

ASX RELEASE

12 July 2024

BIOSHARES CONFERENCE PRESENTATION

Melbourne, Australia: Amplia Therapeutics Limited (ASX: ATX), (“Amplia” or the “Company”) is pleased to announce that Amplia’s CEO and MD Dr Chris Burns is presenting today at the annual Bioshares conference, being held in Fremantle, WA, Australia. The presentation outlines recent progress and development plans.

A copy of the presentation is attached to this announcement.

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

- End -

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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 and Amplia has a particular development focus in fibrotic cancers such as pancreatic cancer. FAK also plays a significant role in a number of chronic diseases, such as idiopathic pulmonary fibrosis (IPF). For more information visit www.ampliatx.com and follow Amplia on [Twitter](https://twitter.com/ampliatx) (@ampliatx), [Threads](https://www.threads.net/@ampliatx) (@ampliatx) and [LinkedIn](https://www.linkedin.com/company/amplia-therapeutics).



BioShares Presentation

12 July 2024

ampliatx.com | [@ampliatx](https://twitter.com/ampliatx)



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Amplia is developing a pipeline of small molecule **inhibitors of Focal Adhesion Kinase (FAK)** - a validated target in cancer

Amplia's drugs were discovered at the Cancer Therapeutics CRC, in collaboration with Australia's premier Medical Research Institutes (WEHI, Peter MacCallum Cancer Centre, St Vincent's Institute) and Universities (Monash and Griffith)

Amplia's lead compound **narmafotinib is the best-in-class FAK inhibitor** in development

DEVELOPMENT HIGHLIGHTS



Phase 2a clinical trial in advanced pancreatic cancer underway

- Well tolerated
- Preliminary signs of efficacy
- Interim readout planned for Q3 2024



Orphan Drug Designation from US FDA for pancreatic cancer and IPF



Open IND* for narmafotinib trial in pancreatic cancer



Compelling preclinical data in disease models:

- Pancreatic cancer
- Ovarian cancer
- Idiopathic Pulmonary Fibrosis (IPF)

Promising clinical and preclinical data positions narmafotinib as the preferred agent to enhance therapies used in the treatment of pancreatic cancer and other solid tumours

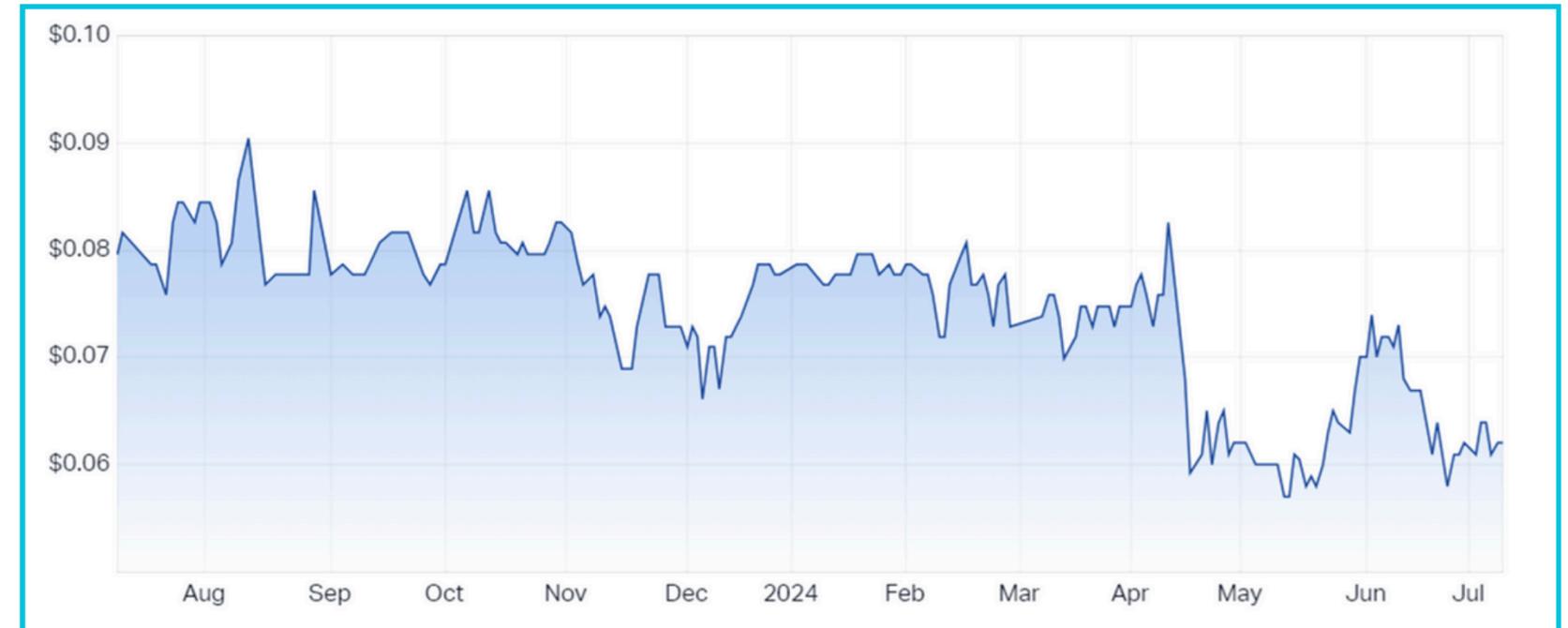
CORPORATE SUMMARY



ASX:ATX

12 month share price chart

Share price (9-Jul-24)	A\$0.063
Shares on issue	271.9m
Market cap (9-Jul-24)	A\$16.8m
Substantial Shareholders	<ul style="list-style-type: none">• Platinum Investment Management Ltd• Blueflag Holdings Pty Ltd• Acorn Capital Ltd• Pengana



EXPERIENCED BOARD AND MANAGEMENT



BOARD



Warwick Tong

MB ChB MPP GAICD
Chair



Robert Peach

PhD
Director



Jane Bell

LLB, LLM (Lond), FAICD
Director



Chris Burns

PhD GAICD
CEO and MD



EXPERIENCED BOARD AND MANAGEMENT



SENIOR TEAM



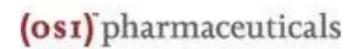
Rhiannon Jones

PhD GAICD
COO



Terrie-Anne Cock

PhD
Director Translational Science



Charlotte Mulder

BVSc (Hons) MBA
Director Early Clinical Development



Adrian Sulistio

B Eng (Hons), B Com, PhD
Manager Product Development

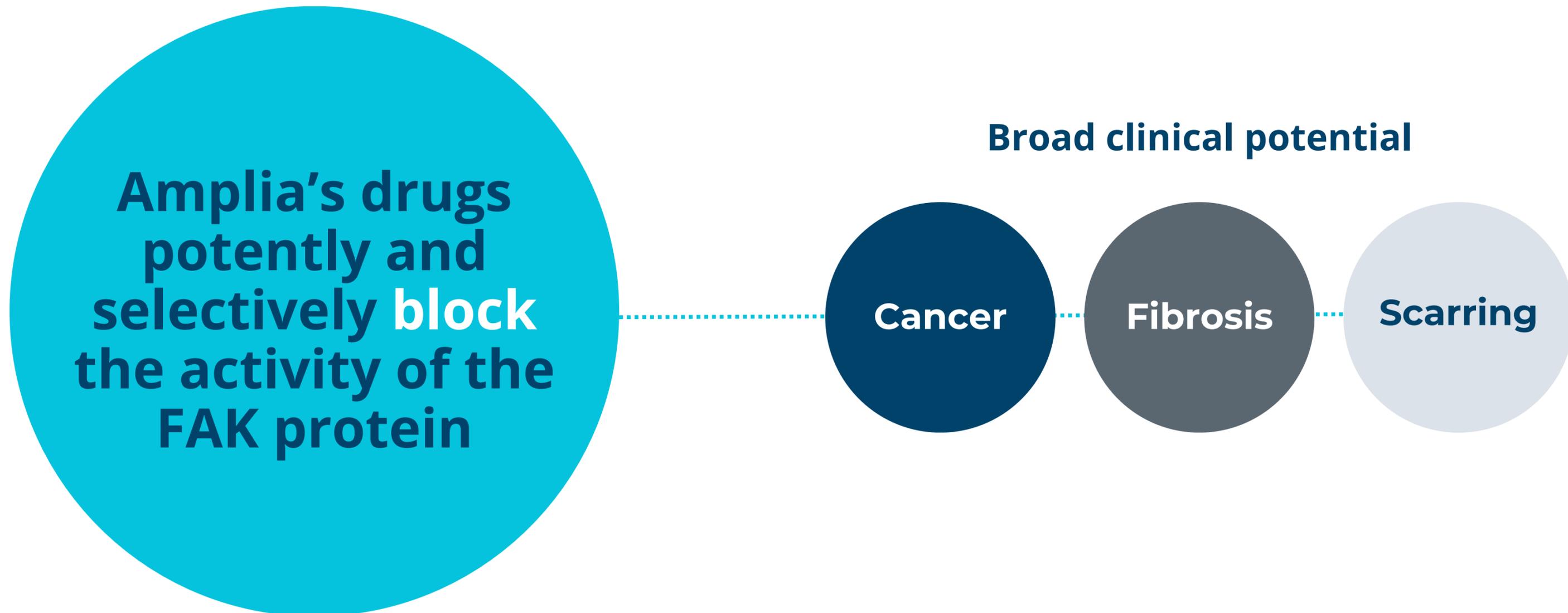


Amplia's drugs inhibit the enzyme Focal Adhesion Kinase (FAK)



FOCAL ADHESION KINASE (FAK)

FAK is a critical protein in cancer growth and spread, and in formation of fibrotic (scar) tissue



FAK INHIBITORS IN DEVELOPMENT



Only 3 companies with bona fide FAK inhibitors in development



Narmafotinib has a superior profile to other compounds: best-in-class

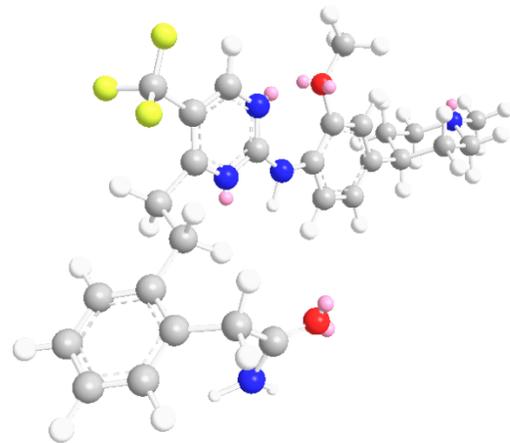
	Selectivity	Good PK profile	Good DDI profile	Clinical Notes	Stage
Narmafotinib (Amplia)	✓	✓	✓	Safe and well tolerated	Ph 2a
Defactinib (Verastem)	✗	✗	?	Promising data in Phase 2 LGSOC	Ph 2 and 3
Ifebemtinib (Inxmed)	✗	✓	?	High incidence of proteinuria (protein in urine)	Ph 2

PK = Pharmacokinetics
 DDI = Drug-Drug Interaction
 LGSOC = Low grade serous ovarian cancer

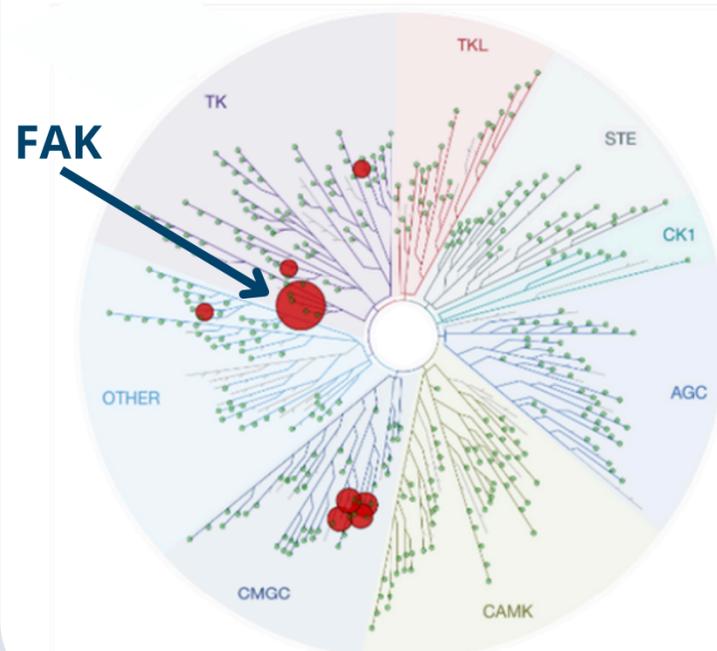
NARMAFOTINIB

- Drug-like small molecule
- Highly potent and selective
- Excellent PK; once-a-day dosing
- Minimal DDI* risk when combining with other drugs

Narmafotinib
Drug-like small molecule



Selectivity
Highly selective for FAK

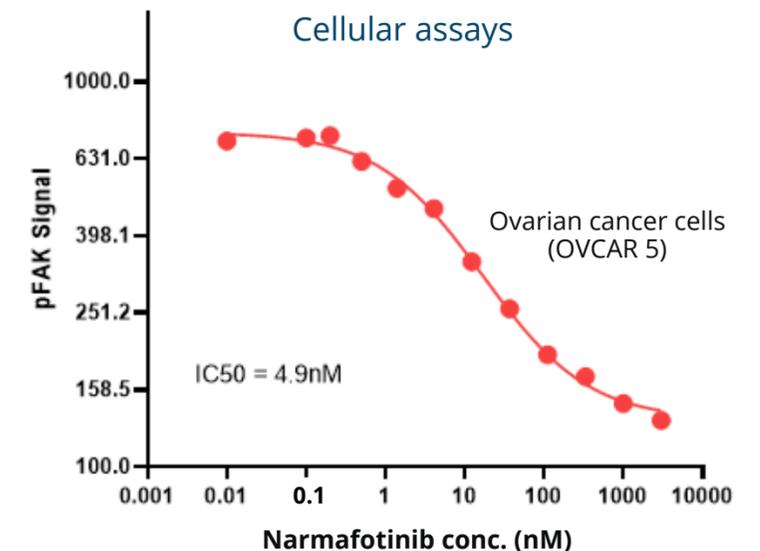


FAK Activity
Highly potent FAK inhibitor

Biochemical assays

IC ₅₀	2.2 nM
K _D	29 pM

Cellular assays



NARMAFOTINIB IN CANCER

Extensive preclinical data showing narmafotinib activity in cancer models

Early signals of efficacy from ACCENT clinical trial

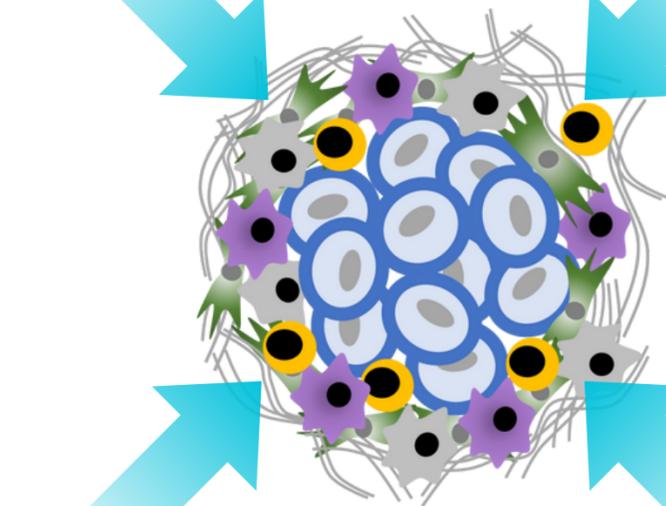
Developing clinical datasets from Verastem and Inxmed further validate approach

FAK inhibitors block critical pathways supporting tumour growth

Multi-action of narmafotinib

Anti-proliferative
Reduces cell's ability to proliferate and migrate

Synergy with chemotherapies
Enhances activity of drugs and other therapies



Tumour (blue - cancer cells; green- fibroblasts; purple, grey and yellow - suppressive immune cells)

Anti-fibrotic
Reduces scar-tissue in TME*, improving permeability to drugs

Immunomodulatory
Improves immune cell reactivity to tumour cells

BROAD POTENTIAL FOR FAK INHIBITORS IN CANCER

FAK inhibitors can enhance effects of existing therapeutic approaches in solid tumours

- Chemotherapy
- Radiotherapy

... but also newer targeted treatments

- Kinase Inhibitors
- Immune Checkpoint Inhibitors
- Antibodies and ADCs
- kRas Inhibitors
- Cell Therapies



Clinical studies of narmafotinib in pancreatic cancer



PANCREATIC CANCER

An unmet need



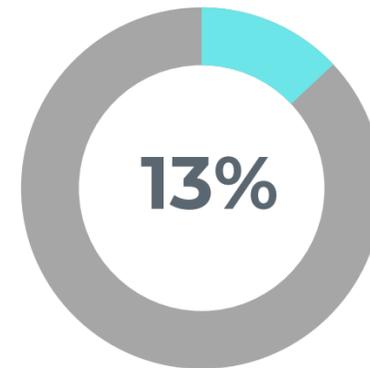
Increasing Prevalence

Estimated 66,000 diagnoses and 50,000 deaths in US this year*

4,500 diagnoses in AU in 2023**

* American Cancer Society ([link](#))

** Cancer Australia ([link](#))



5 year survival

Difficult-to-treat: typically detected late in disease progression**



Market size

Global treatment market estimated over US\$6 billion in 2023

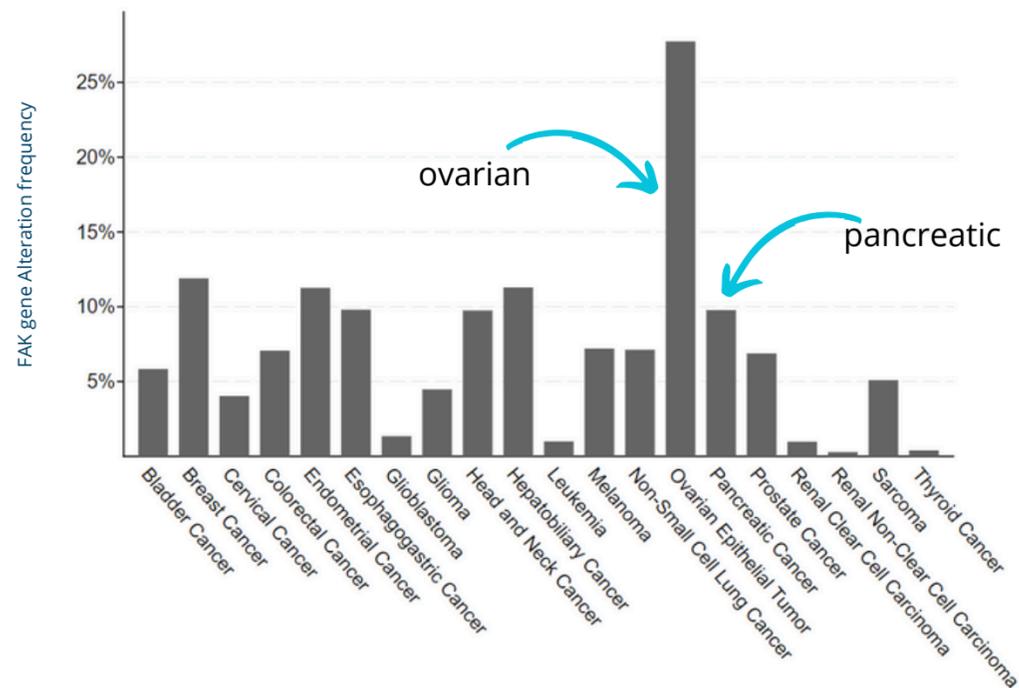
Projected to grow to ~US\$36 billion by 2036†

† Research Nester ([link](#))

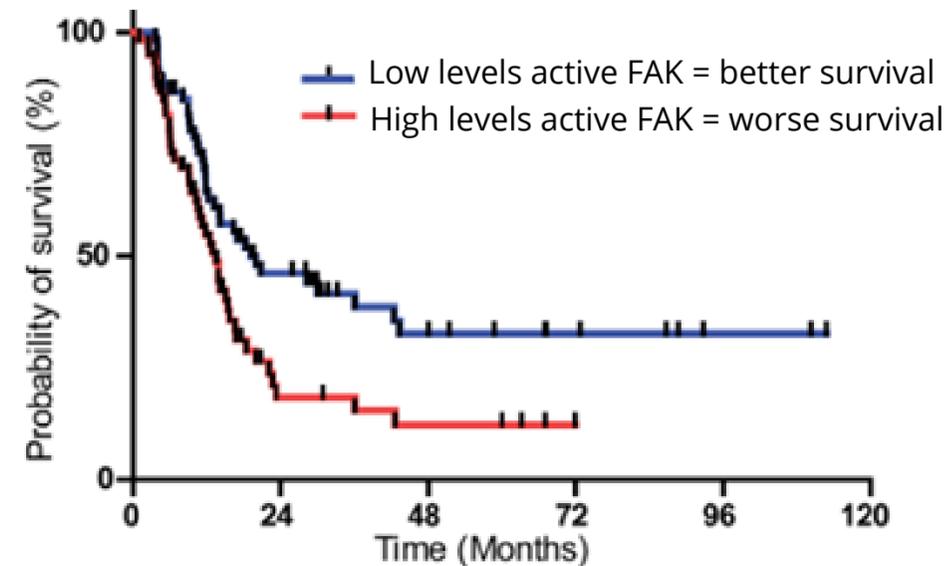
PANCREATIC CANCER

Undisputed role of FAK in disease progression

Over-expression and increased FAK activity

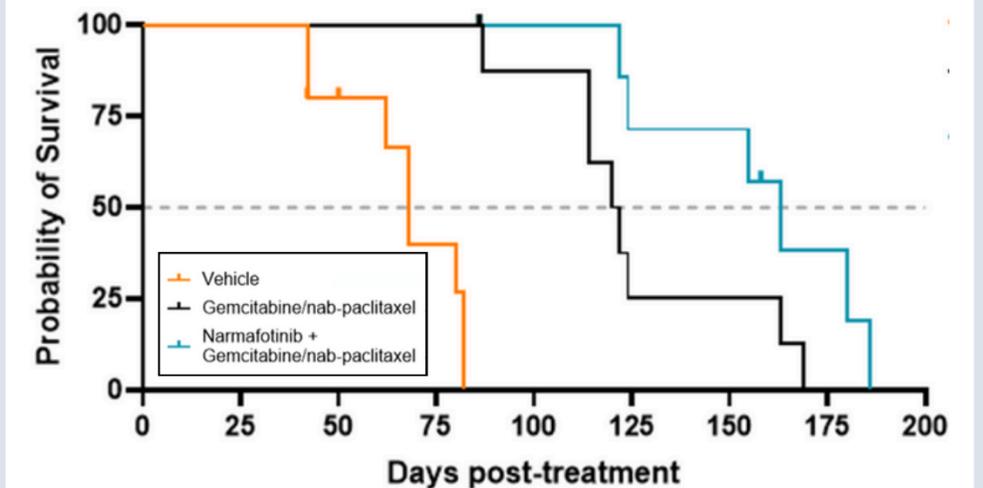


FAK activity correlates with worse outcome



Beneficial preclinical efficacy with FAK inhibition

- Narmafotinib decreases tumour fibrosis (collagen)
- Narmafotinib treatment improves survival in disease models



- FAK inhibition synergises with SOC* chemotherapies and targeted therapies

*Standard-of-care

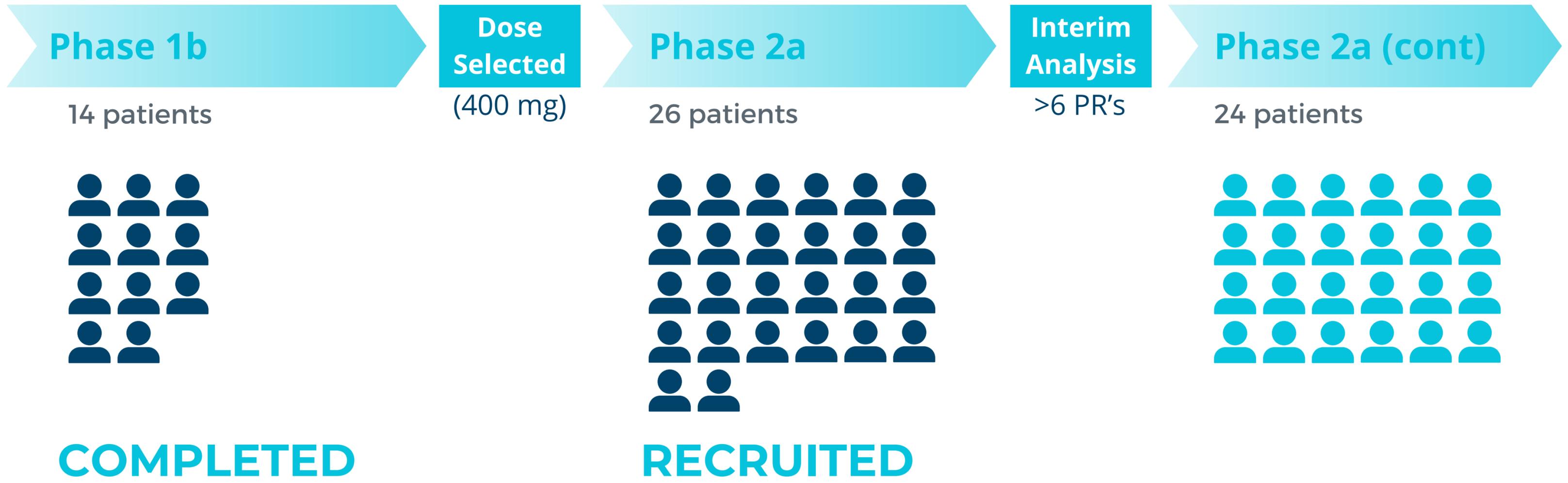
**Clinical data indicates
narmafotinib safe and
well tolerated with
preliminary signs
of efficacy**



ACCENT TRIAL DESIGN

Narmafotinib in combination with standard-of-care gemcitabine and Abraxane

- Orally-dosed narmafotinib in the days preceding weekly chemotherapy



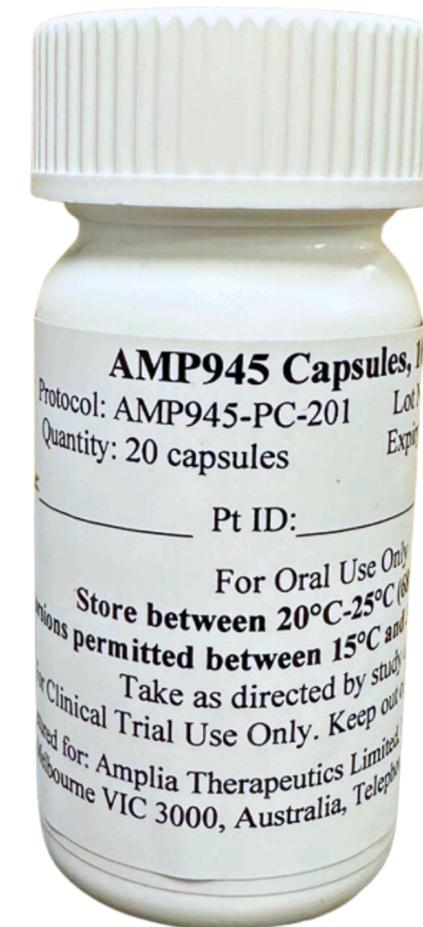
ACCENT PHASE 1b

3 Cohorts (100 mg, 200 mg, 400 mg)

- Orally dosed (capsules)
- Once-a-day

Safe and well tolerated

- All patients elected to stay on drug post cycle 1
- One DLT*: uncontrolled nausea
- Fatigue (Grade 3 or below) in more than 1 patient likely drug related



*DLT = Dose Limiting Toxicity

ACCENT PHASE 1b



Preliminary signs of efficacy observed

Improved response rate (PR and SD) compared to historical gemcitabine/Abiraxane alone

- Comparison to pivotal trial (2013)**

Better objective response (tumour reduction) at higher doses

- 4 of 6 PRs with top dose narmafotinib

Duration on trial significantly improved vs gemcitabine/Abiraxane alone

- Average treatment time at top dose ~2x longer

Best Response (all patients)

Classification	ACCENT Best Overall Response* n=14	Historical Best Overall Response** (n=431)
Complete Response (CR)	0 (0%)	<1%
Partial Response (PR)	6 (43%)	23%
Stable Disease (SD)	8 (57%)	27%
Disease Control Rate (CR+PR+SD)	14 (100%)	50%
Progressive Disease (PD)	0 (0%)	20%
Not evaluable	0 (0%)	30%

* Investigator reviewed

** Independent review as part of MPACT trial (NEJM 2013; 369; 1691-1703)

NB. Phase 1b trial not powered for efficacy

ACCENT PHASE 1b

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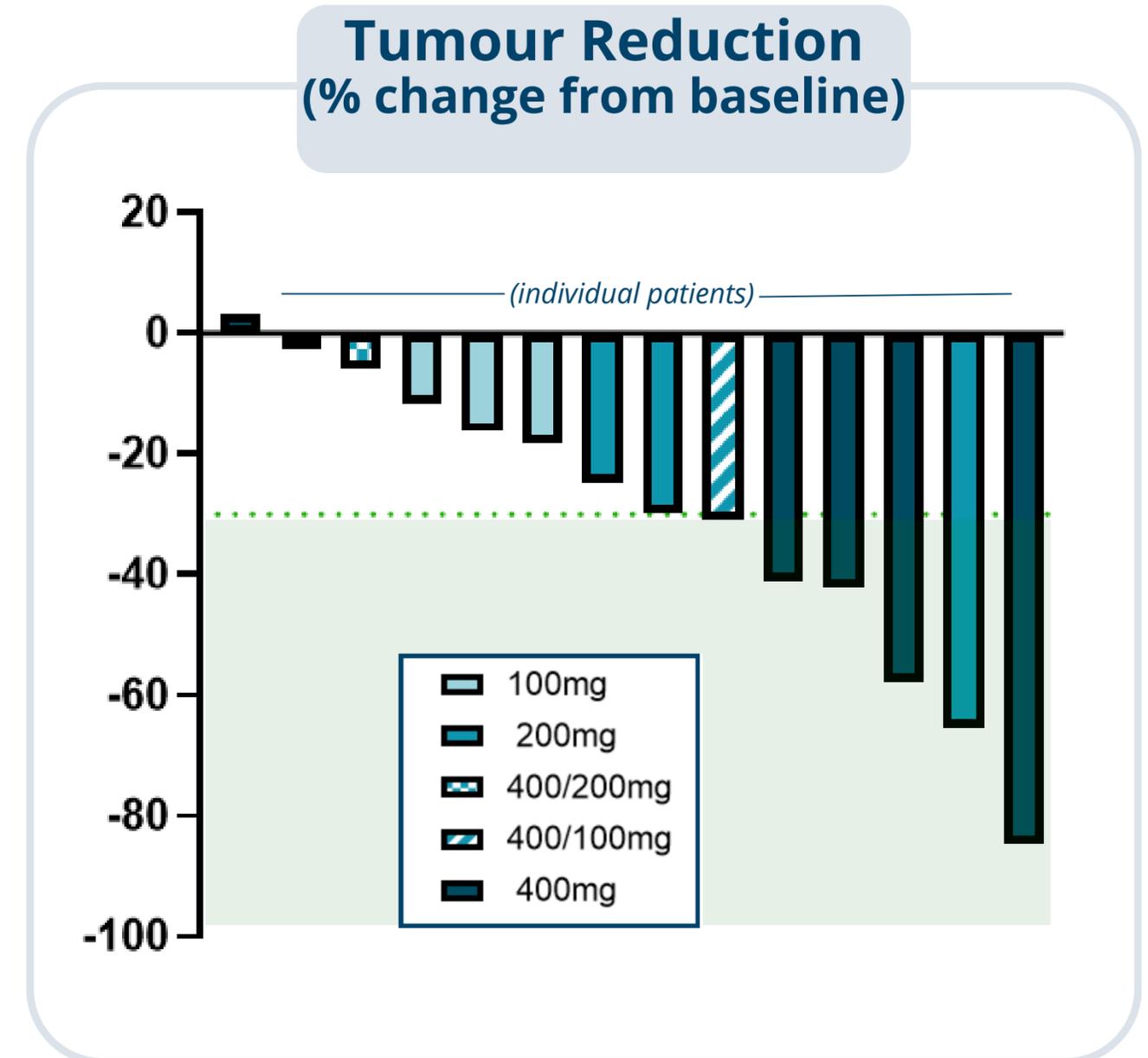
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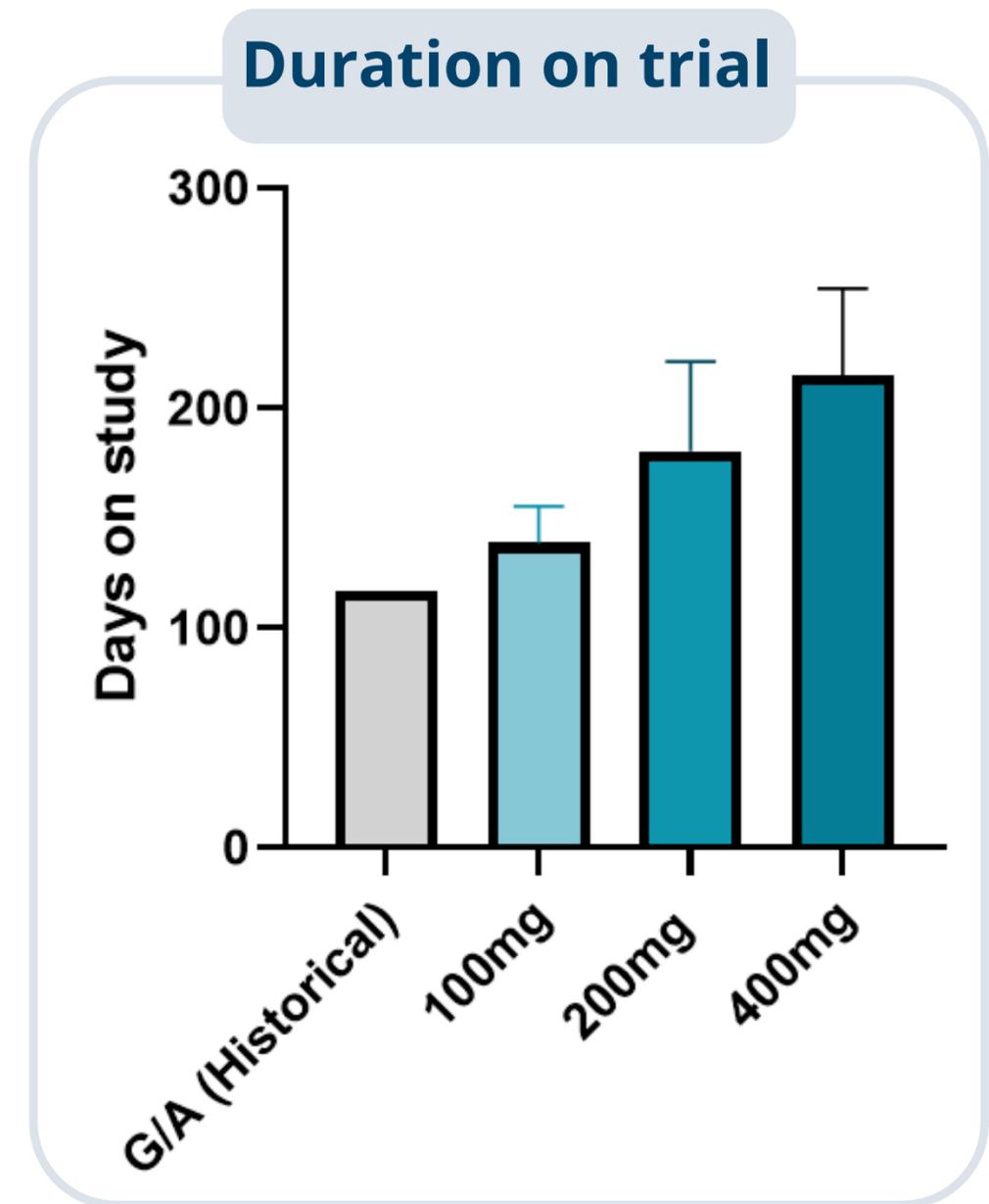
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NB. Phase 1b trial not powered for efficacy

A healthcare professional in blue scrubs is holding a patient's hand, symbolizing care and support. The background is a blurred clinical setting.

**Positioning narmafotinib
as the preferred agent
to enhance activity
of drugs for solid
tumours**

 **Amplia**
THERAPEUTICS

CLINICAL FOCUS AND OPPORTUNITY

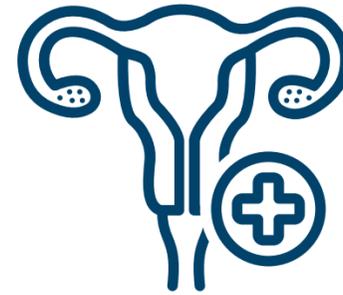


Combinations in pancreatic cancer

Gemcitabine and Abraxane
(ACCENT trial)

-

FOLFIRINOX (US trial with
open IND)

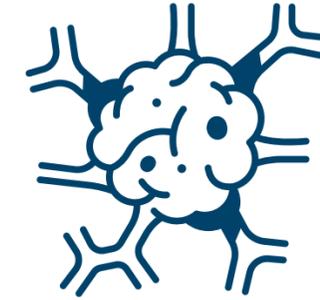


Combinations in ovarian cancer

Platinum resistant disease

-

Maintenance therapy post
surgery



Preclinical evidence - other solid cancers

Bile duct, oesophageal, head
and neck cancer

-

kRAS-mutant cancers
(e.g. lung, colorectal)

-

Other fibrotic cancers
(e.g. liver cancer)

RECENT AND PLANNED MILESTONES



2H 2023 / 1H 2024	2H 2024	1H 2025
<input checked="" type="checkbox"/> Complete Phase 1b ACCENT trial - October	<input checked="" type="checkbox"/> 26 Patients recruited ACCENT trial - July	<input type="checkbox"/> Completion enrolment 50 pts ACCENT trial - March
<input checked="" type="checkbox"/> Korean regulatory approval - November	<input type="checkbox"/> Interim ACCENT trial data - October	<input type="checkbox"/> Initiation ovarian cancer trial - April
<input checked="" type="checkbox"/> First patient dosing Phase 2a ACCENT trial - January	<input type="checkbox"/> Preclinical data (KRAS inhibitor combinations) - November	<input type="checkbox"/> Initiation pancreatic cancer trial (combination FOLFIRINOX under IND) - April
<input checked="" type="checkbox"/> Clearance of IND - January	<input type="checkbox"/> Rolling regulatory submissions	
<input checked="" type="checkbox"/> Completion of CMC campaign - May		

VALUATIONS OF SIMILAR SMALL MOLECULE ONCOLOGY COMPANIES



Company	Lead Asset	Lead Indication	Current Status	Market Cap (US\$)
Verastem	Defactinib / Avutometinib	LGSOC	Positive Phase 2 results in KRAS mutant cancers	74.5M
Ikena Oncology	IK-595	RAS & RAF mutant cancers	Ongoing Phase 1 trial	78.6M
Revolution Medicine	RMC-6236	PDAC / NSCLC	Successful FIH studies will lead to Phase 2 2L studies	6.09B
Nurix Therapeutics	NX-2127	B-Cell Malignancies	Phase 1b	1.15B
Erasca Therapeutics	Naporafenib	NRASm melanoma	Dose optimisation for Phase 3	559.2M
Ideaya Biosciences	Darovasertib	metastatic Uveal Melanoma	Ongoing Phase 2/3	2.99B

ONCOLOGY LICENSING DEALS



Company	Buyer	Nature of Deal	Year	Indication	Asset	Stage	Value (USD)
Joyo Pharmatech	Erasca	Exclusive license (excl mainland China)	May 2024	RAS and KRAS mutant tumours	small molecule	Preclin	12.5M upfront; 176M in milestones
Medshine Discovery	Erasca	Exclusive License	May 2024	RAS and KRAS mutant tumours	small molecule	Preclin	10M upfront; 160M in milestones
G1 Therapeutics	Pepper Bio	License	May 2024	HCC	small molecule	Phase 2	135M in milestones
SystImmune	BMS	Collaboration	Dec 2023	NSCLC	ADC	Phase 1	800M upfront; 7.6B in milestones
Hansoh Pharma	GSK	Exclusive License (excl Greater China)	Oct 2023	Ovarian and Endometrial Cancer	ADC	Phase 1	85M upfront; 1.485B in milestones
AnHeart Therapeutics	Nippon Kayaku	Regional License Japan	Oct 2023	NSCLC	small molecule	Phase 2	40M upfront

PHASE 2 ONCOLOGY M&A



Company	Buyer	Nature of Deal	Year	Indication	Lead Asset	Value (USD)
Profound Bio	Genmab	Acquisition	May 2024	Ovarian Cancer	ADC	1.8B
AnHeart Therapeutics	Nuvation Bio	Acquisition	Mar 2024	NSCLC	small molecule	undisclosed
Fusion Pharma	AstraZeneca	Acquisition	Mar 2024	Prostate Cancer	radio-pharmaceutical	2B
Ambrex	J&J	Acquisition	Jan 2024	Prostate Cancer	ADC	2B
Apexigen	Pyxis	Acquisition	May 2023	solid tumours	antibody	16B
Turning Point Therapeutics	BMS	Acquisition	Jun 2022	NSCLC; advanced solid tumours	small molecule	4.1B



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CEO and MD

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