ABN 16 165 160 841

ASX RELEASE **30 October 2024**

INTERIM DATA FROM ACCENT PANCREATIC CANCER TRIAL SUPPORTS CONTINUATION OF TRIAL

HIGHLIGHTS

- *Data analysis up to 27 September 2024 from the ongoing ACCENT trial of narmafotinib in combination with chemotherapy has been undertaken*
- *Fifteen patients of the 26 enrolled in the study remain on trial with six (6) confirmed PRs having been recorded along with four (4) unconfirmed PRs and five (5) SDs*
- *The median duration on trial is longer than for comparative trials of chemotherapy alone*
- *The ACCENT trial has resumed recruitment for the final cohort of 24 patients and as of 24 October 2024, 3 patients have been recruited*

Melbourne, Australia: Amplia Therapeutics Limited (ASX: ATX), ("Amplia" or the "Company"), is pleased to report the interim data analysis from the Company's Phase 2a clinical trial investigating narmafotinib in the treatment of advanced pancreatic cancer (the ACCENT trial). The trial is investigating the combination of the Company's best-in-class FAK inhibitor narmafotinib with the standard-of-care chemotherapy regimen of gemcitabine and Abraxane®. Data cut-off for the interim analysis is 27 September 2024.

As previously reported by the Company, narmafotinib continues to be generally well tolerated by patients with no dose reductions. In addition, six (6) patients recorded confirmed partial responses (PRs), meaning in these patients there is at least a 30% decrease in the overall size of tumour lesions, with no new tumour lesions, sustained for two or more months.

Further details regarding the responses observed by trial participants are summarised below and presented in the attached slides:

- 6 patients have recorded unconfirmed PRs, 4 of which are awaiting confirmation whilst 2 have subsequently recorded progressive disease (PD)
- 8 patients recorded sustained stable disease (SD), with 5 of these patients remaining on study
- 3 patients recorded PD as best response, while 3 other participants were considered ineligible or withdrew from the trial
- Of the 24 evaluable patients, 19 have recorded a decrease in tumour size as best response at any scan
- Median duration on trial at data cut-off is 136 days, which compares favourably with historical data for chemotherapy alone of 117 days
- Preliminary analysis indicates patients have a faster response to therapy in terms of tumour reduction, compared to historical data for chemotherapy alone

A total of 50 patients are planned for the Phase 2a ACCENT trial. With the six (6) confirmed PRs obtained, recruitment of the remaining 24 patients has begun. Recruitment of the second cohort of patients is expected to be completed by end of Q1 2025 and three patients have already been enrolled as of 24 October 2024.

Amplia CEO and MD Dr Chris Burns commented: “We continue to be excited by the data coming from the clinical study of narmafotinib in this challenging disease. We thank the patients and their loved ones for their involvement in the study. Further trial updates will be provided to the market in due course. "

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 and other cancers, 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. The drug has successfully completed a healthy volunteer study, and is currently in an open-label Phase 2a trial in pancreatic cancer where a combination of narmafotinib and the chemotherapies gemcitabine and Abraxane® is being assessed for safety, tolerability and efficacy.

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 ACCENT trial explores the use of narmafotinib in combination with standard-of-care chemotherapy of gemcitabine and Abraxane® in first-line patients with advanced pancreatic cancer. The trial is a single-arm open label study conducted in two stages. The first stage (Phase 1b), completed in November 2023, identified a 400 mg oral daily dose of narmafotinib, given in the days preceding regular chemotherapy infusion, as safe and well tolerated.

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

More information about the ACCENT trial, including a list of participating sites, can be found via the Amplia Therapeutics website and at ClinicalTrials.gov under the identifier NCT05355298.

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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 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 (@ampliatx), Threads (@ampliatx) and LinkedIn.

Amplia THERAPEUTICS

ACCENT Trial Interim Data

30 October 2024

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ACCENT TRIAL DESIGN

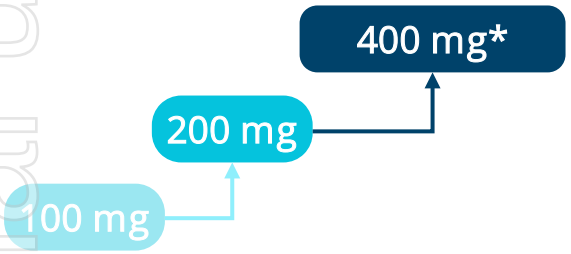
An open-label trial of narmafotinib in combination with gemcitabine and Abraxane® in first-line patients with advanced pancreatic cancer

Trial Read-outs:

Phase 1b: *Primary endpoint* – Safety and Tolerability; *Secondary endpoint* – PK and preliminary efficacy
Phase 2a: *Primary endpoint* – Objective Response Rate; *Secondary endpoint* – Duration on Trial

Phase 1b (Australia)

14 patients

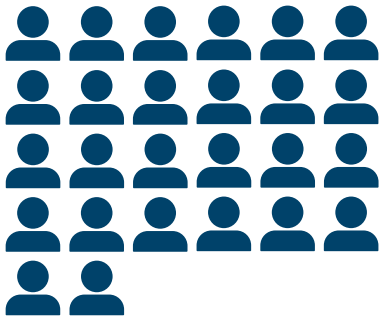


COMPLETED

Dose Selected

Phase 2a (Australia and South Korea)

26 patients



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Interim Analysis

≥6 PR

Phase 2a (cont) (Australia and South Korea)

24 patients

UNDERWAY

*Dose selected for Phase 2

ACCENT PHASE 2a Preliminary Data

Data cut-off 27 September 2024

Narmafotinib continues to be generally well tolerated in this patient group with no dose reductions

6 confirmed PRs observed at 4 month timepoint by 23 September 2024

- >30% reduction in tumour lesion size sustained over 2 months
- No new lesions

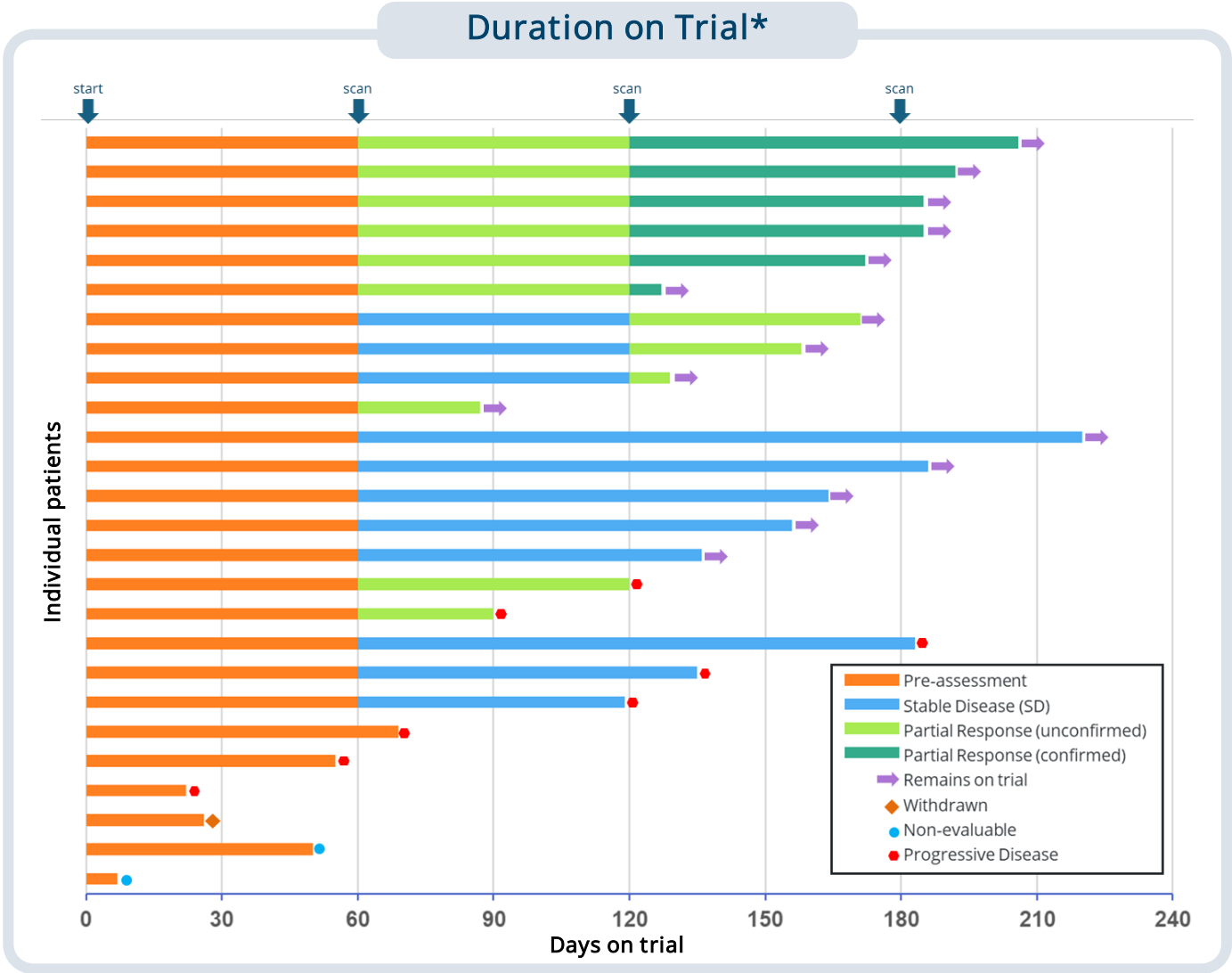
Developing data-set sufficiently positive, compared to historical data, to continue trial and complete recruitment of 50 patients

ACCENT PHASE 2a Preliminary Data

High-level data as of 27 September 2024*

Trial is ongoing - dataset is developing

- 15 patients remain on study
- 6 confirmed PRs (= PR sustained over 2 or more months)
- 4 PRs yet to be confirmed
- 7 SDs for 2 or more months
- 8 patients whose disease has progressed
- 3 patients that have withdrawn or were considered ineligible for assessment



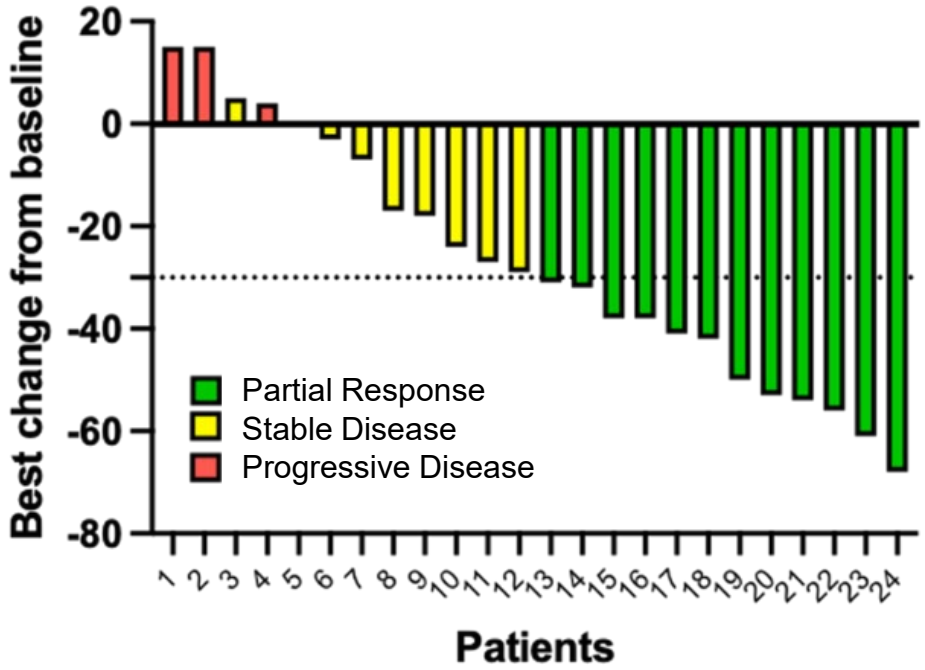
*Based on data available in trial database on Sep 27; responses are investigator read; analysis may change as data matures.
PR = Partial response, SD = Stable Disease

ACCENT PHASE 2a Preliminary Data

Collated data of 'best response' at any scan indicates promising activity

- 19 patients have recorded a decrease in tumour size
- 12 patients have recorded a decrease in tumour size >30%

Best Response (evaluable patients)*



*Based on data available in trial database on Sep 27; responses are investigator read; analysis may change as data matures.

ACCENT PHASE 2a Preliminary Data

Comparison with historical gemcitabine/ Abraxane data indicates promising response trends, noting

- Different data-set sizes
- ACCENT trial still ongoing – 15 patients remain on trial

	ACCENT Phase 2a Part A*	Historical MPACT Trial
Response Classification	**Best Response (n=26)**	**Best Overall Response** (n=431)**
Complete Response (CR)	0 (0%)	<1%
Partial Response (PR)	12 (46%)†	23%
Stable Disease (SD)	8 (31%)	27%
Progressive Disease (PD)	3 (12%)	20%
Not evaluable (NE)	3 (12%)‡	30%
Median Duration on Treatment	136 days	117 days

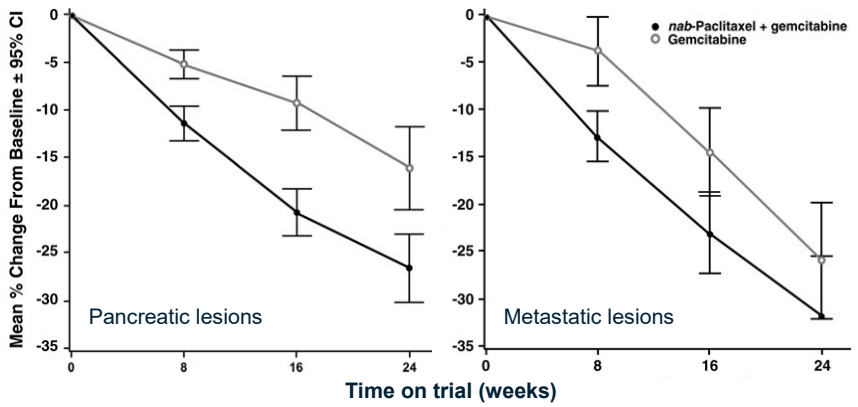
* Based on data available in trial database on Sep 27; responses are investigator read; analysis may change as data matures.
** Confirmed data from MPACT trial (independent review); *NEJM* 2013: 369; 1691-1703
† Partial response as best response includes 6 confirmed PRs, 4 unconfirmed PRs, 2 PRs that converted to PD
‡ Includes one patient who withdrew

ACCENT PHASE 2a Preliminary Data

Comparison with historical gemcitabine/ Abraxane data suggests combination with narmafotinib leads to:

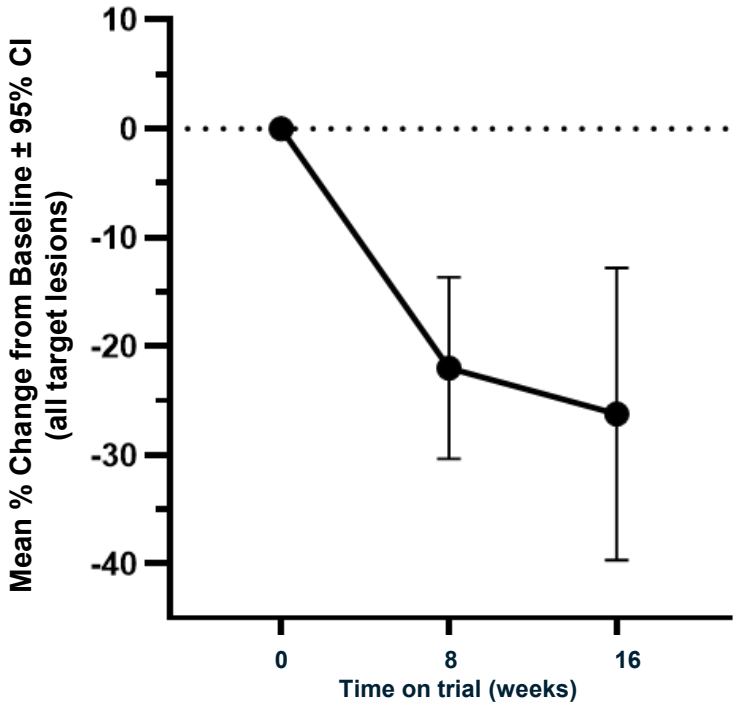
- Faster response
- Longer/sustained response

Historical gemcitabine/Abraxane data‡



‡ *Pancreas* 2017: 46; 203

ACCENT Phase 2a Response over time (all lesions)*



*Based on data available in trial database on Sep 27; responses are investigator read; analysis may change as data matures.

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