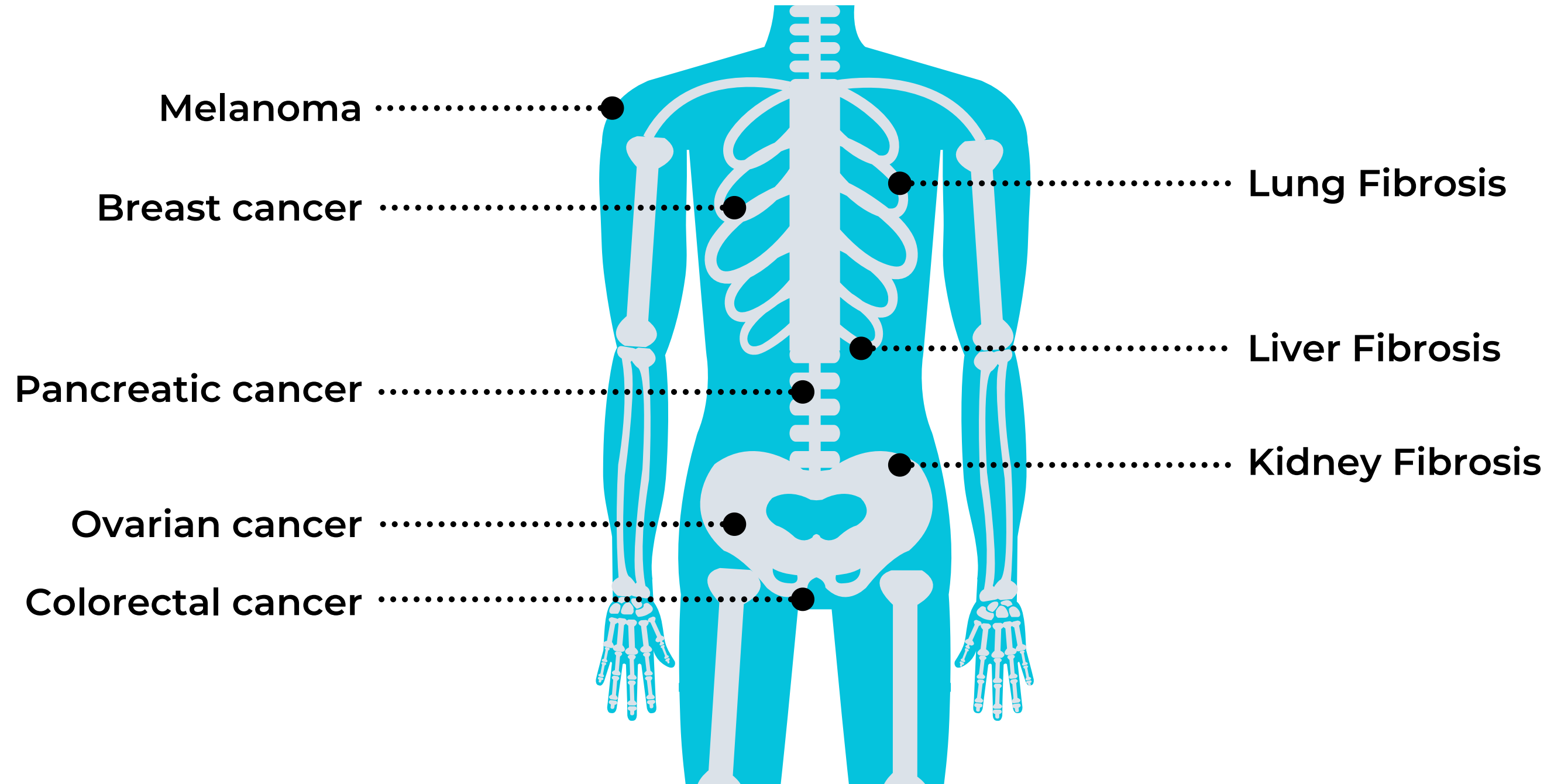
Next 12-months

Drug	Indication	Therapy	Preclinical	Phase 1	Phase 2	Phase 3 (approval)
AMP945	Pancreatic Cancer	Combination Therapy				
AMP945	Idiopathic pulmonary fibrosis (IPF)	Monotherapy				
AMP945	Other cancers & fibrotic diseases	Combo/ Monotherapies				
AMP886	Cancers & fibrotic disease	Monotherapy				

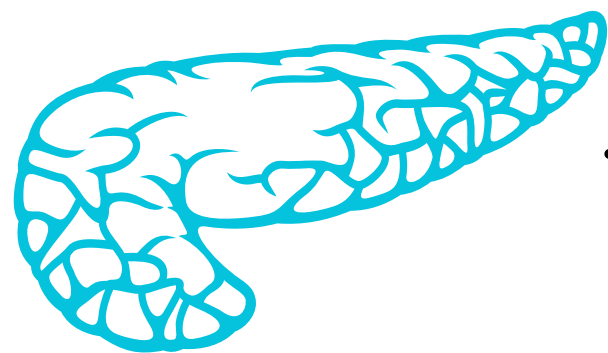




# Amplia's Therapeutic Opportunities



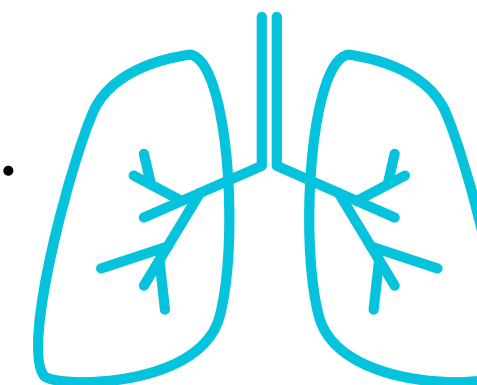
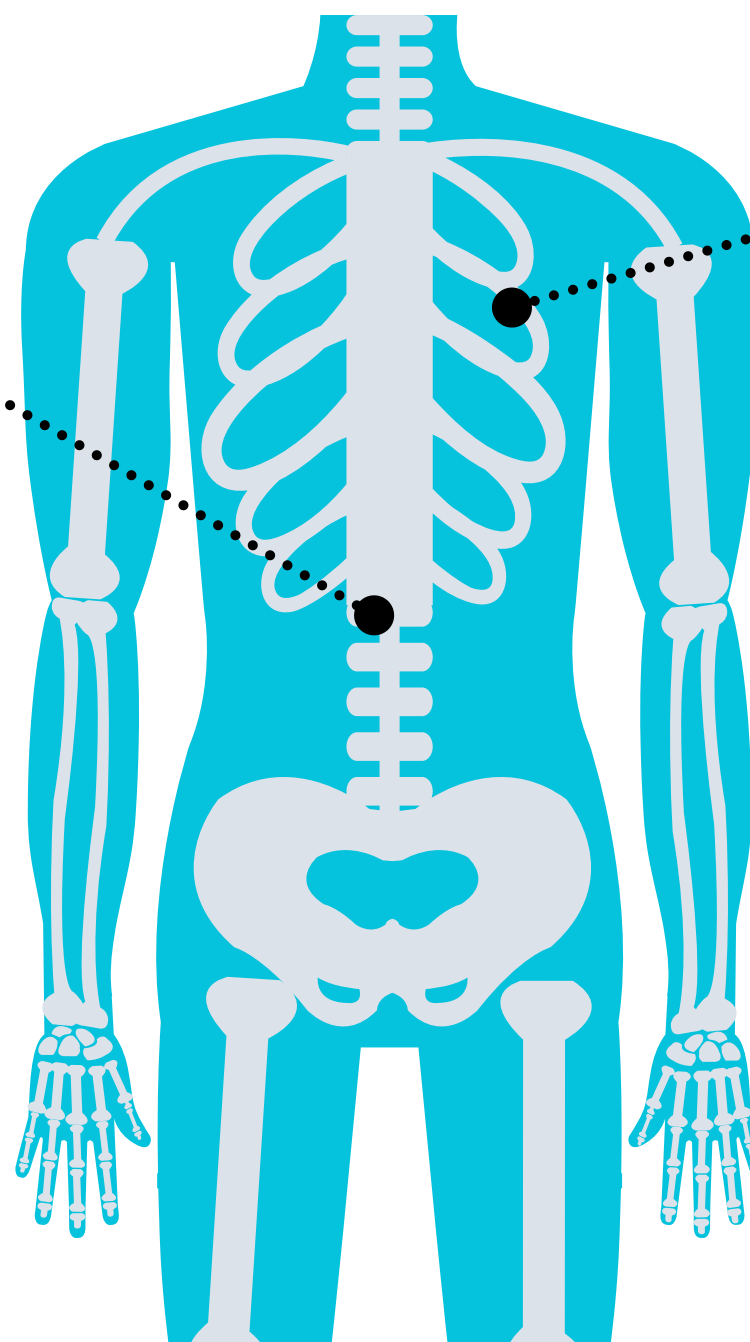
# Amplia's Current Focus



## Pancreatic Cancer

- 60,000 new diagnoses and 48,000 deaths from pancreatic cancer in the US each year\*
- Difficult-to-treat cancer
- Less than 20% of patients eligible for surgery
- Most patients treated with cytotoxic chemotherapy drugs

\* American Cancer Society, 2021

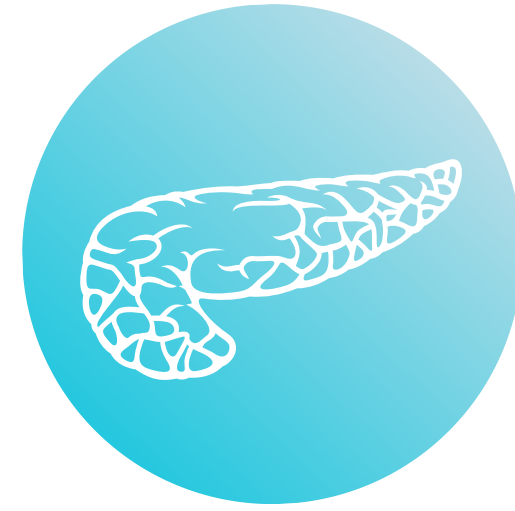


## Idiopathic Pulmonary Fibrosis (IPF)

- Affects ~3M people worldwide\*\*
- Devastating, progressive disease caused by the build up of fibrotic tissue in the lungs
- Two drugs approved which only slow progression
- Median survival time is 3-5 years

\*\*The American Journal of Managed Care, 2021

# Why Focus on Pancreatic Cancer and Pulmonary Fibrosis?



**Pancreatic Cancer**



**Pulmonary Fibrosis**

Unmet need



AMP945 Orphan Drug Designation (US FDA)



Preclinical data supports rationale for clinical assessment



Available clinical safety data supports proposed trial



Gateway to other indications and therapeutic opportunities



## Section Two

# Targeting FAK in Cancer and Fibrosis

Fibrotic shields protect many solid tumours from chemotherapy - Amplia's FAK inhibitors aim to remove the shield.

Next Page



# Amplia's Drug Target | Focal Adhesion Kinase



Fibrotic Diseases

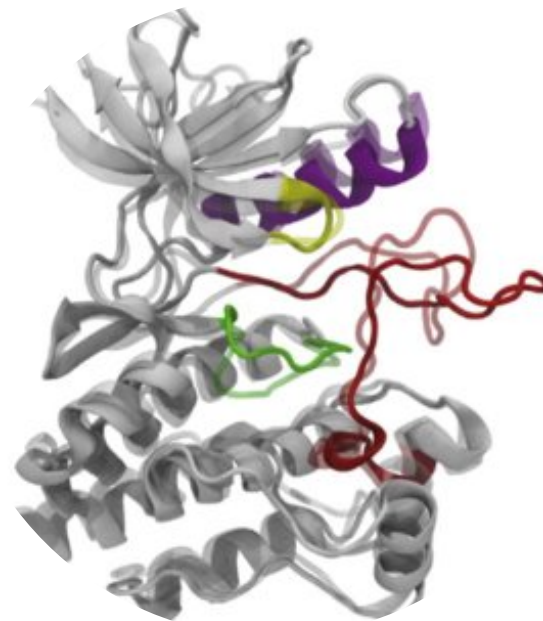


Solid Cancers



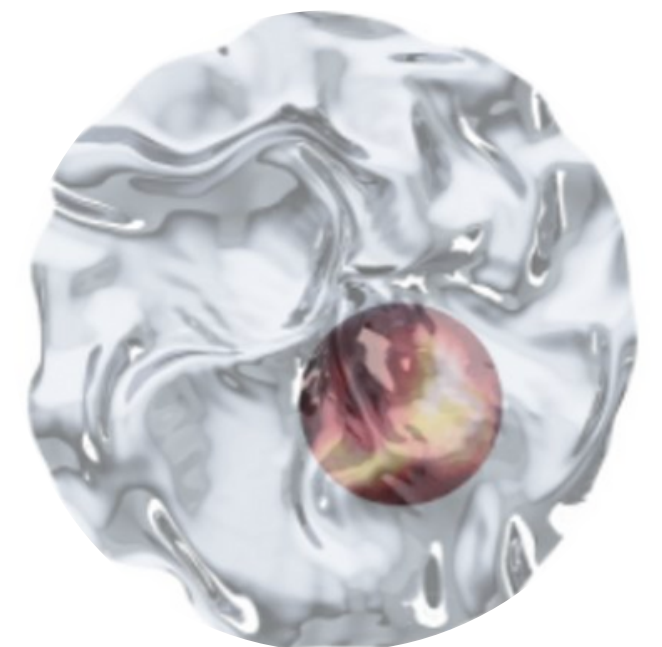
Fibrotic Tissue

Promotes fibrosis



Focal Adhesion Kinase (FAK)

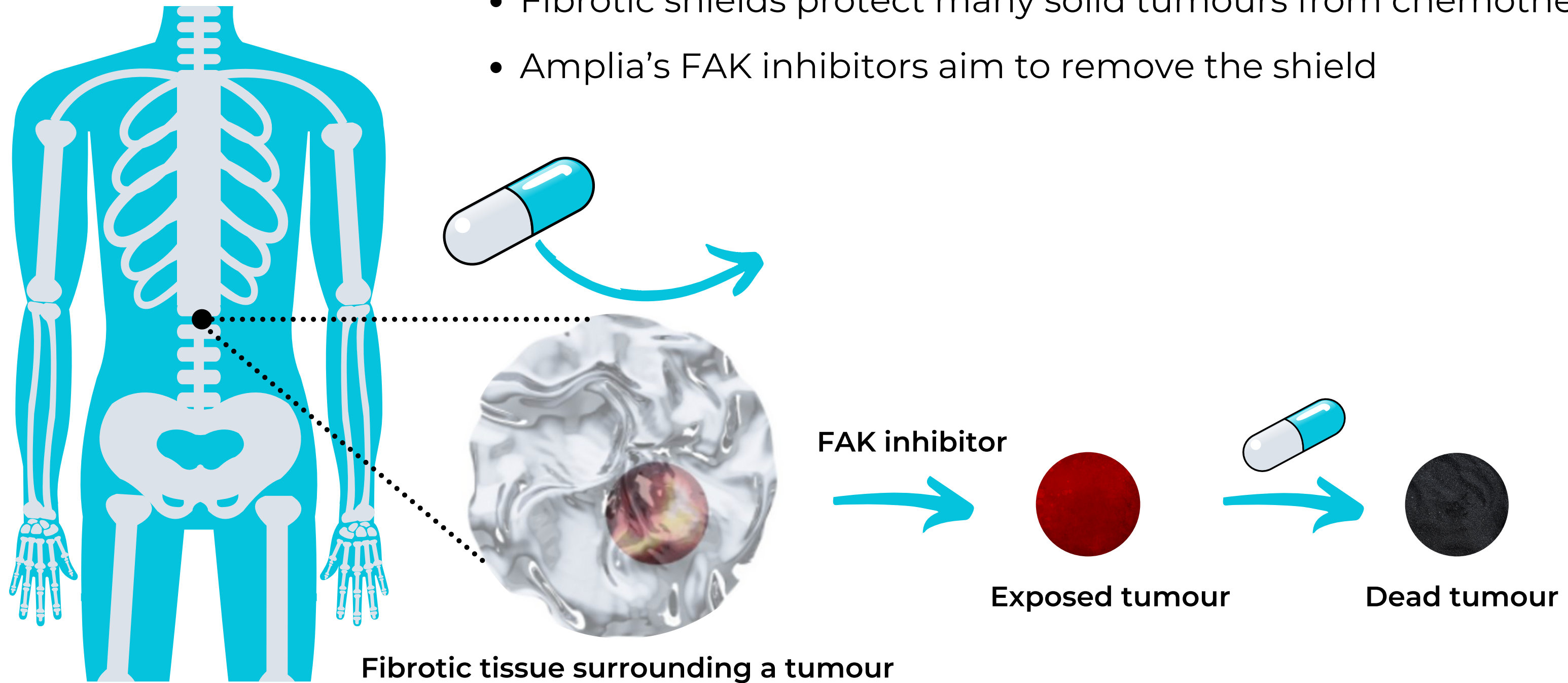
Shields tumours from chemotherapy



Fibrotic tissue surrounding a tumour

# Amplia's Hypothesis | Enhancing Chemotherapy

- Fibrotic shields protect many solid tumours from chemotherapy
- Amplia's FAK inhibitors aim to remove the shield



# Rationale for Phase 2 Pancreatic Cancer Trial



Preclinical evidence highlights potential synergy of FAK inhibition with current standards of care

## Key findings:

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

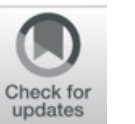


Journal of Experimental & Clinical Cancer Research

RESEARCH

Open Access

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

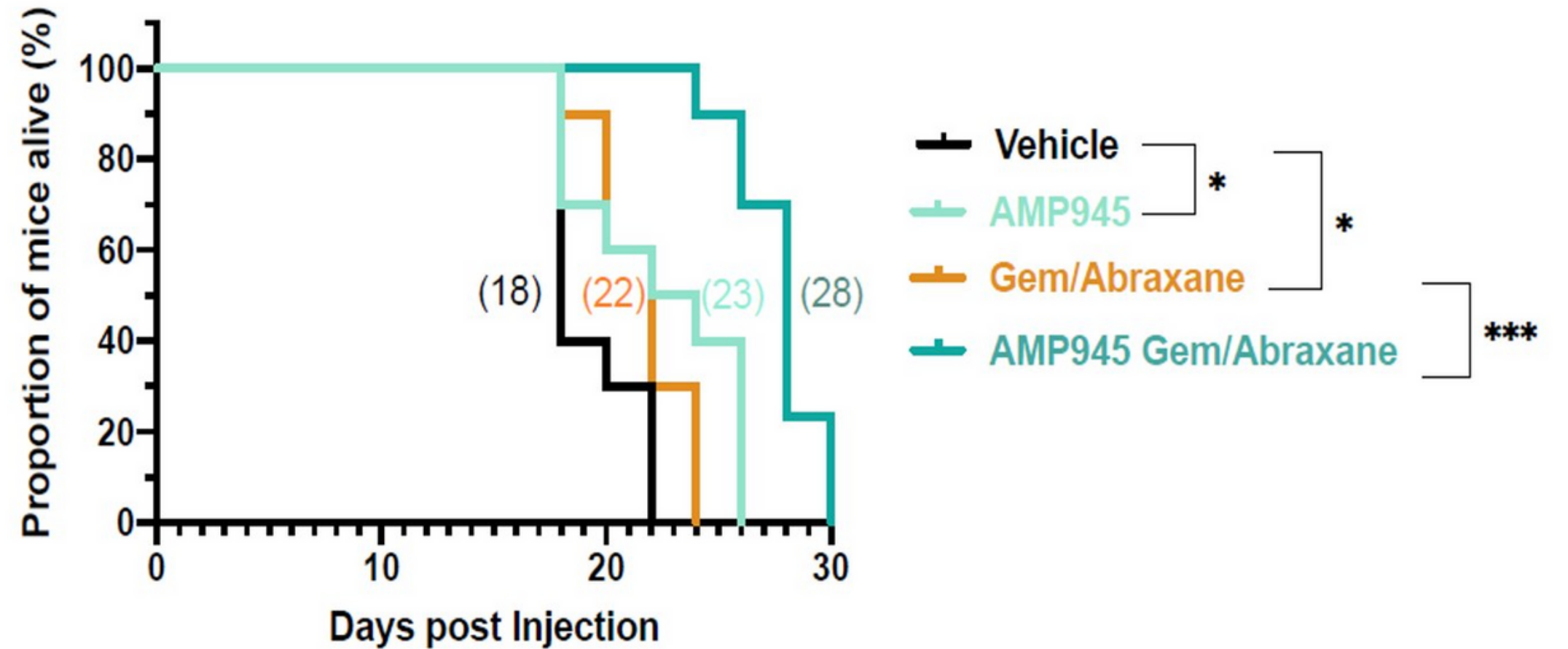


Le Large, T. Y. S., Bijlsma, M. F., et al., *Journal of Experimental & Clinical Cancer Research*, 40 (2021), 91.

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

# AMP945 Improves Survival in Pancreatic Cancer Model

- 25% improvement in survival when added to standard of care ( $p \leq 0.001$ )
- KPC\* is a highly aggressive animal model of pancreatic cancer
- FAK inhibition by 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

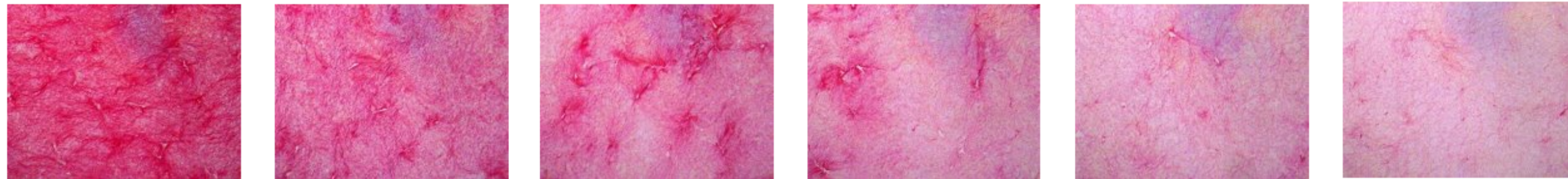
- Professor Paul Timpson

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

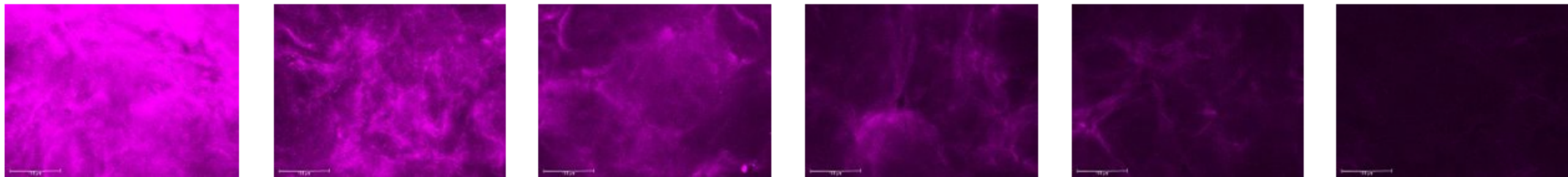


# AMP945 Inhibits Deposition and Crosslinking of Collagen

Total collagen decreases ●.....●



Cross-linked collagen decreases ●.....●



- Cross-linked collagen is a key component of fibrotic tissues
- AMP945 inhibits collagen formation and collagen cross-linking in a dose-dependent manner



# AMP945 in Lung Fibrosis

## Bleomycin animal model of lung fibrosis

### Prevention

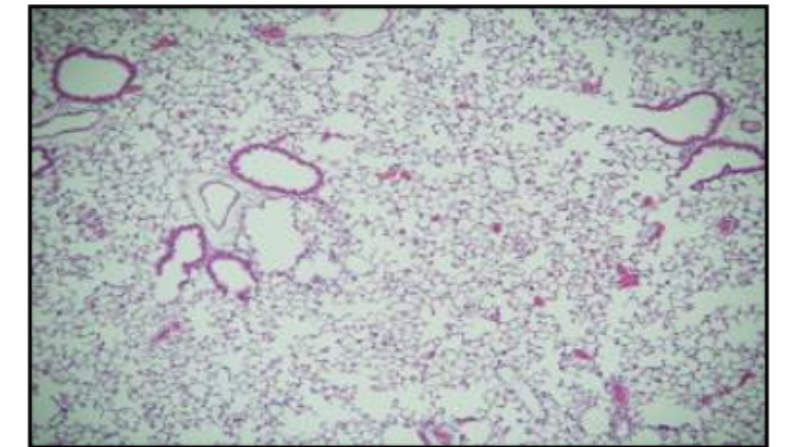
- AMP945 administered before onset of fibrosis
- Evaluating ability of AMP945 to prevent fibrosis from becoming established

### Treatment

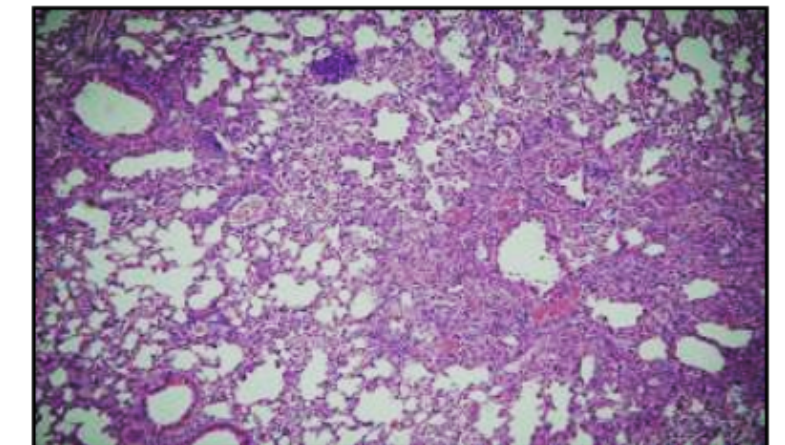
- AMP945 administered after onset of fibrosis
- Evaluating ability of AMP945 to treat established fibrosis

AMP945 both prevents and treats fibrosis in the industry-standard disease model of lung fibrosis

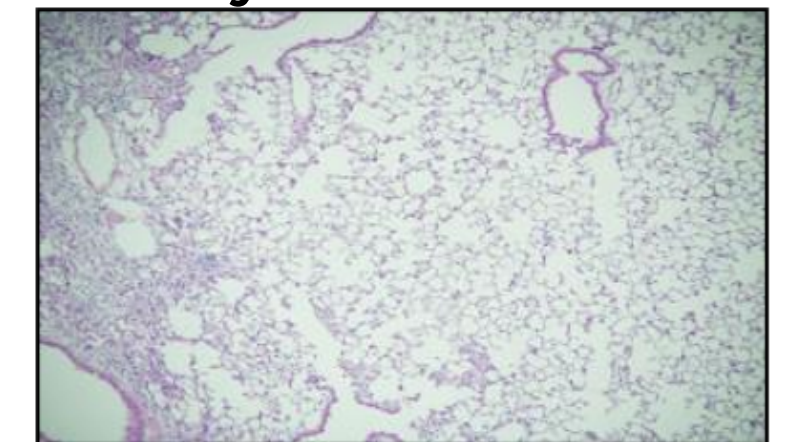
Control: healthy lung



Bleomycin: fibrotic lung



Bleomycin + AMP945



Section Three

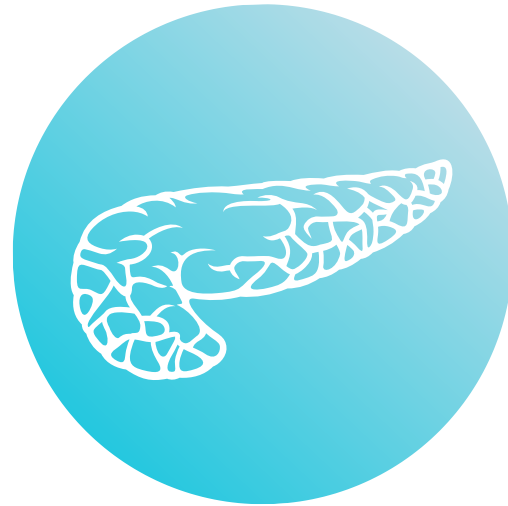
# Clinical Development

Amplia's clinical schedule provides multiple potential value inflections within the next 12-months.

Next Page



# Phase 2 Trials Planned in 2022



## Phase 2 pancreatic cancer clinical trial

- Protocol and design work completed
- Funded through recent capital raise
- Drug manufacture complete
- Dosing expected to commence in Q2 CY2022



## Phase 2 pulmonary fibrosis clinical trial

- Vendors, designs and schedules for preliminary toxicology locked in
  - Drug manufacture complete
- Clinical design work is at an advanced stage
- Recruitment to commence in H2 CY2022

# Phase 2 Study of AMP945 in Pancreatic Cancer



## Key trial elements

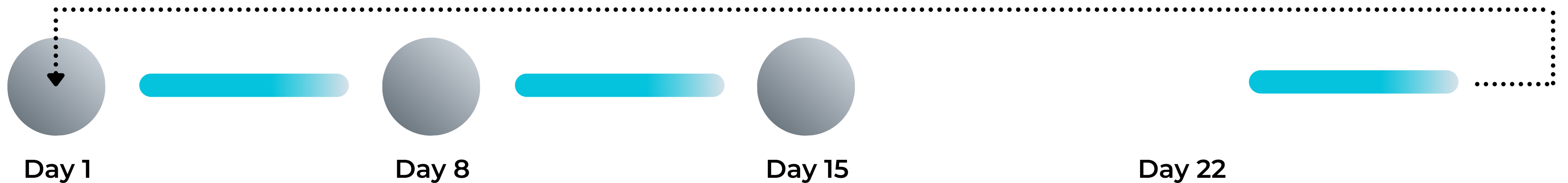
- First-line therapy
  - Largest patient cohort
  - Healthier patients
  - Aims to position AMP945 as a first-line treatment option
- Patients with non-resectable or metastatic pancreatic cancer
- Intermittent dosing of AMP945 between normal chemotherapeutic doses of gemcitabine/Abraxane®
  - Designed to enhance standard of care
  - Mirrors design of preclinical efficacy studies

# Pancreatic Cancer Priming Dose Regimen

## Normal chemotherapy treatment cycle



## Amplia's investigational chemotherapy treatment cycle



AMP945 priming doses

Chemotherapy dose: gemcitabine and Abraxane®

# Phase 2 Pancreatic Cancer Trial Summary



## Population

- Patients with Stage III or IV pancreatic cancer
- First line therapy
- ECOG status  $\leq 1$
- Life expectancy of  $>3$  month



## Design

- Phase 1b/2a open label, single arm study to evaluate safety, PK, PD and efficacy of AMP945 in combination with gemcitabine/Abraxane®



## Treatment

### Dose escalation

- Fixed doses of G/A, escalating doses of AMP945
- 4 cohorts of 3-6 pts. 1 month cycle

### Expansion

- Part 1: 26 pts, 5 months
- Interim Analysis

### Expansion

- Part 2: 24 pts, 9 months



## Endpoints

### Dose Escalation

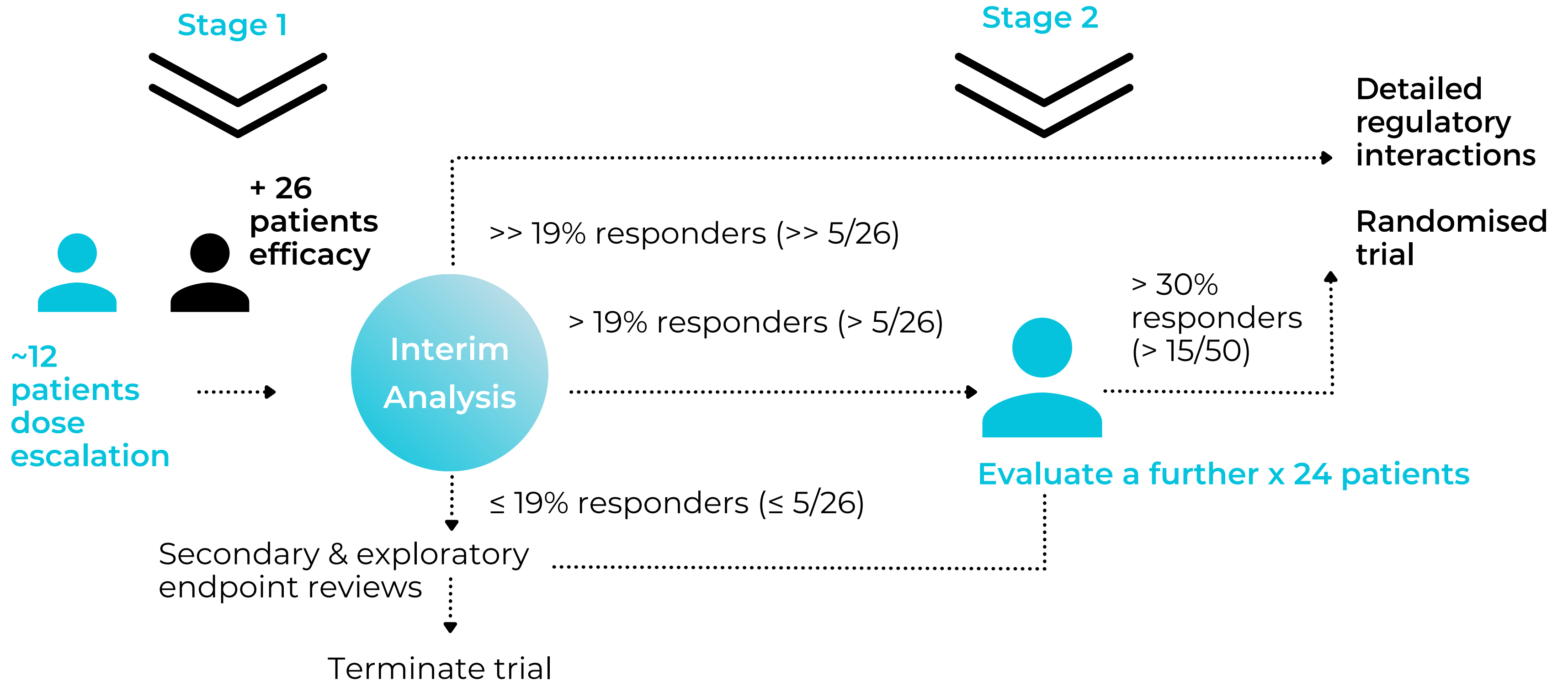
- Safety, PK, RP2D

### Expansion

- Primary: Objective response, duration of response
- Secondary: Overall survival, progression free survival
- Exploratory: Impact on/of biomarkers

ECOG: Eastern Cooperative Oncology Group; PK: pharmacokinetics;  
 PD: pharmacodynamics; G/A: Gemcitabine/Abraxane®;  
 RP2D: Recommended Phase 2 Dose

# Phase 2 Trial Overview and Decision Tree





# Clinical trial supplies

## Manufacture of 2kg batch scale of AMP945 drug substance

- Improved process
- Increased scale
- GMP




---

## Manufacture of AMP945 drug product (capsules)

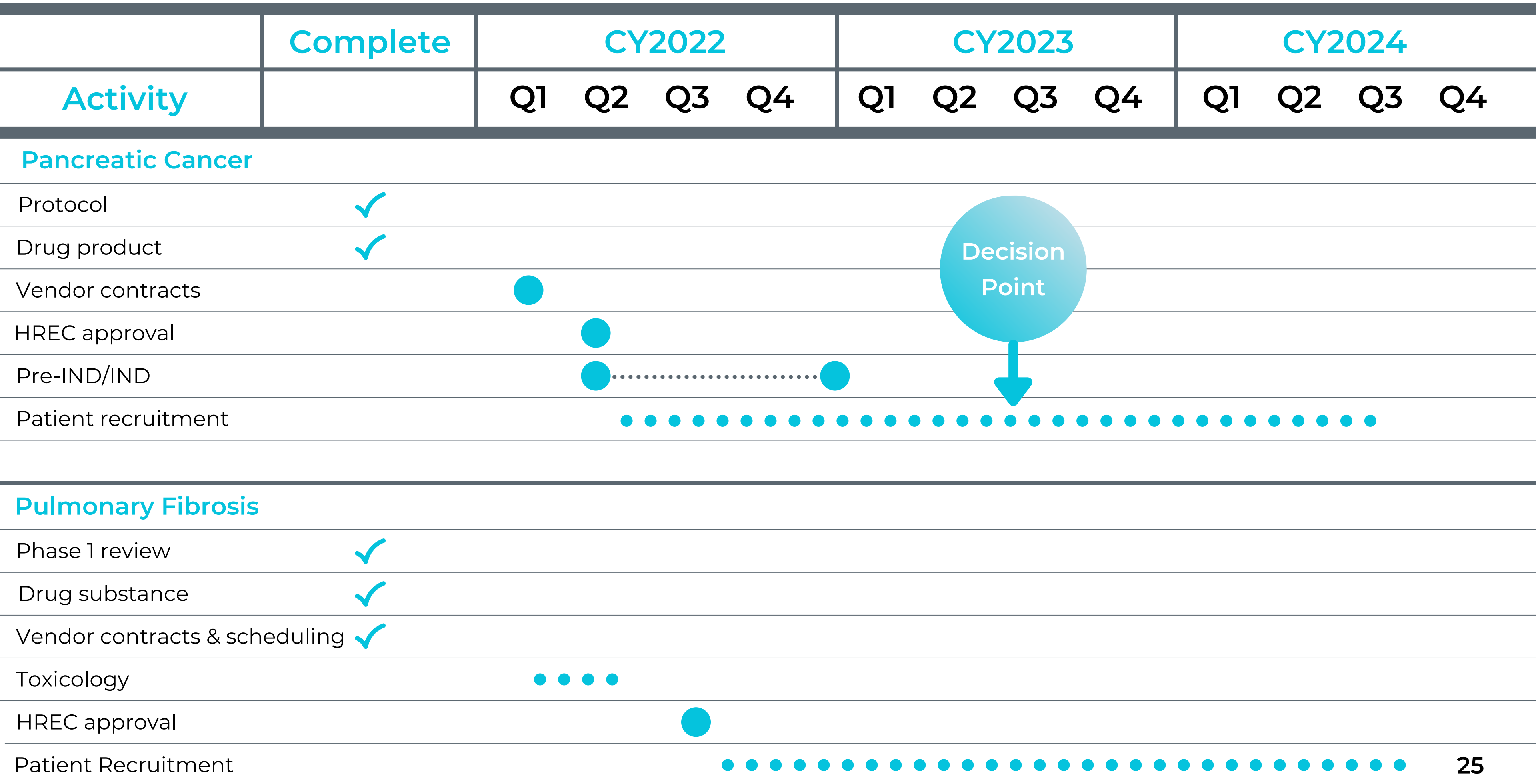
- Machine filling of capsule - supports commercial development
- Supplies pancreatic cancer trial
- GMP



# Amplia's Clinical Schedule

HREC: Human Research Ethics Committee

IND: Investigational New Drug



## Section Four

# Growth Plans for 2022

Amplia will continue to build momentum by hitting key development and corporate milestones this year.

Next Page



# Performance Track Record

## 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



**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.**

**- Amplia CEO, Dr John Lambert**

# Top Line Objectives for 2022



## Initiate recruitment of patients in two Phase 2 trials of AMP945

- Pancreatic cancer
  - Pulmonary fibrosis
- .....● Report early results



## Regulatory engagement to refine development plans



## Expand therapeutic opportunities for AMP945

- Cancer
- Fibrosis



## Expand pipeline by progression of AMP886 into early development

# Thank You.

Amplia Therapeutics Limited

ABN 16 165160 841

ASX: ATX

[info@ampliatx.com](mailto:info@ampliatx.com)

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



John Lambert  
Chief Executive Officer  
[john@ampliatx.com](mailto:john@ampliatx.com)