

ASX RELEASE

6 August 2025

POSITIVE ACCENT TRIAL TOPLINE DATA RELEASED

HIGHLIGHTS

- **Progression Free Survival (PFS)** of 7.6 months has been determined with current data which represents a 2-month improvement over chemotherapy alone (benchmark MPACT study)
- **Days on Trial (DOT)** of 202 days is a material improvement on chemotherapy alone (117 days)
- **Objective Response Rate (ORR)** currently at 31%, is significantly better compared to chemotherapy alone (23%), with 17 patients still on study
- **Excellent tolerability profile** apparent with adverse events being very similar in type and occurrence to those observed for chemotherapy alone
- **Disease Control Rate (DCR)** of 73% is superior to that observed in the MPACT study (50%)
- **Further patient updates** from the ACCENT trial expected in 2H 2025 and mature data expected in Q1 2026
- **Company accelerating towards** potential initiation of pivotal phase 2b/3 trial in 2H 2026

Melbourne, Australia: Amplia Therapeutics Limited (ASX: ATX), (“Amplia” or the “Company”), is pleased to announce important new interim data from the ongoing [ACCENT clinical trial](#) in advanced pancreatic cancer. The trial is investigating the Company’s best-in-class FAK inhibitor narmafotinib in combination with standard-of-care chemotherapies gemcitabine and Abraxane®.

In addition to the 31% ORR previously reported, including a confirmed Complete Response and a pathological Complete Response¹, topline data, available up to 20 July 2025, has now been analysed.

Key findings are as follows:

- The adverse event profile of the narmafotinib combination is very similar to adverse events previously reported for the chemotherapy combination of gemcitabine and Abraxane, in both type of event, rate of occurrence and severity. Narmafotinib treatment results in negligible patient burden in the majority of patients.
- Durability of response is excellent with, at this time, 7 patients having stayed on trial for >12 months. The mean Days on Trial for evaluable patients is 202 days, substantially better than the 117 days reported for chemotherapy alone in the benchmark MPACT study². At data cut-off 17 patients remained on trial.
- The interim PFS analysis indicates a median PFS of 7.6 months, two months better than previously reported for chemotherapy alone. Importantly, this is also superior to the PFS obtained with the more aggressive, but less well tolerated, FOLFIRINOX chemotherapy.

¹ ASX Release 11 July 2025

² *New England Journal of Medicine* 2013, 369, 1691 – 703

	ACCENT Trial (Narmafotinib/Gemcitabine/ Abraxane)	MPACT Trial (Gemcitabine/ Abraxane)	NAPOLI 3 (Gemcitabine/ Abraxane) ³	PRODIGE Trial (FOLFIRINOX) ⁴
PFS	7.6 months	5.5 months	5.6 months	6.4 months

Amplia CEO and MD Dr Chris Burns commented: “The data from the ACCENT trial of narmafotinib combined with chemotherapy continues to out-perform chemotherapy alone across a variety of measures. A PFS of 7.6 months at this interim stage of the trial is a significant improvement on existing chemotherapy regimens. We will provide further updates on the data as the trial matures.”

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

About Narmafotinib

Narmafotinib (AMP945) is the company’s best-in-class inhibitor of the protein FAK, a protein over-expressed in pancreatic cancer and a drug target gaining increasing attention for its role in solid tumours. The drug, which is a highly potent and selective inhibitor of FAK, has shown promising data in a range of preclinical cancer studies.

About the ACCENT Trial

The ACCENT trial is entitled ‘*A Phase 1b/2a, Multicentre, Open Label Study of the Pharmacokinetics, Safety and Efficacy of AMP945 in Combination with Nab-paclitaxel and Gemcitabine in Pancreatic Cancer Patients*’.

The trial is a single-arm open label study conducted in two stages. The first stage (Phase 1b), completed in November 2023, determined an optimal dose of narmafotinib (AMP945) by assessing the safety, tolerability, pharmacokinetics and preliminary efficacy when dosed in combination with gemcitabine and Abraxane in first-line patients with advanced pancreatic cancer.

The second stage (Phase 2a) of the trial is designed to assess efficacy in combination with gemcitabine and Abraxane. The primary endpoints are Objective Response Rate (ORR) and safety and tolerability, with secondary endpoints including Progression Free Survival (PFS), Overall Survival (OS) and Duration on Trial (DOT).

The trial is being conducted at seven sites in Australia and five sites in South Korea.

More information about the ACCENT trial can be found via the ACCENT trial [site](#), the Amplia Therapeutics [website](#) and at ClinicalTrials.gov under the identifier [NCT05355298](#).

The Company will provide further updates on the trial as data is accrued.

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³ *The Lancet* 2023, 402(10409), 1272-1281

⁴ *New England Journal of Medicine* 2011, 364, 1817-1825

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 and ovarian 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) and [LinkedIn](https://www.linkedin.com/company/amplia-therapeutics).

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ACCENT TRIAL TOPLINE DATA

August 2025

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EXECUTIVE SUMMARY

Developing a pipeline of small molecule inhibitors of FAK



Lead drug **narmafotinib** is best-in-class FAK inhibitor in development



Promising efficacy, durability and tolerability in Phase 2a ACCENT clinical trial in pancreatic cancer



US trial of narmafotinib in pancreatic cancer to start imminently

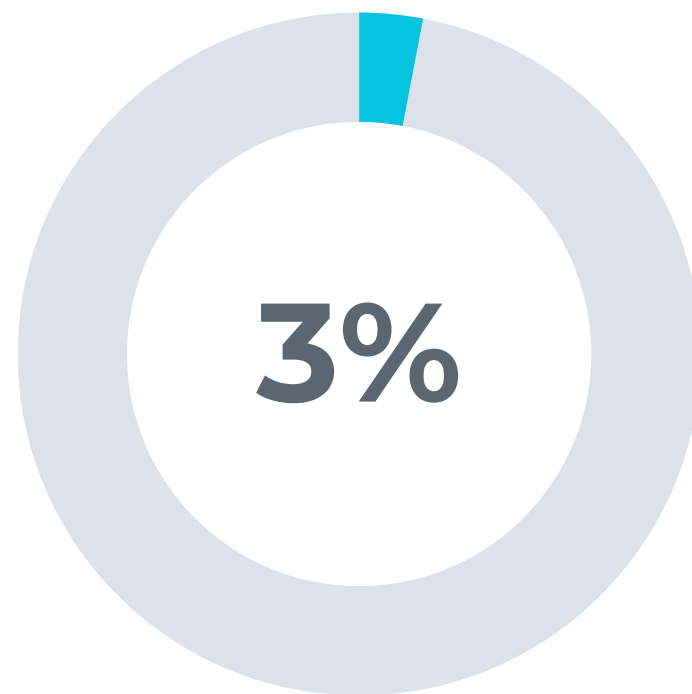


FAST-track and **Orphan Drug Designation** granted from US FDA

METASTATIC PANCREATIC CANCER

Limited treatment options; poor patient outcomes

5Y Survival



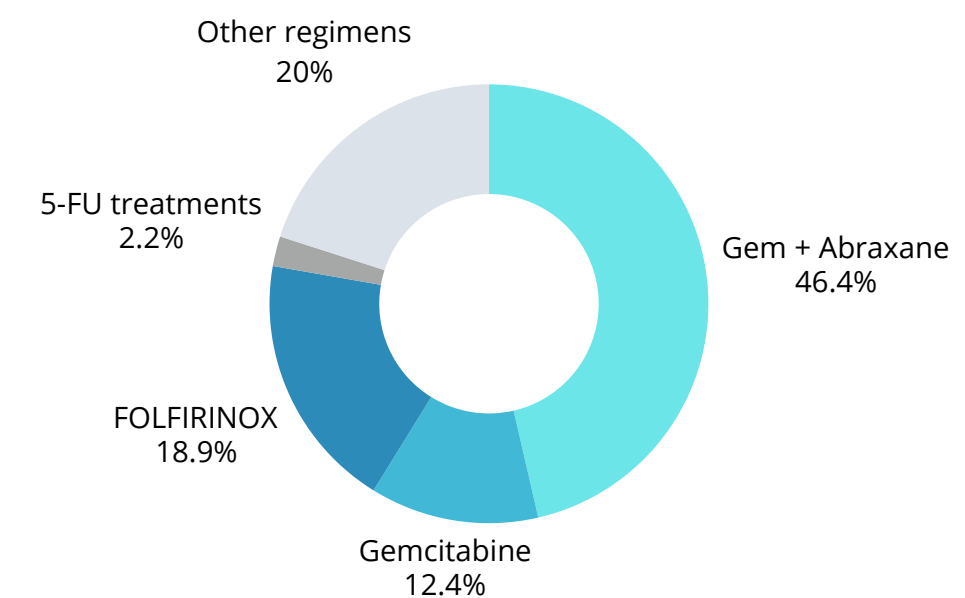
Highly aggressive with multiple genetic drivers

>50% pancreatic cancer patients diagnosed with advanced (metastatic, stage 4) disease at the time of diagnosis

Limited Treatment Options

Treatment	Median Progression Free Survival	Median Overall Survival	Tolerability
Gemcitabine + Abraxane [®] (MPACT study)	5.5 months	8.5 months	☹️
FOLFIRINOX (Prodige study)	6.4 months	11.1 months	☹️

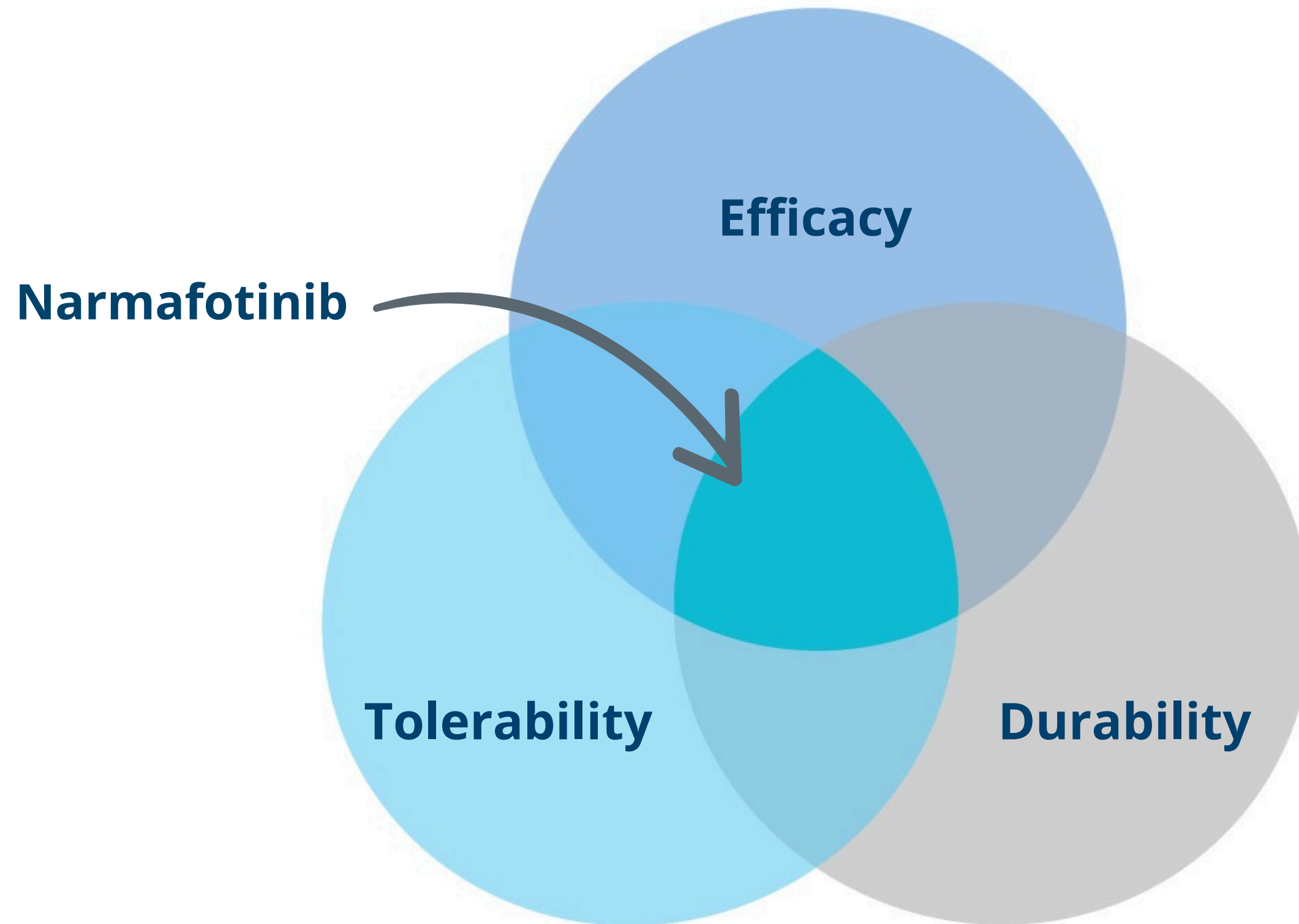
Most patients receive gemcitabine + Abraxane or FOLFIRINOX or variations of these[†]



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THE AMPLIA ADVANTAGE

Three critical features



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ACCENT TRIAL IN PANCREATIC CANCER

Phase 1b/2a study in Australia and Korea

OBJECTIVE

- To determine safety and efficacy of narmafotinib when added to standard of care in newly diagnosed patients

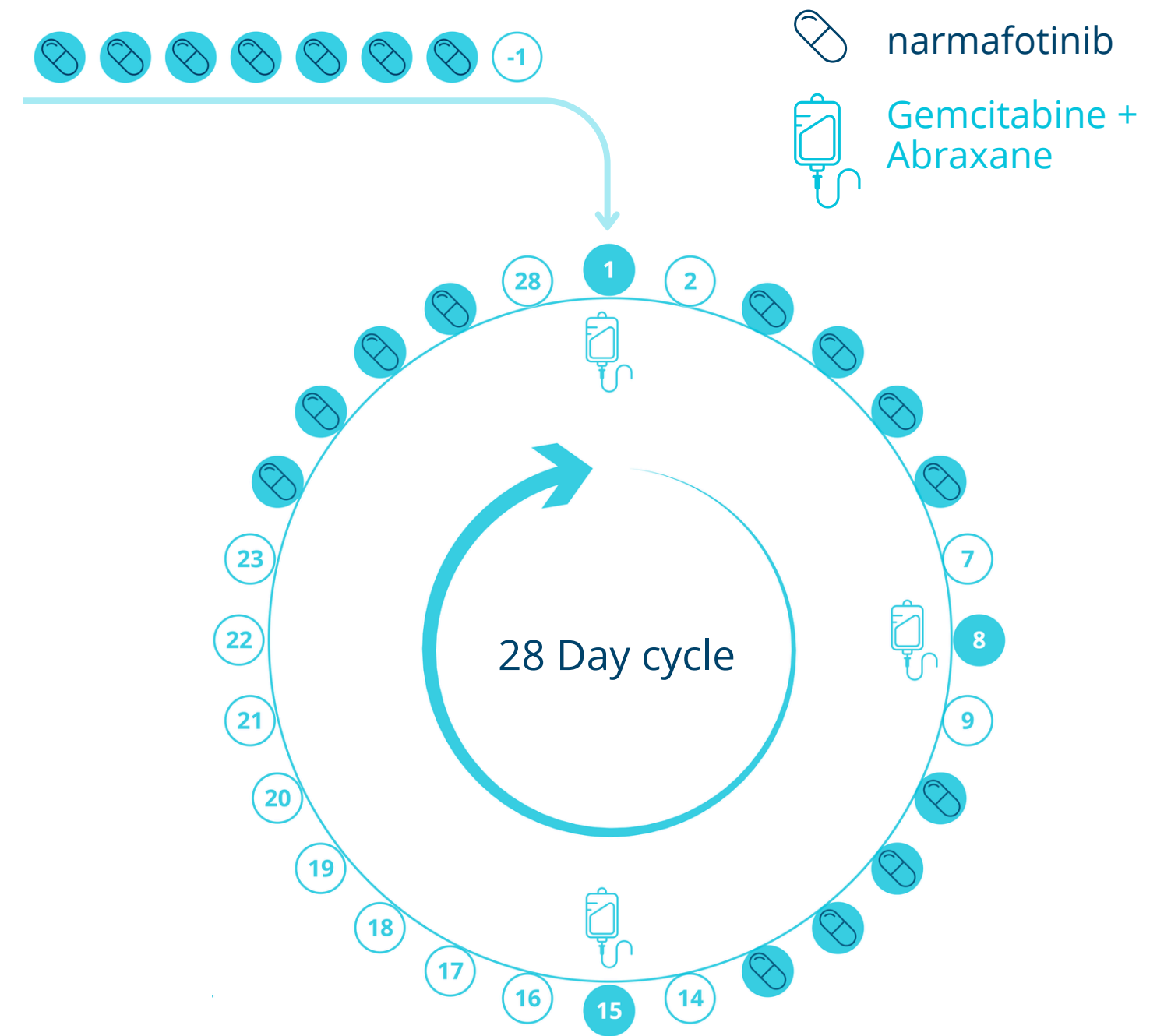
PRIMARY ENDPOINTS

- Safety, Tolerability
- ORR (RECIST 1.1)*

ADDITIONAL ENDPOINTS

- Duration on Trial
- Progression free survival (PFS)
- Overall Survival (OS)
- Disease Control Rate

Intermittent dosing schedule



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ACCENT TRIAL TOPLINE DATA

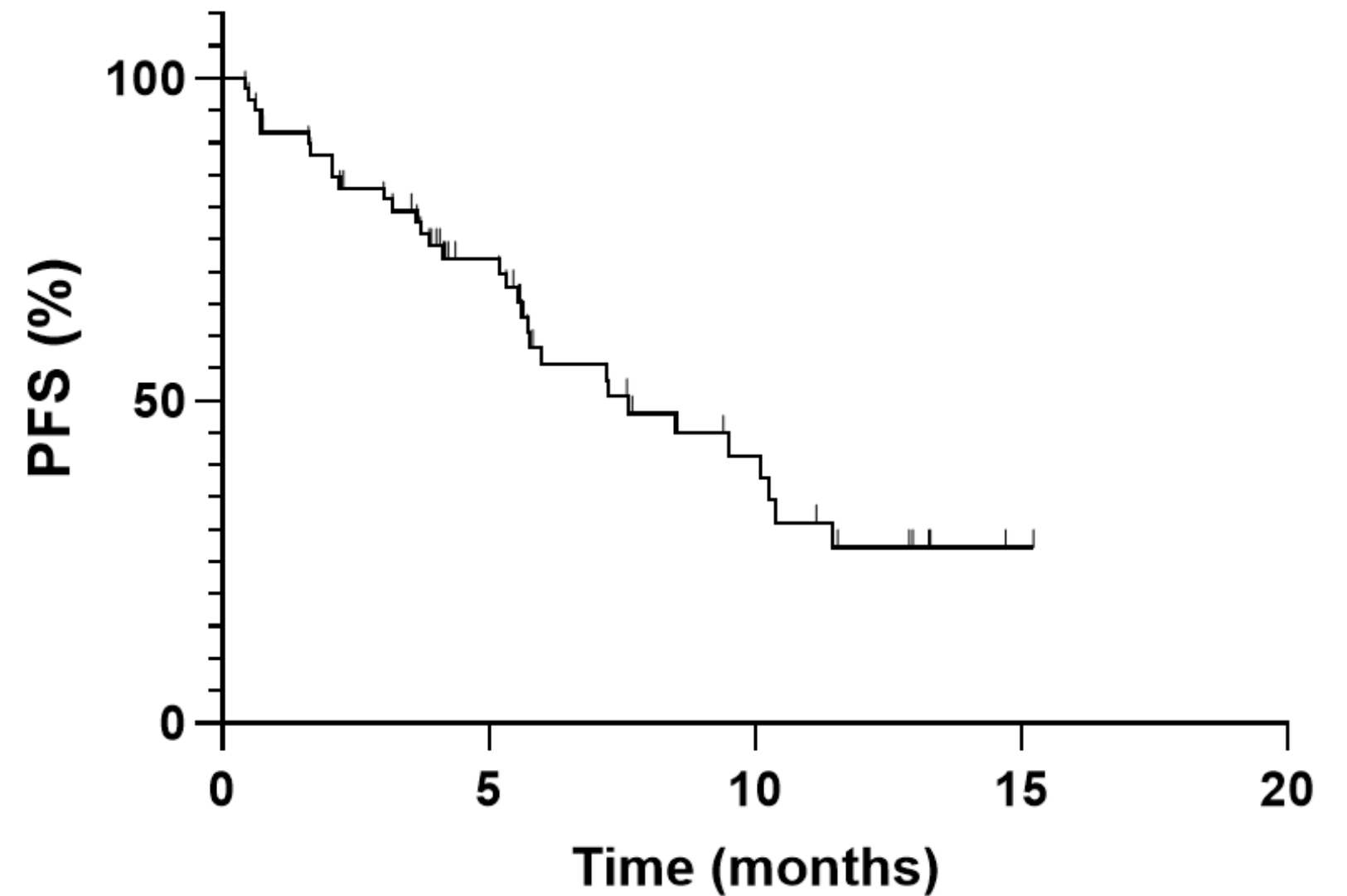
Promising evidence of efficacy, durability and tolerability

Progression Free Survival (PFS) data

- Currently determined at 7.6 months - substantially better than chemotherapy alone (5.5 months)
- Improvement over FOLFIRINOX chemotherapy (6.4 months)

	ACCENT Trial (Narmafotinib/Gemcitabine/Abiraxane)	MPACT Trial (Gemcitabine/Abiraxane)	PRODIGE Trial (FOLFIRINOX)
PFS	7.6 months	5.5 months	6.4 months

All ACCENT patients @ 400 mg (n = 64)



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ACCENT TRIAL TOPLINE DATA

Promising evidence of efficacy, durability and tolerability

17 confirmed responses observed to date

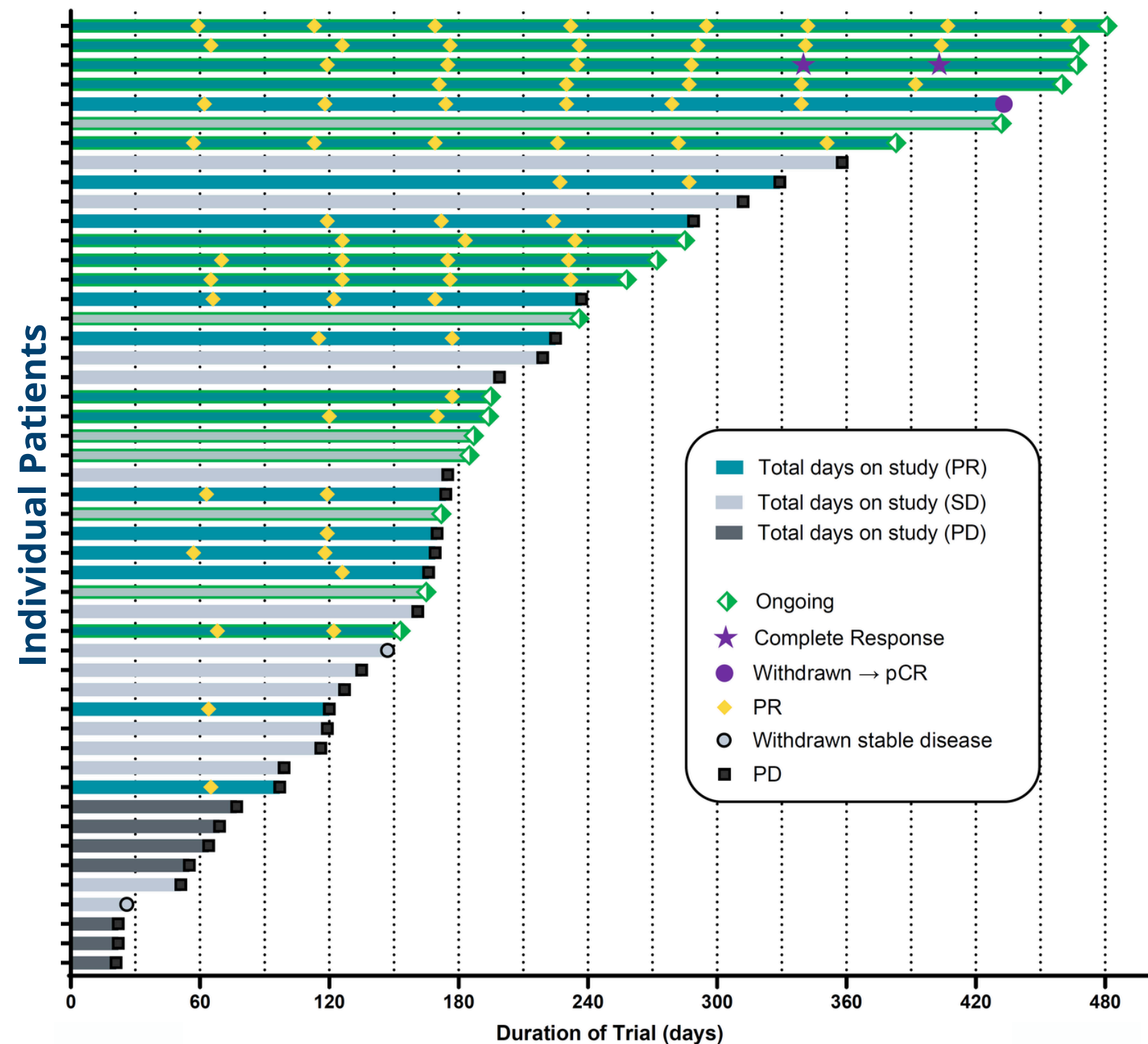
- Includes:
 - 1 confirmed Complete Response (CR)
 - 1 pathological Complete Response (pCR)
- Indicating narmafotinib + chemotherapy is **superior** to chemotherapy alone

7 patients on study > 1 year

- Mean DoT = 201 days

At data cut-off (20 Jul 2025):

- 17 patients remain on study
- Data for 6 patients at 6 months yet to be collected



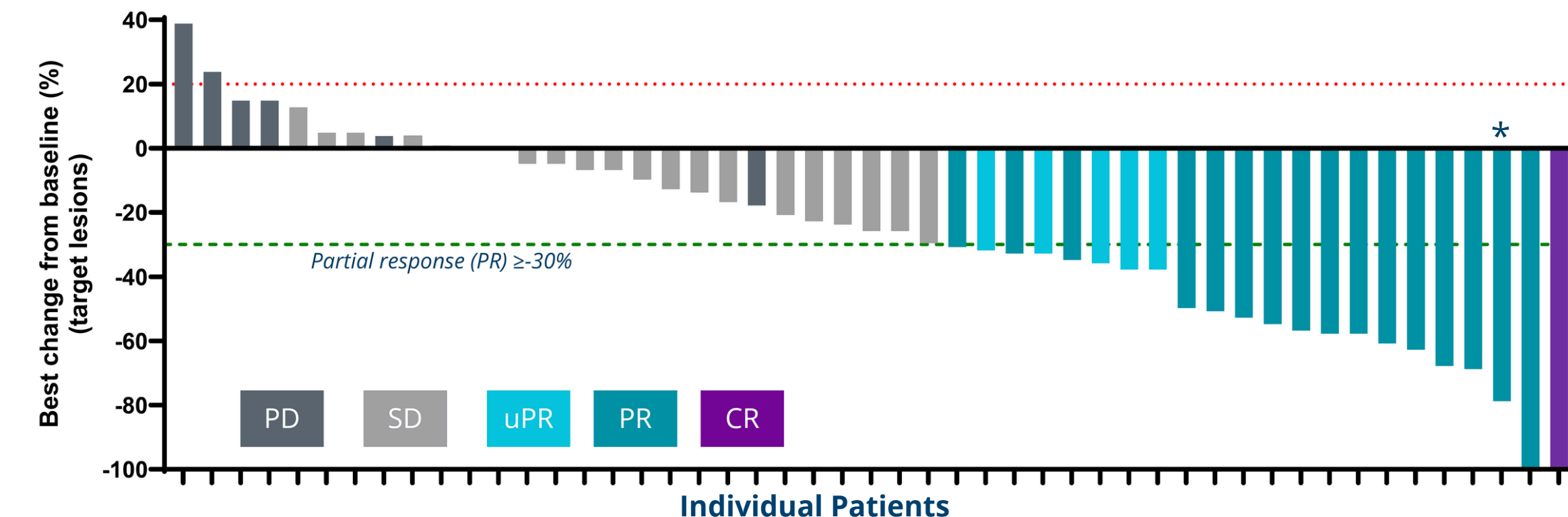
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ACCENT TRIAL TOPLINE DATA

Promising evidence of efficacy, durability and tolerability

Excellent response rate observed

- 1 confirmed Complete Response
- 16 confirmed Partial Responses
 - Incl. 1 patient determined to be a **pathological Complete Response**
- Objective response rate (ORR) of 31%
- Disease control rate (DCR) of 73%



* Pathological Complete Response

Peter's pancreatic marvel: meet the luckiest man in the country

EXCLUSIVE
Test results stunned doctors in Australia – and across the world

NATASHA ROBINSON
HEALTH EDITOR

Peter Moulding was recovering from surgery when his oncologist received the Melbourne trader's pathology results – and the doctor couldn't believe his eyes. "I actually called the pathologist and said, 'Are you sure you're looking at the right specimen?'" says Prasad Cooray, an oncologist at the Jervis Bay Pancreatic Centre at the Epworth Hospital in Melbourne. "Because I think all of us had difficulty believing this was true."



Peter Moulding can now see the funny side after going into remission from pancreatic cancer, an almost unprecedented event

The pancreatic cancer case here really hasn't been any significant development in treatment for decades," Dr Cooray says. "Yes, there's been some improvement in chemotherapy drugs, but a drug that looks at the cancer from a different angle has not happened in pancreatic cancer ever. So if this drug proves to be effective, this will be a groundbreaking development in pancreatic cancer."

AMP945 was developed by Amplia Therapeutics under the umbrella of Australia's Cancer Therapeutics Co-operative Research Centre – set up by the federal government in 2007 to bridge the gap between research breakthroughs and commercialisation – in conjunction with scientists from the nation's top universities and scientific institutes. The Garvan Institute of Medical Research had previously established that targeting FAK prior to treatment makes pancreatic cancer cells more sensitive to chemotherapy and reduces cancer spread by 50 per cent in mice. The drug has been shown in early studies to also have application for ovarian cancer, which also involves fibrosis.

Despite the promising results in animal studies, Amplia chief executive Chris Burns said the results of the human trial so far have exceeded his company's expectations. "To see a pathological complete response was totally unexpected. We never thought it would happen."

"I've never come across a case like Peter's where there is no residual cancer left"

"I actually called the pathologist and said: 'Are you sure you're looking at the right specimen?'"

"To see a pathological complete response was totally unexpected. We never thought it would happen"

CHRIS BURNS
AMPLIA CEO
EXECUTIVE

PRASAD COORAY
ONCOLOGIST

"This drug is still very much investigational, and so it's a potential pointer that this may be a good drug that may have particular activity, but it's a pointer at this stage. It's not a sort of 'lay-down miser'. It's important people understand and that we don't raise false hopes. "But pancreatic cancer has been an orphan cancer in many ways, because people have been nihilistic about the effects of treatment. There are not many patient advocates, because our patients are too unwell for that, and their survival is not good enough for them to be involved. "So I think that a good news story like this will only help to stimulate medical research efforts further, and to look and to review and see what's special about that person who has had such a good response, and how we can learn some deeper lessons from that."

"I just want to do some things that are going to make me happy and enjoy what I've got left of my time, I suppose," he says. "It would be nice to actually get off my butt and do some travelling."

"As a patient, Mr Moulding has immense gratitude for the being part of the clinical trial. "I don't know really what to say except that I'm just so happy," he says. "I was given the opportunity to have a go of it, and it's actually worked."

"We're now in the era of personalised medicine." Dr Zinat says. "Genetic mutations may be driving the fibrosis in pancreatic cancer patients, and if you target the mutation and switch off the fibrosis, you may be able to improve the patient's outcome."

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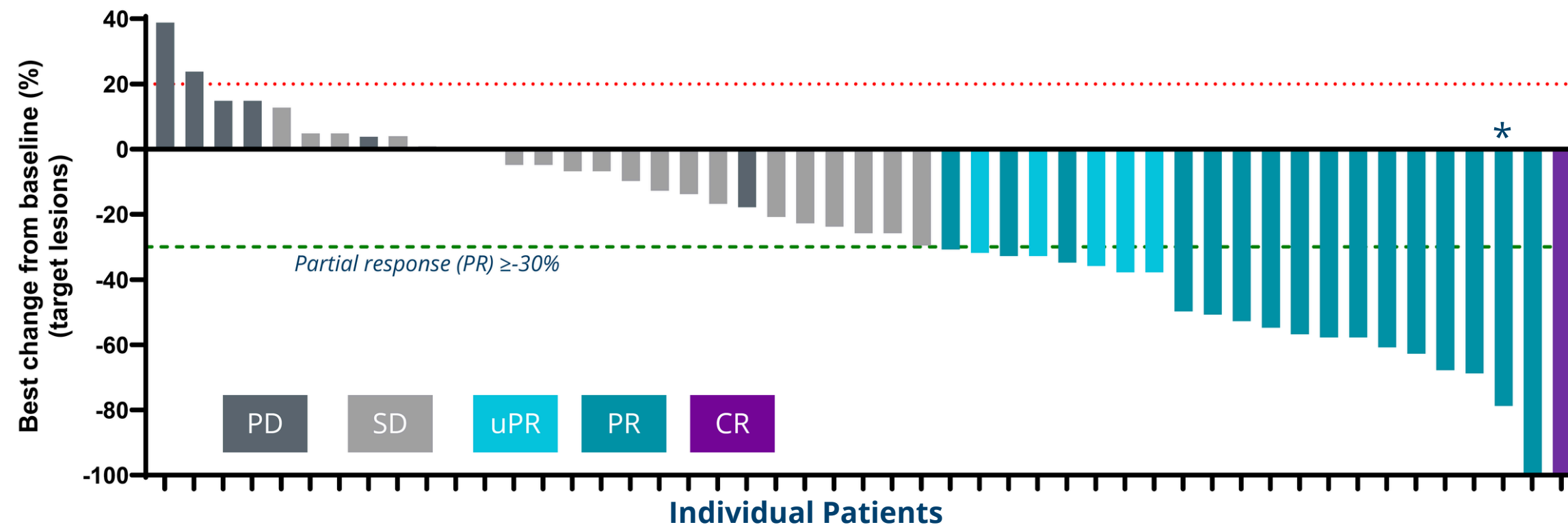
ACCENT TRIAL TOPLINE DATA

Promising evidence of efficacy, durability and tolerability

Excellent response rate observed

- 1 confirmed Complete Response
- 16 confirmed Partial Responses
 - Incl. 1 patient determined to be a **pathological Complete Response**
- Objective response rate (ORR) of 31%
- Disease control rate (DCR) of 73%

	ACCENT Trial (Narmafotinib/Gemcitabine/Abraxane)	MPACT Trial (Gemcitabine/Abraxane)
CR	2%	0.2%
PR	29%	23%
SD	42%	27%
PD	16%	20%
NE	11%	30%
ORR	31%	23%
DCR	73%	50%
DOT	202 days	117 days



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ACCENT TRIAL TOPLINE DATA

Promising evidence of efficacy, durability and tolerability

Excellent tolerability observed to date

- Narmafotinib treatment results in negligible extra patient burden

Adverse Events (Grade 3 or above)

Adverse Event (AE) Grade ≥ 3	Narmafotinib +Gem/Abr (ACCENT; N=55)	Gem/Abr (MPACT; N=421)
Neutropenia	38.2%	38%
Anemia	9.1%	13%
Diarrhea	5.5%	6%
Peripheral neuropathy	3.6%	17%
Vomiting	3.6%	NR
Febrile Neutropenia	5.5%	3%
Thrombocytopenia	NR	13%
Fatigue	NR	17%
Hypokalemia	NR	NR
Nausea	3.6%	NR

Gem/Abr (NAPOLI 3; N=379)	FOLFIRINOX (PRODIGE; N=171)	NALIRIFOX (NAPOLI 3; N=370)
39%	46%	24%
18%	8%	11%
5%	13%	20%
6%	9%	3%
2%	15%	7%
NR	5%	NR
NR	9%	NR
5%	24%	6%
4%	NR	15%
3%	NR	12%

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ACCENT TRIAL SUMMARY

On track to achieve trial goals

Superior Efficacy

For full 55 patient cohort

- **1 CR**
- **16 PR (incl. 1 pCR)**

Improved PFS over Gemcitabine + Abraxane, and FOLFIRINOX



Improved Durability

7 patients on trial for >12 months

Deep and sustained response for a subset of patients

- Biomarker discovery to be initiated



Demonstrated Tolerability

Excellent tolerability profile

Minimal additional burden on the patients above standard of care

No evidence or likelihood of drug-drug interactions



FUTURE OPPORTUNITIES

FAK inhibition will enhance multiple therapeutic strategies

Narmafotinib (FAK inhibition)



CHEMOTHERAPY

Clinical and preclinical data incl.
ACCENT study

IMMUNOTHERAPIES

Preclinical data

KRAS INHIBITORS

Preclinical data, incl.  NEXT&BIO
collaboration

RADIOOTHERAPY

Published data

ANTIBODY DRUG CONJUGATES

Published data

AMPLICITY TRIAL in mPDAC

Phase 1b/2a study in the US and Australia

OBJECTIVE

- To determine safety and efficacy of narmafotinib when added to FOLFIRINOX in newly diagnosed patients
- To identify recommended phase 2 dose (RP2D)

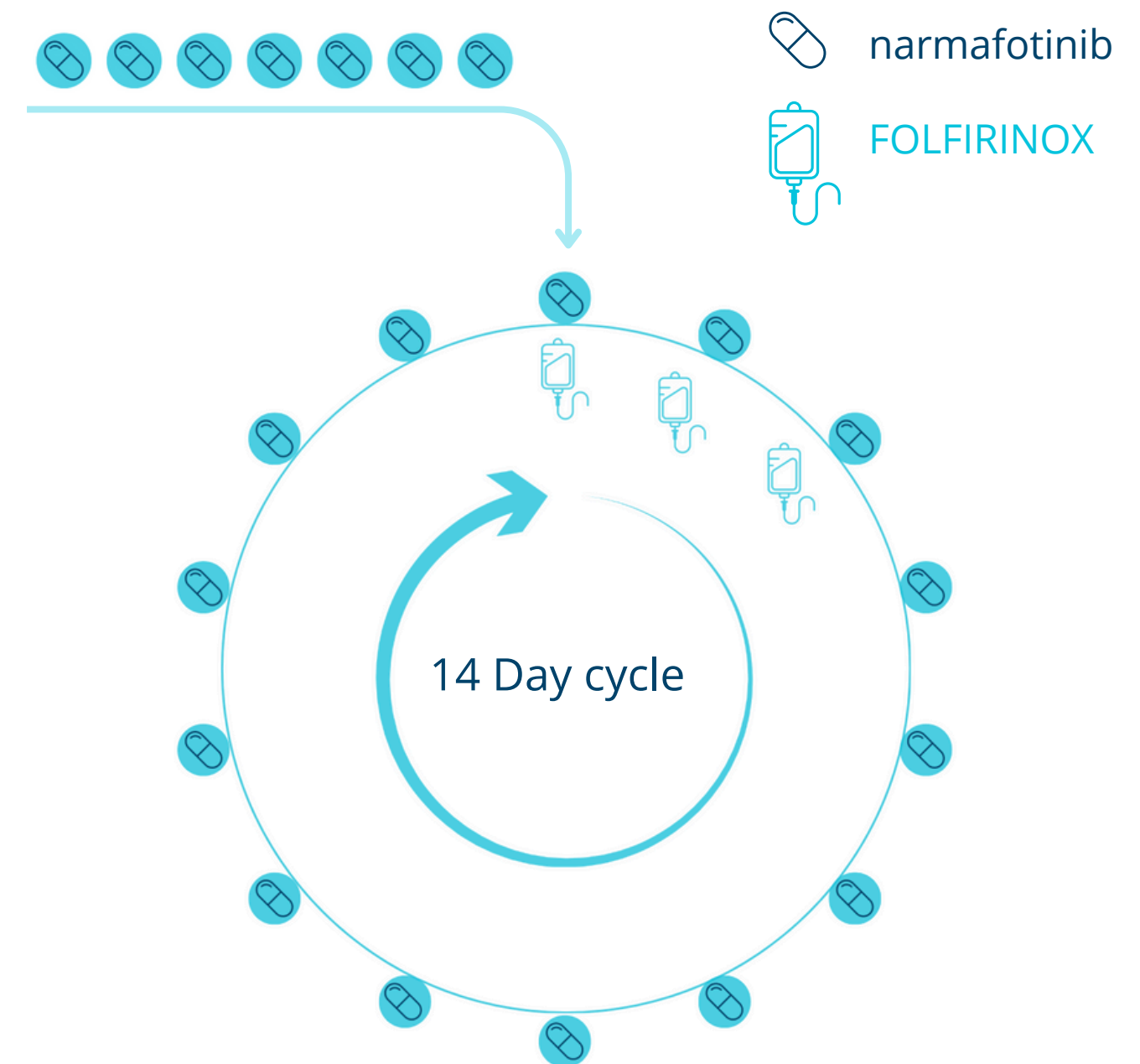
PRIMARY ENDPOINTS

- Safety, Tolerability
- RP2D

ADDITIONAL ENDPOINTS

- ORR (RECIST v1.1)
- Duration of Response
- Progression free survival (PFS)
- Overall Survival (OS)
- Disease Control Rate

Moving from intermittent to daily dosing



NARMAFOTINIB: A POTENT AND SELECTIVE FAK INHIBITOR

FAK enzyme overactive in pancreatic cancer

FAK levels are elevated in pancreatic cancer

- Correlate with worse patient outcome

FAK inhibition blocks processes that support:

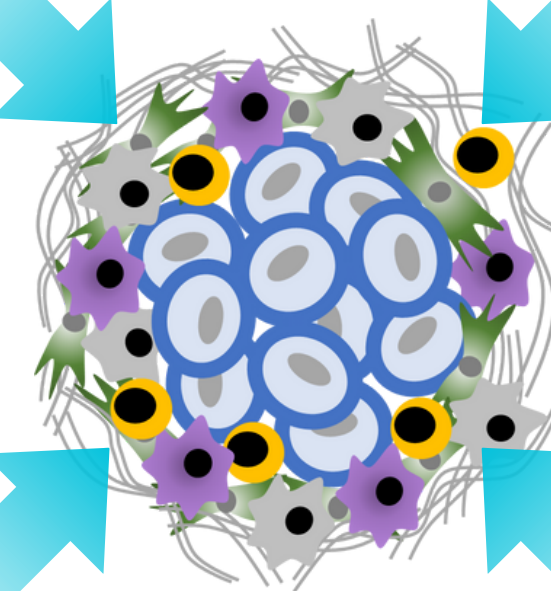
- Tumour growth
- Metastasis
- Treatment resistance

Demonstrated efficacy in preclinical models of human pancreatic cancer

Benefits of FAK Inhibition

Anti-proliferative
Reduces cells' 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

NARMAFOTINIB: A POTENT AND SELECTIVE FAK INHIBITOR

Best-in-class profile

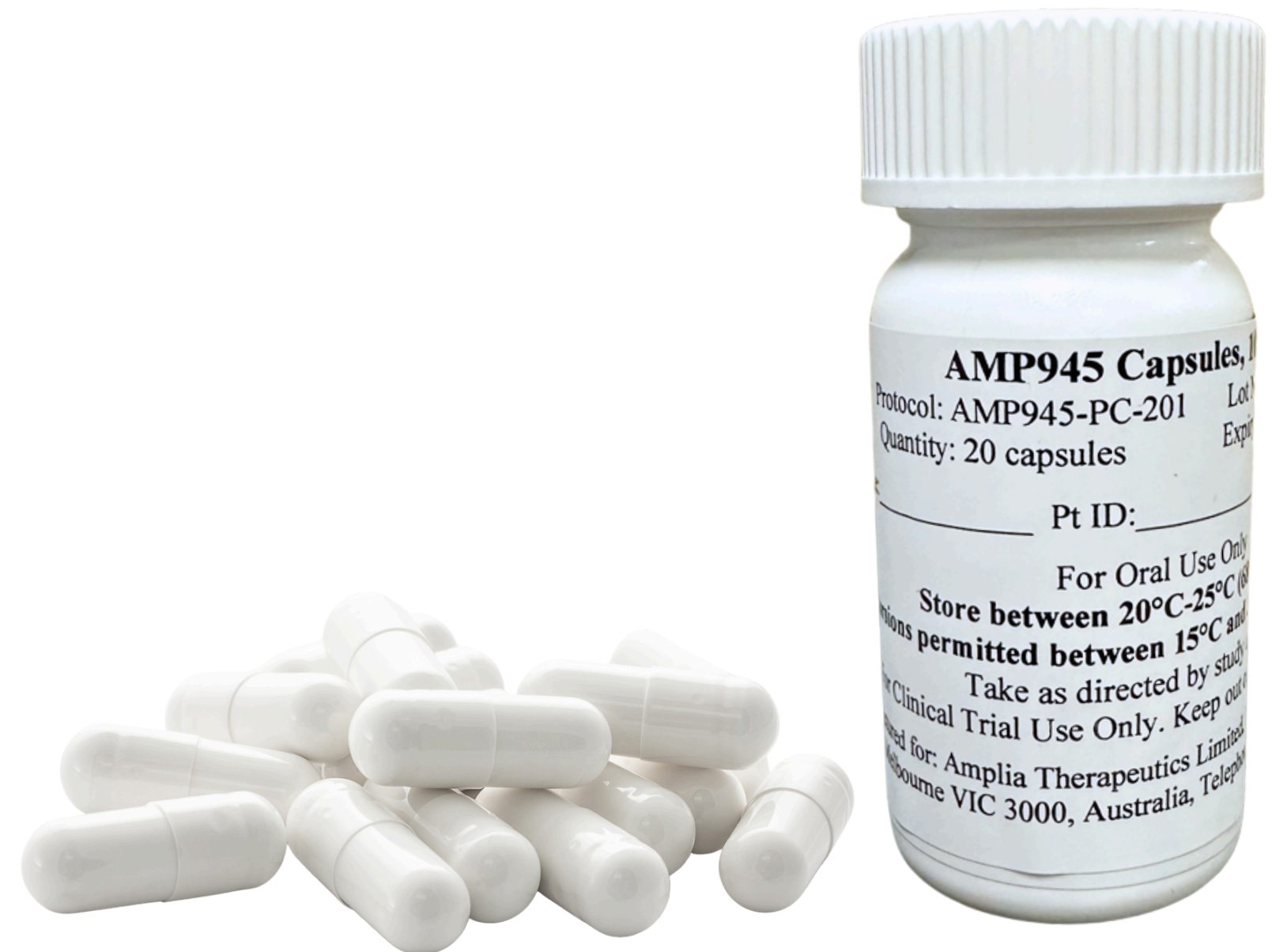
Convenient to take

- Once a day oral dosing by capsule
- Storage at room temperature

Safe to combine with other medicines

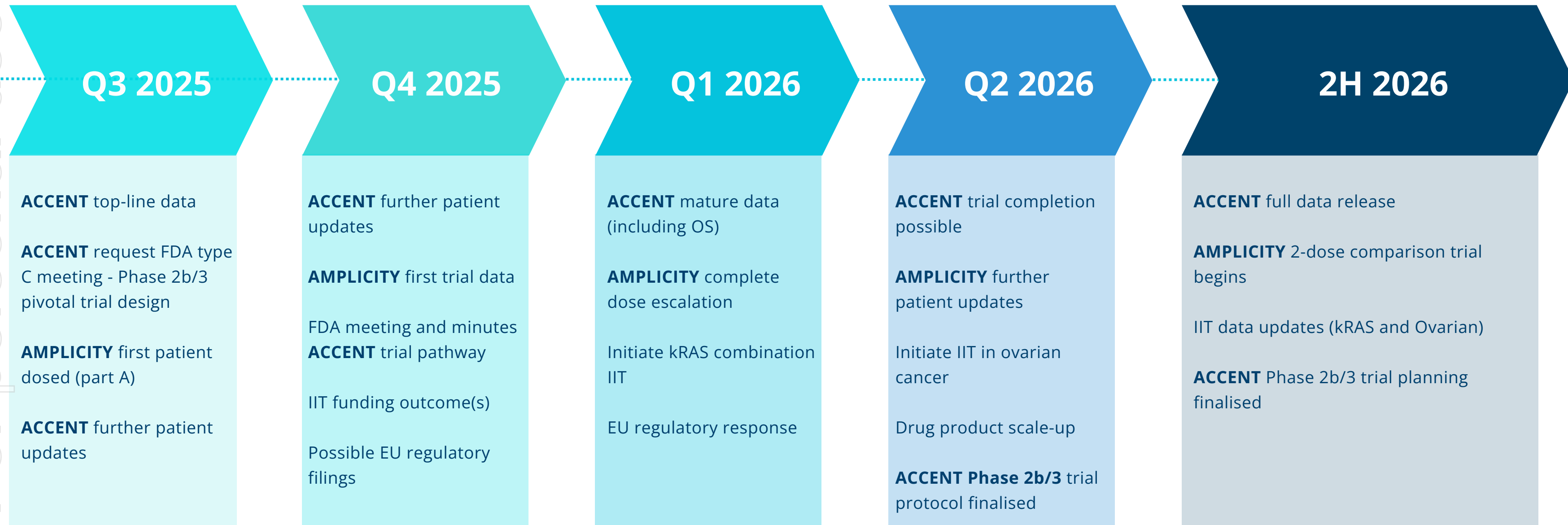
- No evidence of drug-drug interactions

Evidence of FAK target engagement preclinically and in the clinic



UPCOMING MILESTONES

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THANK YOU

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