

ASX RELEASE

12 May 2022

**Amplia Therapeutics to Present at 16th Bioshares Biotech Summit**

Amplia Therapeutics Limited (ASX: ATX) today announced that the Company will present at the Bioshares Biotech Summit on Thursday, May 12<sup>th</sup>, 2022 in Albury, NSW.

A copy of the presentation is attached.

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).



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

# A New Approach to Cancer Therapy

BioShares Conference 2022

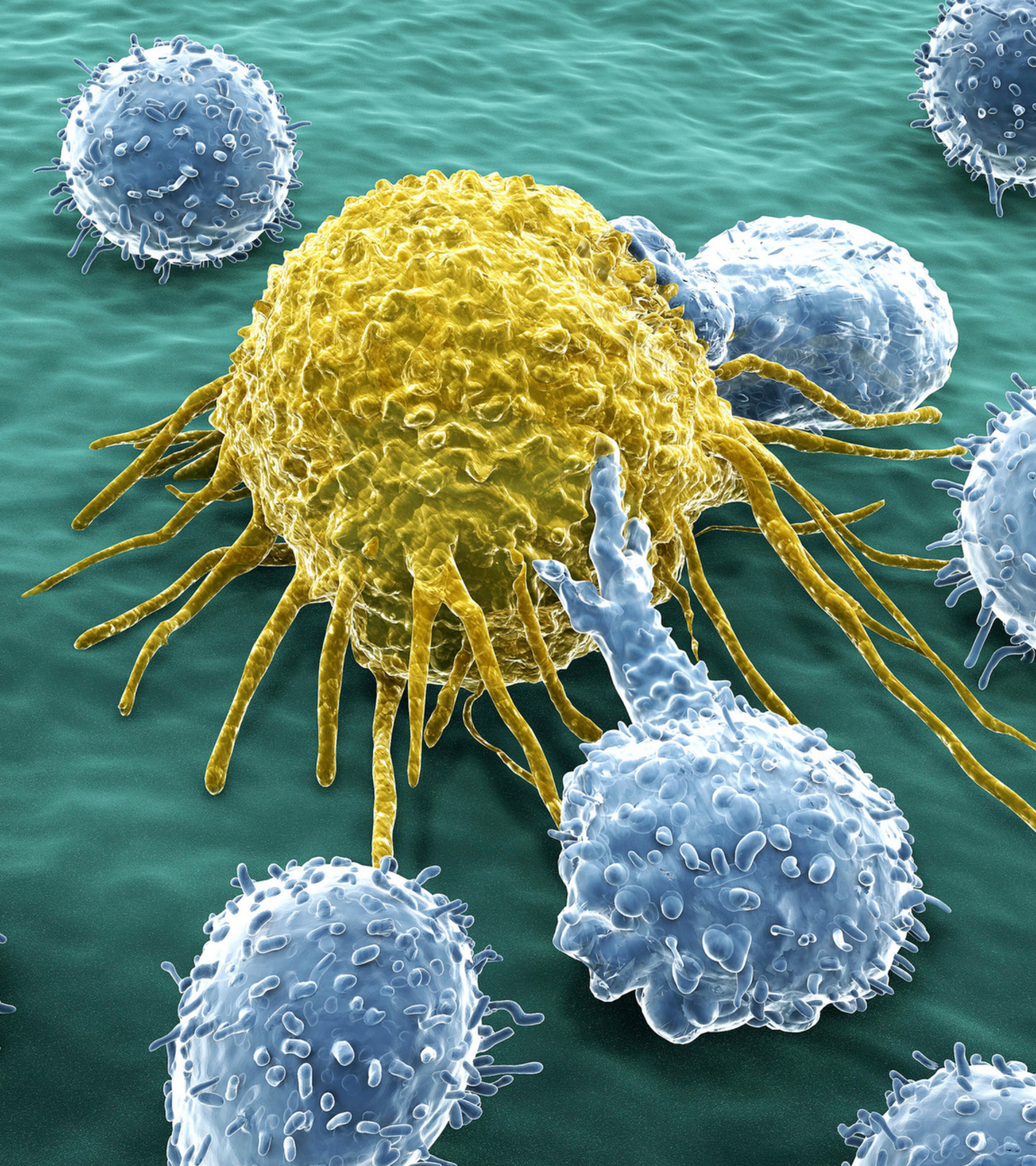


# Disclaimer

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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.

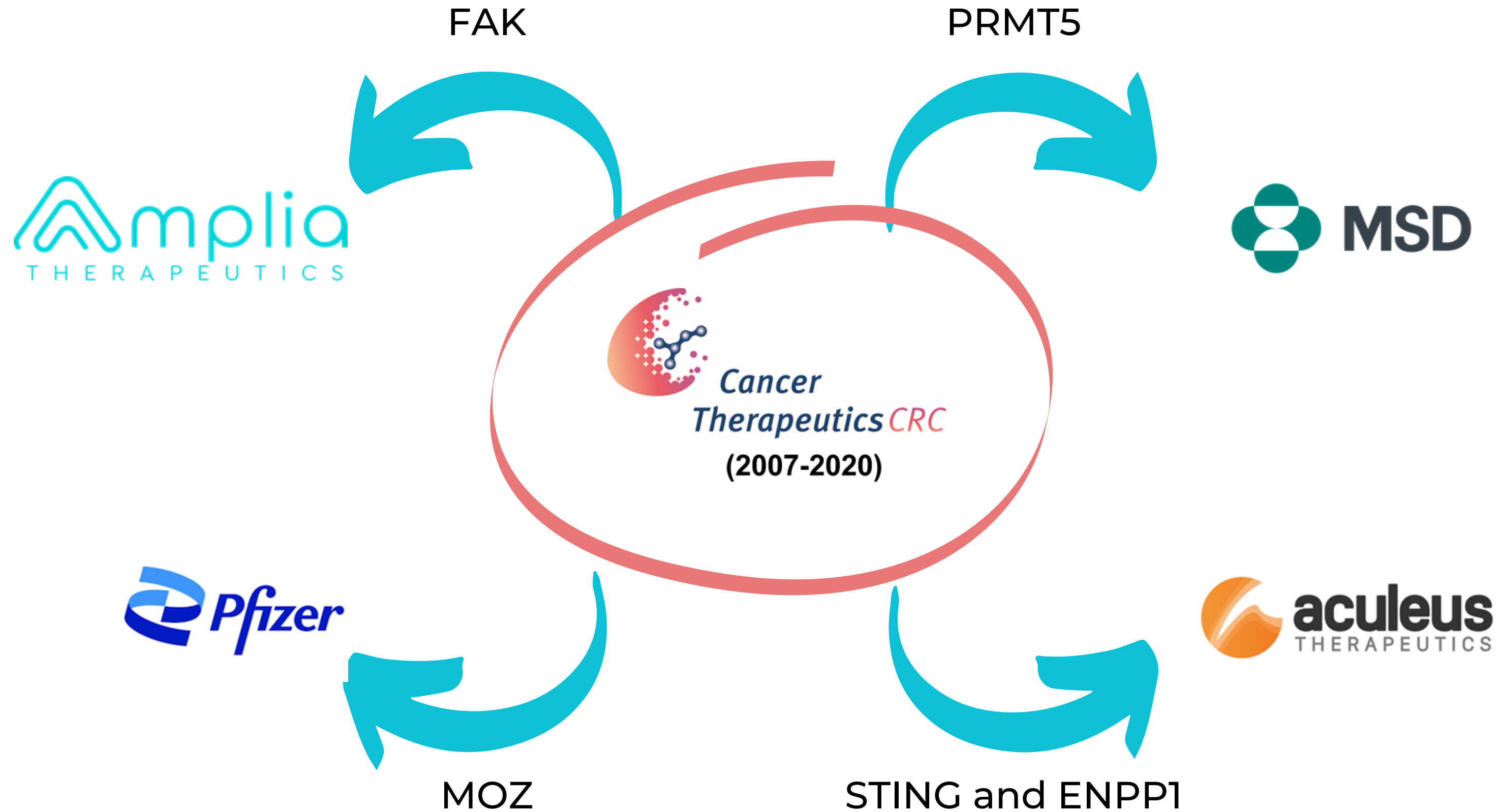
There can be no assurance or guarantee that actual outcomes will not differ materially from these statements. The data and results pertaining to clinical subjects used in this presentation are illustrative of medical conditions and outcomes associated with potential applications of Amplia’s acquired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



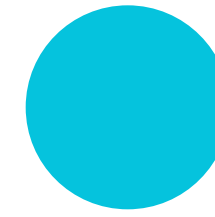
# Introducing Amplia

- ASX: ATX
- Melbourne-based
- Developing inhibitors of Focal Adhesion Kinase (FAK)
  - Oncology
  - Fibrosis
- Clinical stage (Phase 2)
  - First-line advanced pancreatic cancer

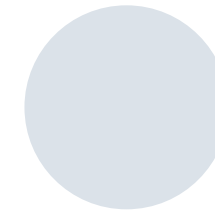
# Origins of Amplia's FAK Inhibitors



# 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	Cancers & fibrotic disease	Combo/ Monotherapies				
AMP886	Cancers & fibrotic disease	Combo/ Monotherapy				



# Company Snapshot



SHARES | 194m



MARKET CAP | \$23m



CASH | \$14.6m



LAST QUARTER BURN | \$2.3m



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

## ATX Price and volume – 6 months to 30 April 2022



PRICE | \$0.12  
12-MONTH HIGH | \$0.35  
AV DAILY VOLUME | 169k

# Agenda



- 1 Background
- 2 Why is FAK a good target?
- 3 Preclinical results
- 4 Clinical program
- 5 Commercialisation strategy

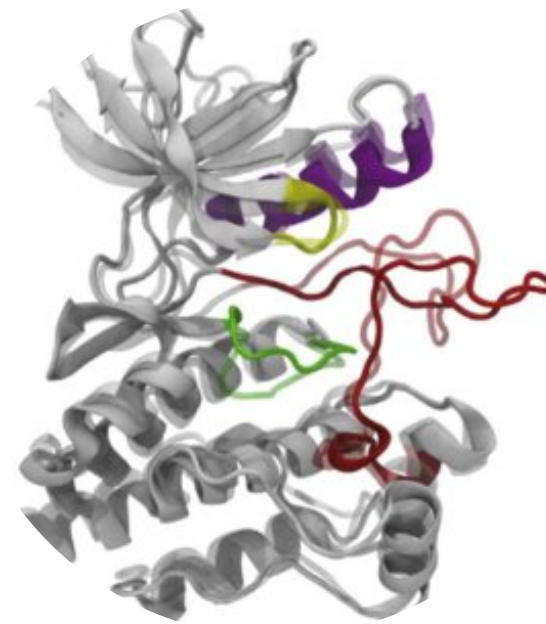


# Amplia's Drug Target | Focal Adhesion Kinase



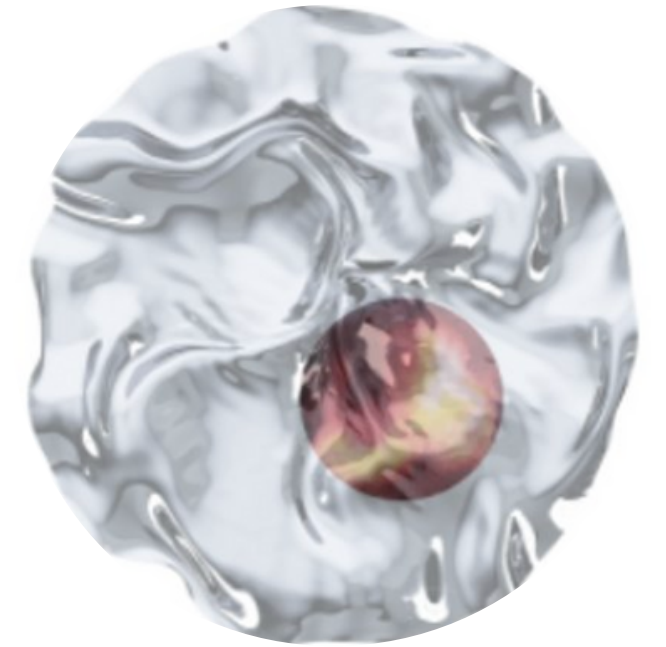
Fibrotic Tissue

Collagen deposition  
Collagen crosslinking



Focal Adhesion  
Kinase (FAK)

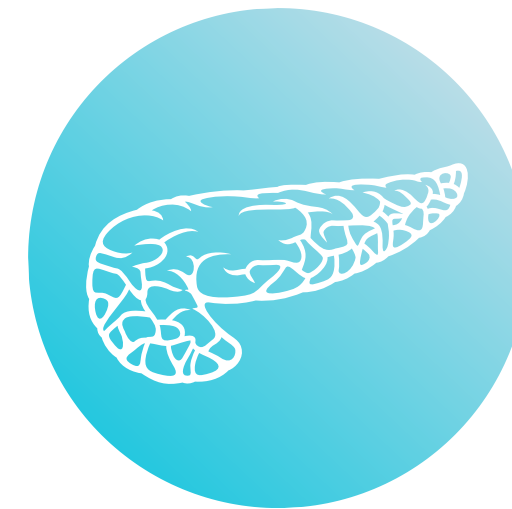
Fibrosis  
Immunosuppression



Fibrotic tumour  
microenvironment



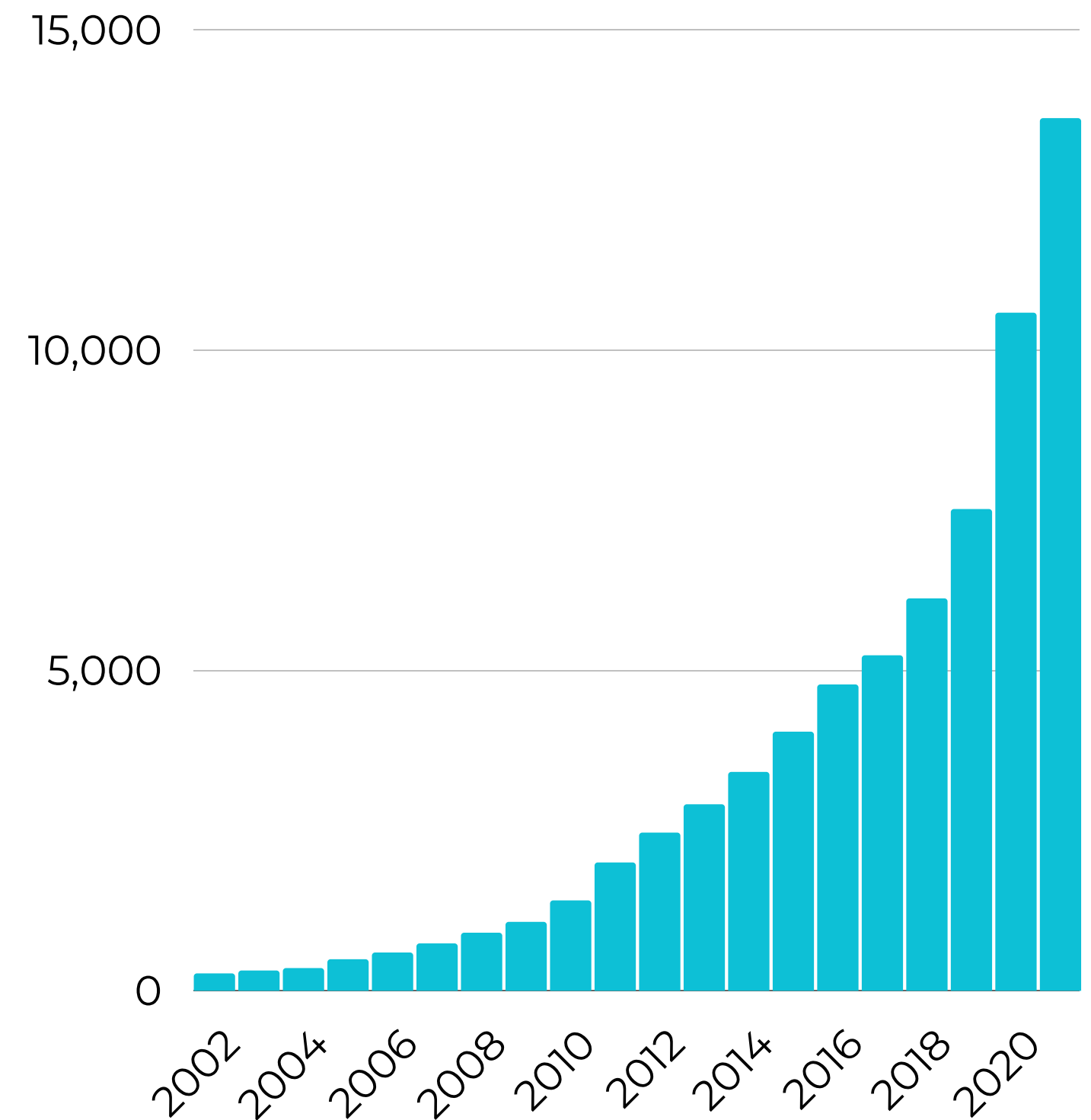
Fibrotic Diseases



Solid Cancers

# PubMed citations of 'tumour microenvironment AND FAK'

- Interest in the tumour microenvironment (TME) has grown exponentially
- The TME is now an important drug target in oncology
- Amplia's FAK inhibitors target the TME



# Sample references - FAK and the TME

Review

## Focal adhesion kinase inhibitors, a heavy punch to cancer

Yueling Wu<sup>1,2</sup> · Ning Li<sup>2</sup> · Chengfeng Ye<sup>1,2</sup> · Xingmei Jiang<sup>2,3</sup> · Hui Luo<sup>3</sup> · Baoyuan Zhang<sup>4</sup> · Ying Zhang<sup>1</sup> · Qingyu Zhang<sup>1,3</sup>

Article



## FAK activity in cancer-associated fibroblasts is a prognostic marker and a druggable key metastatic player in pancreatic cancer

Sonia Zaghdoudi<sup>1,†</sup>, Emilie Decaup<sup>1,†</sup>, Ismahane Belhabib<sup>1</sup>, Rémi Samain<sup>1</sup>, Stéphanie Cassant-Sourdy<sup>1</sup>, Julia Rochotte<sup>1</sup>, Alexia Brunel<sup>1</sup>, David Schlaepfer<sup>2</sup>, Jérôme Cros<sup>3</sup>, Cindy Neuzillet<sup>4</sup>, Manon Strehaiano<sup>1</sup>,



International Journal of  
*Molecular Sciences*



Review

## FAK in Cancer: From Mechanisms to Therapeutic Strategies

Hsiang-Hao Chuang<sup>1,†</sup>, Yen-Yi Zhen<sup>2,†</sup>, Yu-Chen Tsai<sup>1</sup>, Cheng-Hao Chuang<sup>1</sup>, Michael Hsiao<sup>3</sup>, Ming-Shyan Huang<sup>4,\*</sup> and Chih-Jen Yang<sup>1,5,6,\*</sup>

JCI INSIGHT

RESEARCH ARTICLE

## Stromal architecture directs early dissemination in pancreatic ductal adenocarcinoma

Arja Ray,<sup>1,2</sup> Mackenzie K. Callaway,<sup>1,2</sup> Nelson J. Rodríguez-Merced,<sup>1,2</sup> Alexandra L. Crampton,<sup>1,2</sup> Marjorie Carlson,<sup>1,2</sup> Kenneth B. Emme,<sup>1,2</sup> Ethan A. Ensminger,<sup>1,2</sup> Alexander A. Kinne,<sup>1</sup>



*cancers*



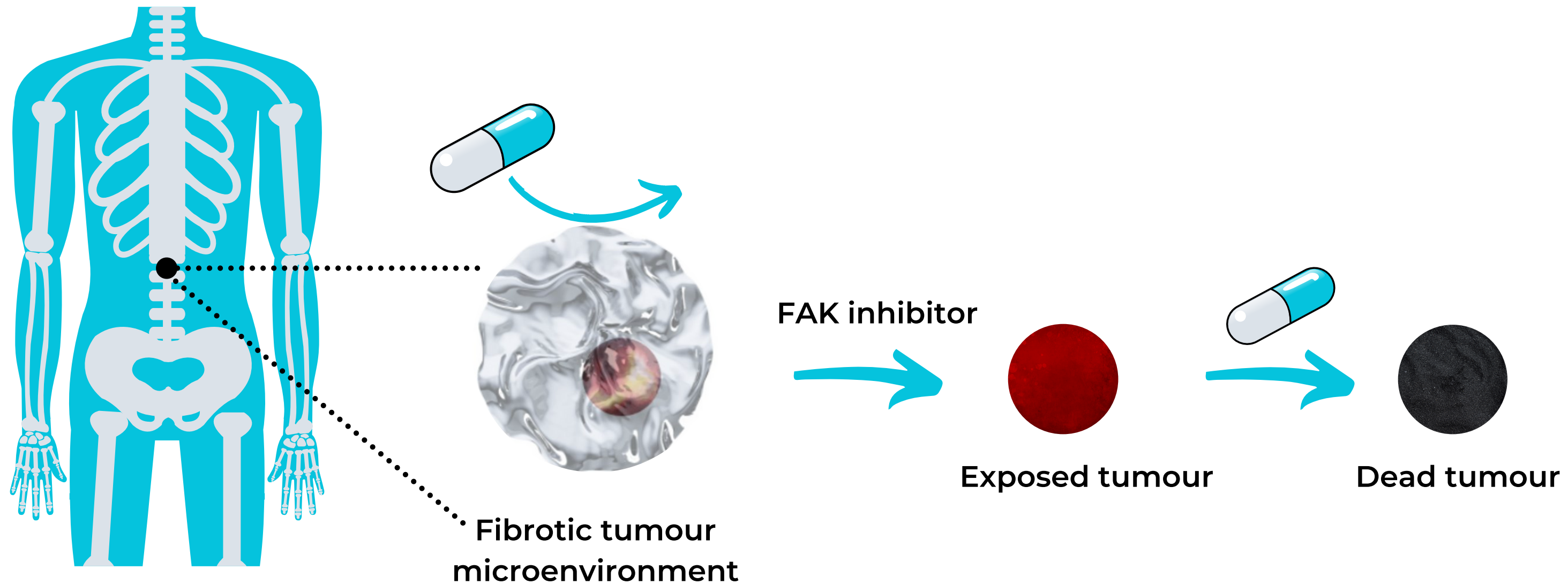
Review

## Advances in Pancreatic Ductal Adenocarcinoma Treatment

Eric M. Anderson<sup>1</sup>, Shant Thomassian<sup>2</sup>, Jun Gong<sup>2</sup>, Andrew Hendifar<sup>2</sup> and Arsen Osipov<sup>2,\*</sup>

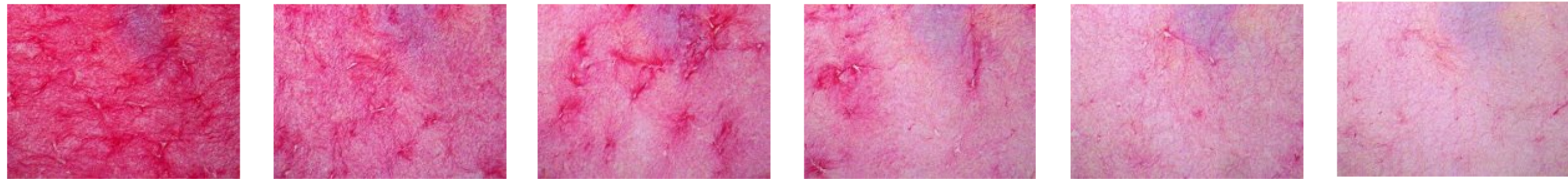
# Amplia's Hypothesis | Enhancing Chemotherapy

- Fibrotic shields (TME) protect many solid tumours from chemotherapy
- Amplia's FAK inhibitors aim to remove the shield
- Unshielded tumours should be more susceptible to chemotherapy

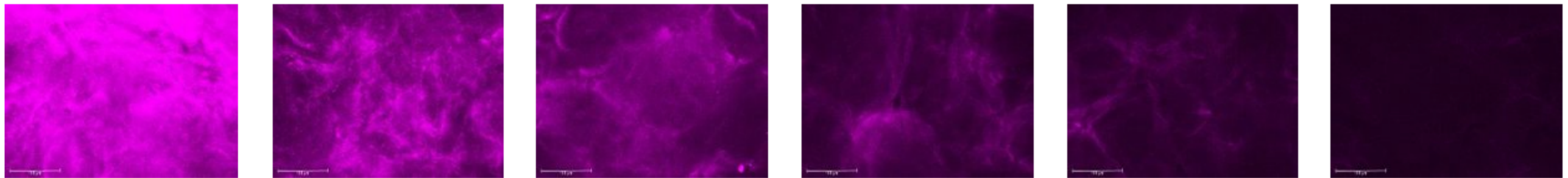


# AMP945 Inhibits Fibrosis

Total collagen decreases ●.....●



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

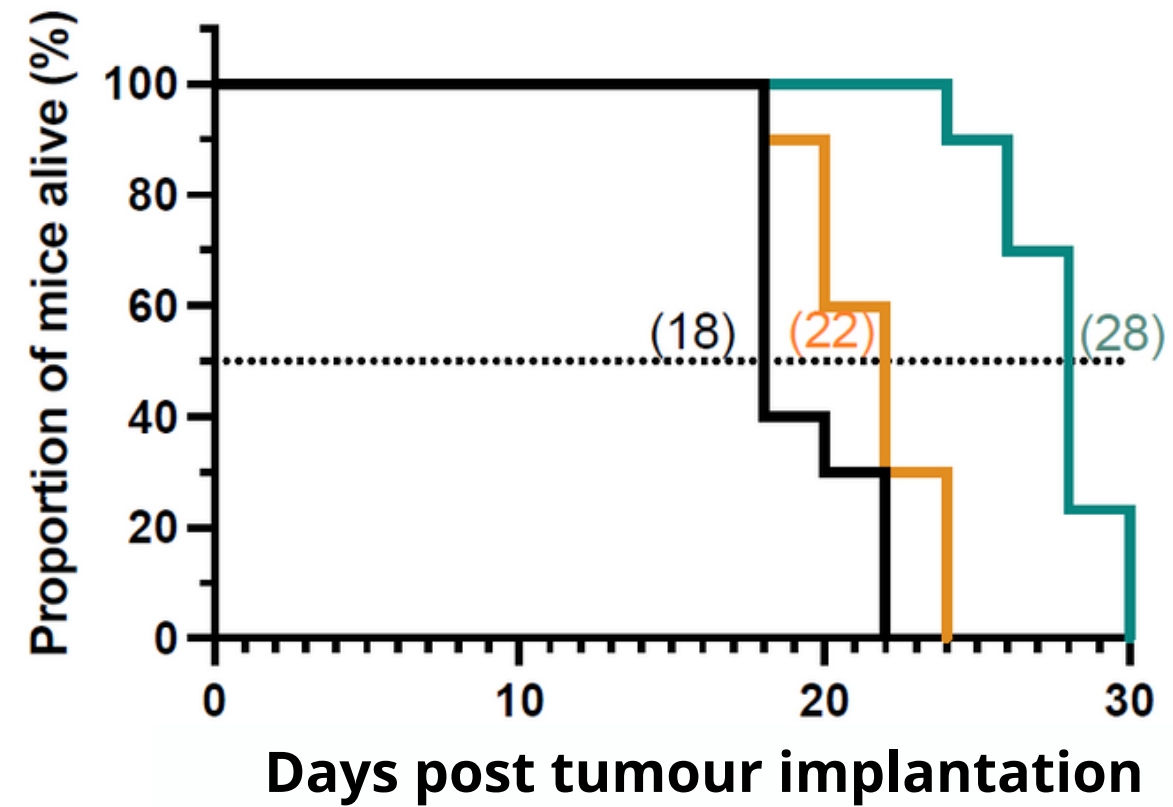


- Cross-linked collagen is a key component of fibrotic tissues

- AMP945 inhibits collagen formation and collagen cross-linking in a dose-dependent manner



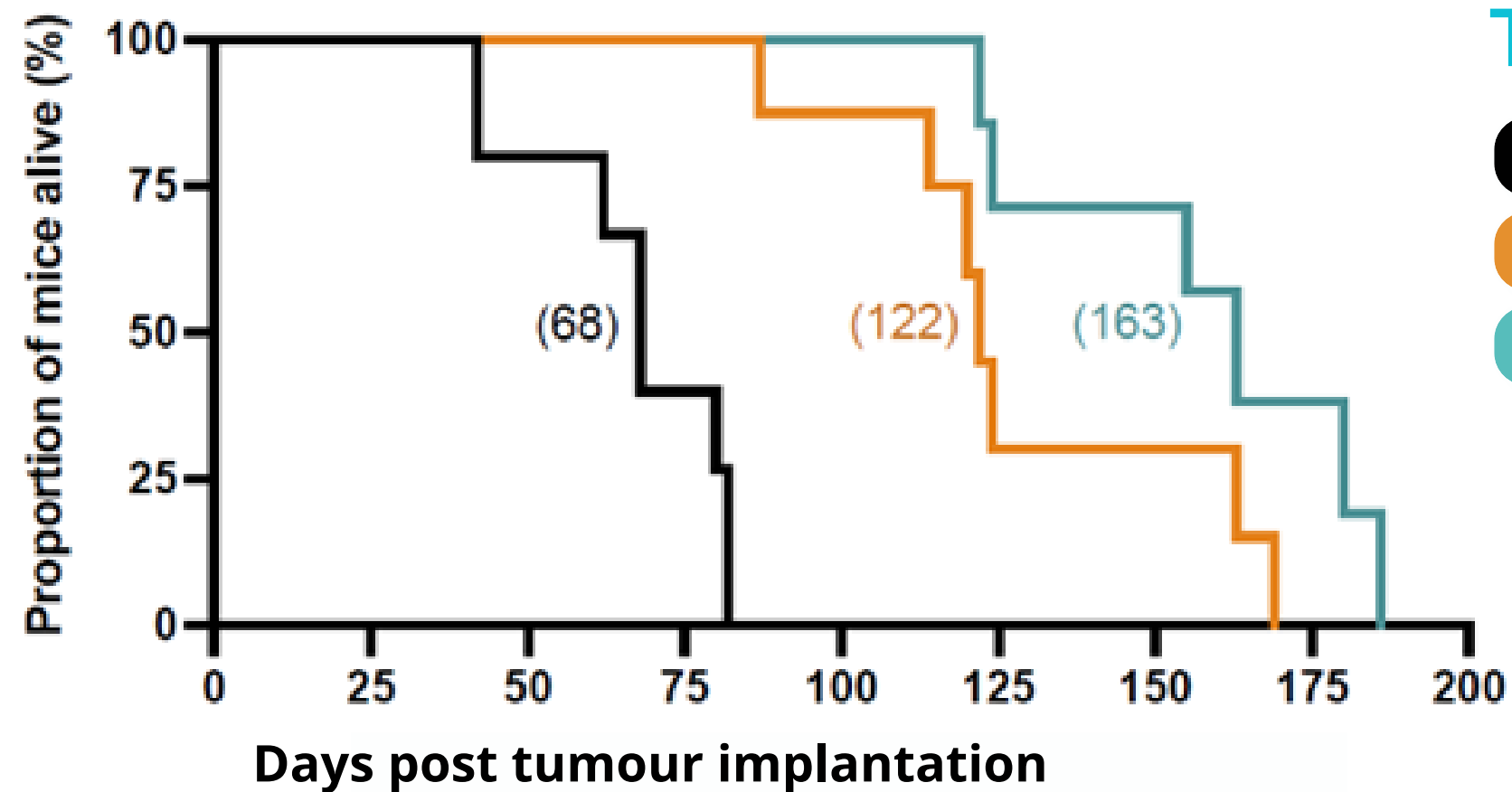
# AMP945 Improves Survival in Pancreatic Cancer Models



## KPC Model

- Vehicle
- gemcitabine / nab-paclitaxel
- AMP945 / gemcitabine / nab-paclitaxel

$P \leq 0.001$   
 $P \leq 0.05$



## TKCC-10-LO Orthotopic Model

- Vehicle
- gemcitabine / nab-paclitaxel
- AMP945 / gemcitabine / nab-paclitaxel

$P \leq 0.0001$   
 $P \leq 0.05$

# AMP945 Clinical Development



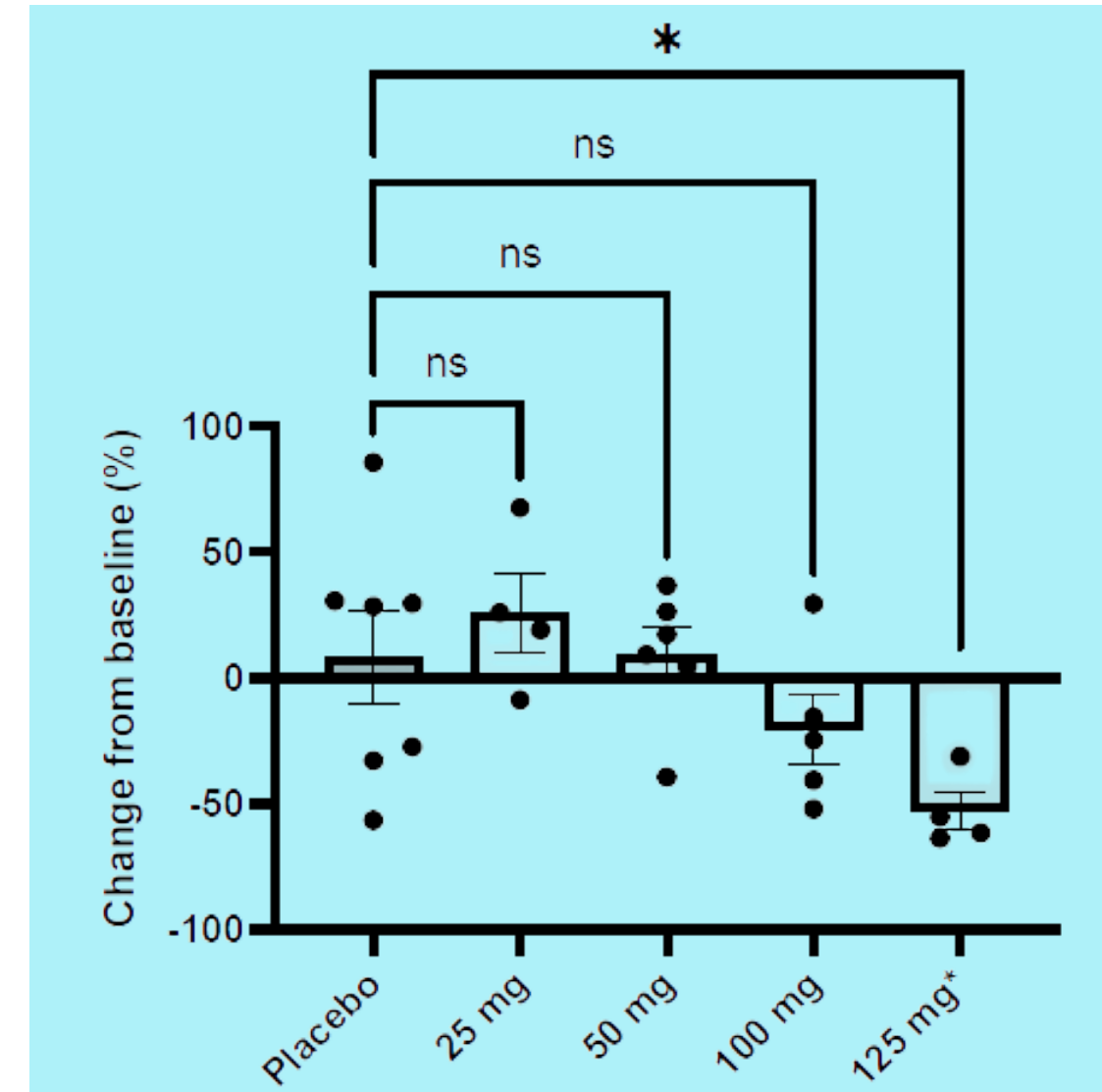
# Phase 1 Trial of AMP945

## Trial Execution

- Recruited 56 healthy volunteers aged 18 – 65
- Single and multiple ascending doses
- 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



Pharmacodynamic effect of AMP945 on p-FAK



# ACCENT: Clinical Study of AMP945 in People with Pancreatic Cancer



## First-line patients with advanced pancreatic cancer

- Open label
- AMP945 added to gemcitabine/nab-paclitaxel standard of care
- Largest patient cohort
- Not previously treated with gemcitabine and/or nab-paclitaxel
- Primary endpoint: Objective Response

## Three-stage trial

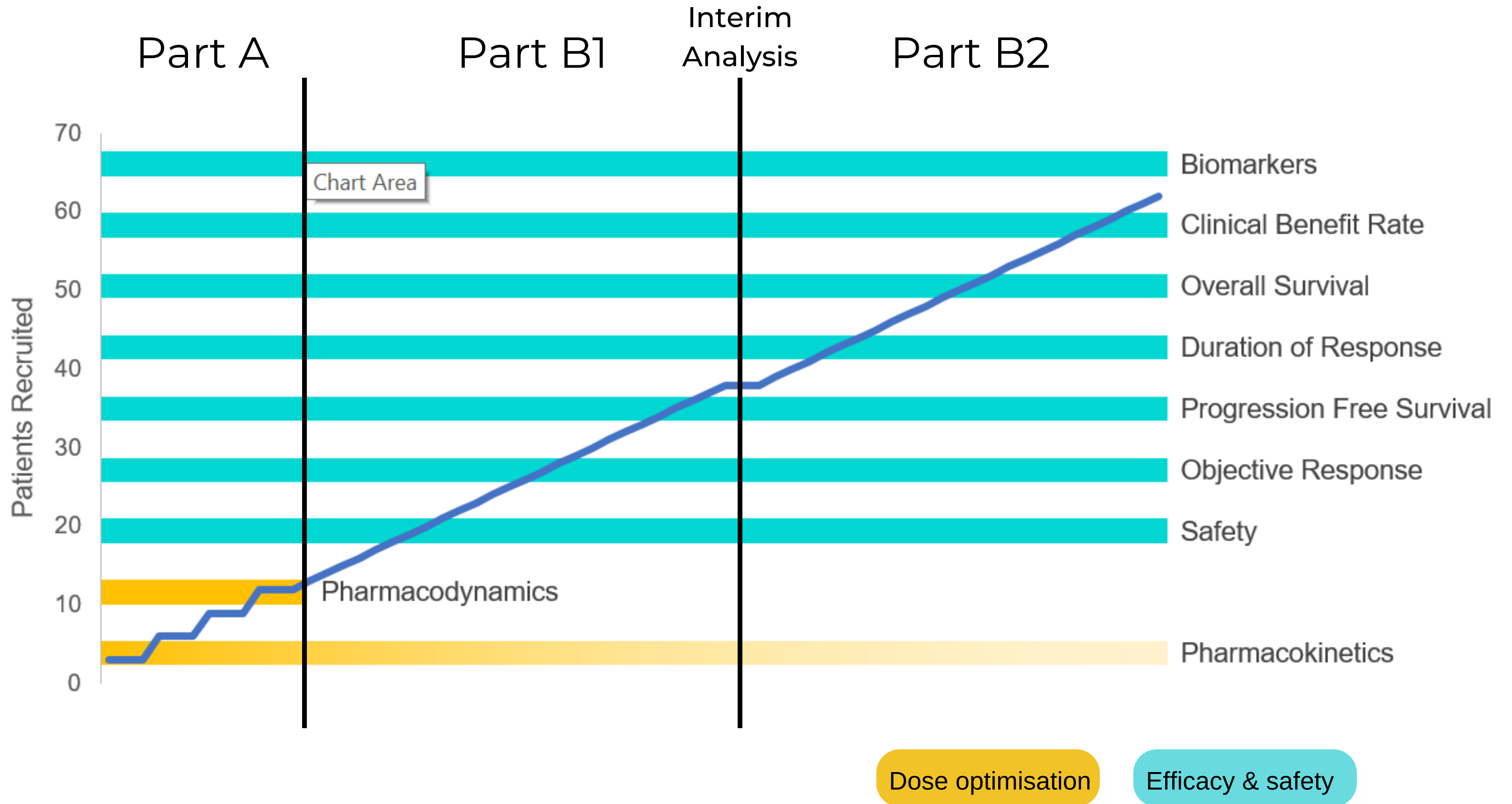
Part A - Dose confirmation (~12 patients)

Part B: Stage 1 - exploratory efficacy (26 patients)

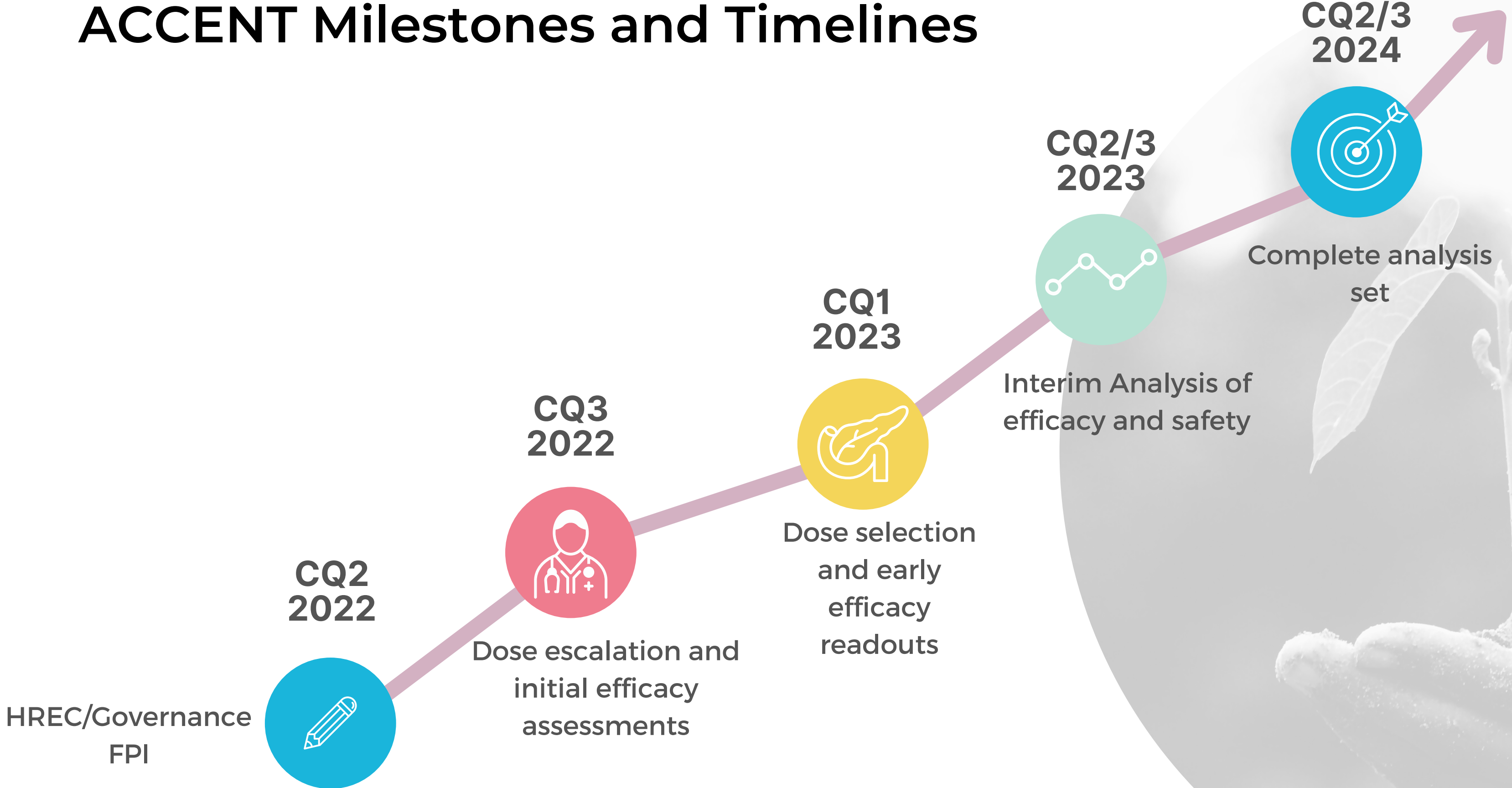
Part B: Stage 2 - verification of efficacy (24 patients)

ClinicalTrials.gov Identifier: [NCT05355298](https://clinicaltrials.gov/ct2/show/study/NCT05355298)

# ACCENT Trial Data Accrual



# ACCENT Milestones and Timelines



# Commercialisation Strategy

## Approval

- Regulatory approvals in oncology are feasible for small-mid biotechs
- Amplia is engaging with key regulators early in development of AMP945

## Partnering

- Partnerships & licensing achievable subject to proof-of-concept data
- Strategic partner engagement is ongoing



# Growth Plans for 2022

# Value Drivers



## Clinical studies

- Pancreatic cancer
- Pulmonary fibrosis



Report early results



## Regulatory engagement

- Pre-IND feedback



## Expand therapeutic opportunities for AMP945

- Cancer
- Fibrosis



## Expand pipeline by progression of AMP886 into early development



# Thank You.

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