

**Capital Raising Presentation** 

October 2024

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#### IMPORTANT INFORMATION

Amplia THERAPEUTICS

This presentation (**Presentation**) has been prepared by Amplia Therapeutics Limited ACN 165 160 841 (the **Company** or **Amplia**) and is dated 30 October 2024. This Presentation has been prepared in relation to a proposed capital raising comprising a placement to sophisticated and professional investors (**Placement**) and a pro-rata accelerated non-renounceable entitlement offer to eligible shareholders (**Entitlement Offer**) of new ordinary fully paid shares in Amplia (**New Shares**) (together referred to as the **Offer**). Participants in the Offer will be entitled to subscribe for 3 options (**Attaching Options**) for every 4 New Shares subscribed for. The Attaching Options will have an exercise price of \$0.1725 and will expire on 31 October 2027. The offer of Attaching Options to participants in the Placement is subject to shareholder approval for the purposes of ASX Listing Rule 7.1.

The Entitlement Offer (including the offer of Attaching Options) and the offer of Attaching Options to participants in the Placement will be undertaken pursuant to a transaction-specific prospectus dated 30 October 2024.

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#### **EXECUTIVE SUMMARY**



#### Best-in-class FAK inhibitor in development with near term clinical milestones

#### Developing a pipeline of small molecule inhibitors of FAK - a validated cancer target

- Lead compound narmafotinib is the best-in-class Focal Adhesion Kinase (FAK) inhibitor in development
- Promising clinical safety and tolerability positions narmafotinib as the preferred agent to enhance activity of drugs for treatment of pancreatic cancer and other solid tumours
- Phase 1b trial in pancreatic cancer showed preliminary signs of efficacy with duration on trial significantly improved vs current standard of care (gemcitabine and Abraxane®)
- Compelling pre-clinical data in ovarian cancer, IPF and other solid tumours



#### Phase 2a ACCENT clinical trial in pancreatic cancer underway with activity threshold already achieved

- Completed enrolment of first 26 patients and recruitment of remaining 24 patients underway
- Achieved activity threshold of 6 confirmed partial responses (PRs) allowing recruitment of full 50 patients. Drug well tolerated and promising signs of efficacy
- Trial recruitment expected to complete Q1 2025 with topline data expected Q3 2025



#### Preparing for narmafotinib trial in pancreatic cancer in the US

- Clearance of IND application for clinical study of narmafotinib in combination with FOLFIRINOX (standard-of-care therapy for advanced pancreatic cancer in US)
- Targeting commencement of dose escalation trial in 1H 2025



#### Orphan Drug and Fast Track Designations granted by US FDA

- Provides 7 years market exclusivity in US
- Receive tax credits for clinical costs and exemptions from certain fees
- Expedited review of documentation
- Eligible for Accelerated Approval and Priority Review Voucher

#### Capital raising of up to approximately A\$13.0m to fund the clinical program



- Undertaking a capital raising of up to approximately \$13.0 million via a Placement, Director Placement and Entitlement Offer at an offer price of \$0.115 per New Share
- Funds raised will be used to complete the Phase 2a ACCENT trial, US FOLFIRINOX dose escalation study, CMC manufacturing for follow on studies, additional preclinical work and costs of the Offer

#### **COMPANY SUMMARY**



#### **ASX:ATX**

Share price (29-Oct-2024)	A\$0.135	
Shares on issue	274.8m	
Market cap (29-Oct-2024)	A\$37.1M	
Cash (30-Sep-2024)	A\$4.6M	
Substantial Shareholders	<ul> <li>Platinum Investment Management Ltd (12.9%)</li> <li>Blueflag Holdings Pty Ltd (6.9%)</li> <li>Acorn Capital Ltd (5.8%)</li> <li>Pengana Capital (4.3%)</li> <li>Board + Management (5.8%)</li> </ul>	

#### 12 month share price chart



#### **EXPERIENCED BOARD + 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** 





\* Co-recipient of 2024 PM's Prize for Innovation

#### **MANAGEMENT**



**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** 



# **PIPELINE**



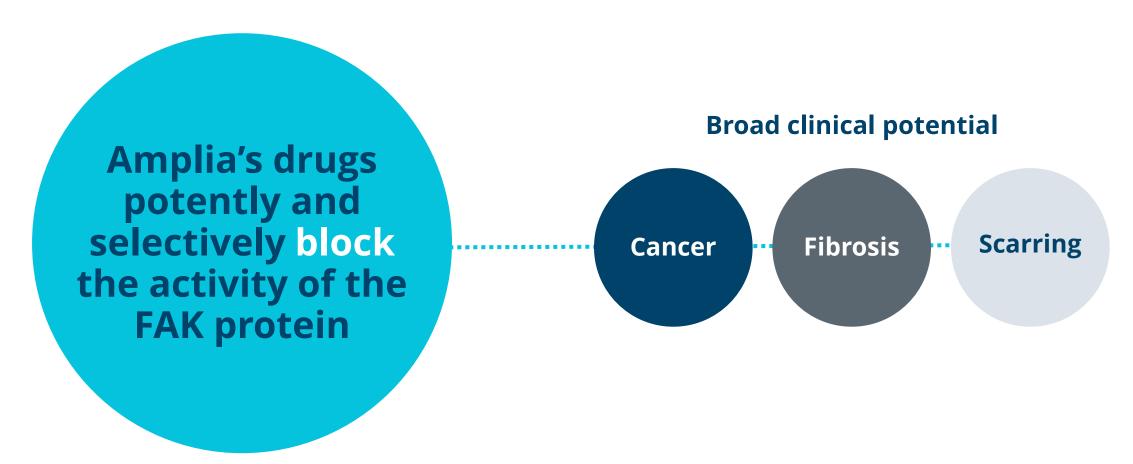
Drug	Target	Indication	Preclinical	IND enabling	Phase 1	Phase 2	Late Phase	Status
ONCOLOGY								
Narmafotinib (AMP945)	FAK	Pancreatic Cancer (ACCENT)						Enrolling
		Pancreatic Cancer (Folfirinox combination)						IND approved
		Ovarian Cancer						In planning
		Other solid tumours						
AMP886	FAK/VEGFR3/FLT3	Solid tumours						
FIBROTIC DISEASE								
Narmafotinib (AMP945)	FAK	Idiopathic Pulmonary Fibrosis						
		Other fibrotic diseases						
TOPICAL								
Narmafotinib (AMP945)	FAK	Scar Reduction						POC developed



# **FOCAL ADHESION KINASE (FAK)**



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



#### **FAK INHIBITION IN CANCER**



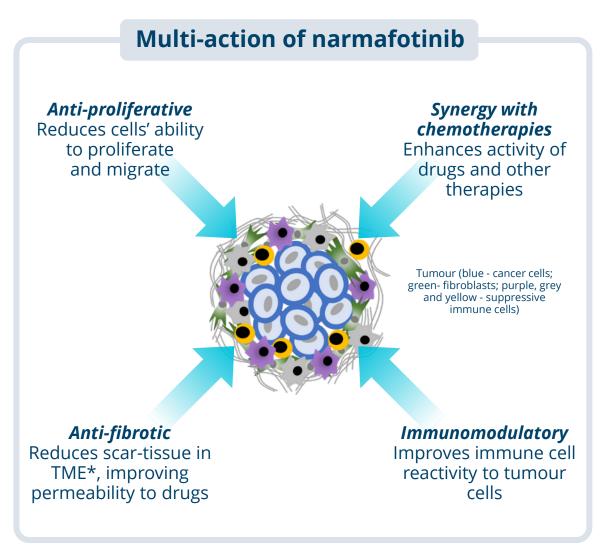
FAK over-expressed and over-active in many cancers

Higher FAK levels correlate with worse patient outcomes

Narmafotinib potently inhibits FAK and thereby reduces cancer growth

- within cancer cell
- in tumour microenvironment

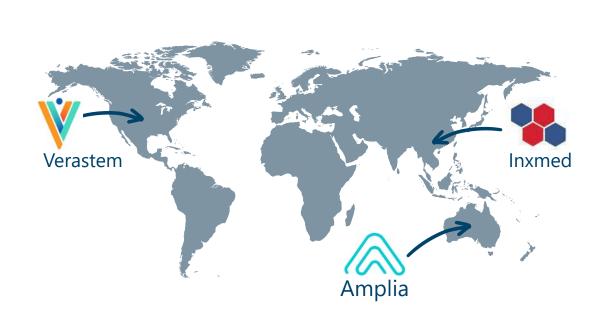
Narmafotinib blocks critical pathways supporting tumour growth



#### **FAK INHIBITORS IN DEVELOPMENT**



#### Only 3 companies with bona fide FAK inhibitors in development



#### Verastem (VSTM.NASDAQ, Mkt Cap US\$136m (A\$207m))

- Co-development with a second drug (avutometinib)
- Promising data in low-grade serous ovarian cancer (~10% patients)
- New Drug Application (NDA) with FDA reported as imminent
- Higher adverse events with drug combination\*
- Completed Phase 2 trials; Phase 3 underway

#### Inxmed (private)

- Promising early data in high-grade serous ovarian cancer study
- High percentage patients on trial presenting with high protein in urine<sup>†</sup> possibly indicating off-target drug effect to kidneys
- Phase 2 studies underway

Narmafotinib has an excellent selectivity profile, improved pharmacokinetics and good tolerability in patients



#### PANCREATIC CANCER





# **Increasing Prevalence**

Estimated 66,440 diagnoses and 51,750 deaths in US this year\*

~4,506 diagnoses in AU in 2023\*\*



# 5 year survival

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



# Market size

Global treatment market estimated at ~US\$2.5 billon in 2024 <sup>†</sup>

Projected to grow to ~US\$12.6 billion by 2037<sup>†</sup>

<sup>\*</sup> American Cancer Society: https://cancerstatisticscenter.cancer.org/)

<sup>\*\*</sup> Cancer Australia: https://www.canceraustralia.gov.au/cancer-types/pancreatic-cancer/statistics

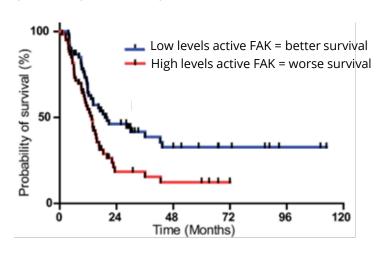
#### **ACCENT PANCREATIC TRIAL**



#### **Background**

#### FAK activity correlates with worse outcome

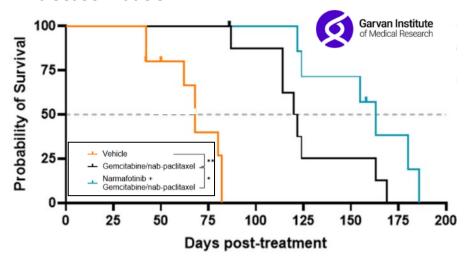
- Fibrosis features within TME,<sup>‡</sup> consistent with activated FAK, correlate with worse patient outcome
- Patients with reduced FAK activity in tumour have improved probability of survival



EMBO Mol Med 2020, 12, e12010

#### Efficacy with FAK inhibition in preclinical studies

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



 FAK inhibition synergises with SOC\* chemotherapies and targeted therapies

<sup>‡</sup> Tumour microenvironment

<sup>\*</sup> Standard-of-care

#### **ACCENT PANCREATIC TRIAL**



#### **FDA Interactions**



#### **Orphan Drug Designation\* granted**

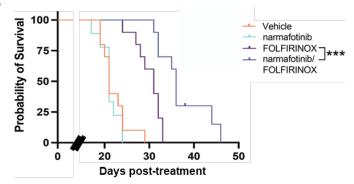
- Assistance with development planning
- Tax credits for clinical costs
- Exemptions from certain fees
- Seven years of post-approval marketing exclusivity

#### **Fast Track Designation**<sup>‡</sup>**granted**

- Increased engagement with FDA
- Expedited review of documentation
- Eligibility for Accelerated Approval and Priority Review, if relevant criteria are met

# **Clearance of Investigational New Drug application**

- Clinical study of narmafotinib in combination with FOLFIRINOX chemotherapy now possible in the US
- FOLFIRINOX standard-of-care therapy for advanced Pancreatic Cancer in US
- Preclinical studies indicate narmafotinib improves activity of FOLFIRINOX in mouse models



Mice bearing human pancreatic cancer cells show improved survival when treated with combination of narmafotinib and FOLFIRINOX, compared to FOLFIRINOX alone.

<sup>\*</sup> www.fda.gov/industry/medical-products-rare-diseases-and-conditions/designating-orphan-product-drugs-and-biological-products

<sup>‡</sup> https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track

#### **ACCENT PANCREATIC TRIAL**



#### **Background**

# 2021 Healthy Volunteer trial demonstrated excellent clinical profile

Narmafotinib safe and well tolerated

No withdrawals or safety trends

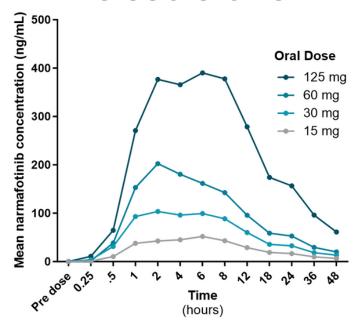
#### **Excellent Pharmacokinetics**

- Once-a-day oral dosing
- No impact of food on drug absorption

Inhibition of FAK demonstrated in skin tissue

Narmafotinib predicted to be safe for co-dosing with other drugs

# Narmafotinib circulating levels over time



#### **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:**

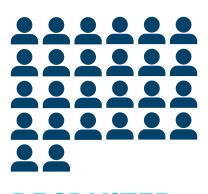
Phase 1b: *Primary endpoint* – Safety and Tolerability; *Secondary endpoint* – PK and preliminary efficacy

Phase 2a: Primary endpoint - Objective Response Rate; Secondary endpoint - Duration on Trial

# Phase 1b (Australia) 14 patients 400 mg\*

#### **COMPLETED**

Phase 2a
(Australia and South Korea)
26 patients

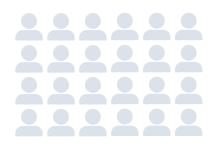


RECRUITED

Interim Analysis ≥6 PR

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

24 patients



**UNDERWAY** 

<sup>\*</sup>Dose selected for Phase 2



#### **ACCENT PHASE 1b SUMMARY**



Narmafotinib safe and well tolerated

- All 14 patients elected to stay on drug post cycle 1
- One DLT\*: nausea >72 hours
- Fatigue (Grade 3 or below) in more than 1 patient likely drug related

**Three dose levels examined,** with 400 mg dose (oral, once-a-day) in days preceding chemotherapy identified as appropriate for Phase 2a study

Data suggests % response and duration on trial is dose dependent with 4/6 patients on top dose recording confirmed PRs<sup>†</sup>

One patient at 400 mg dose remains on study (>12 months)





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

6 confirmed PRs observed at 4 month timepoint by end Sep 2024

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

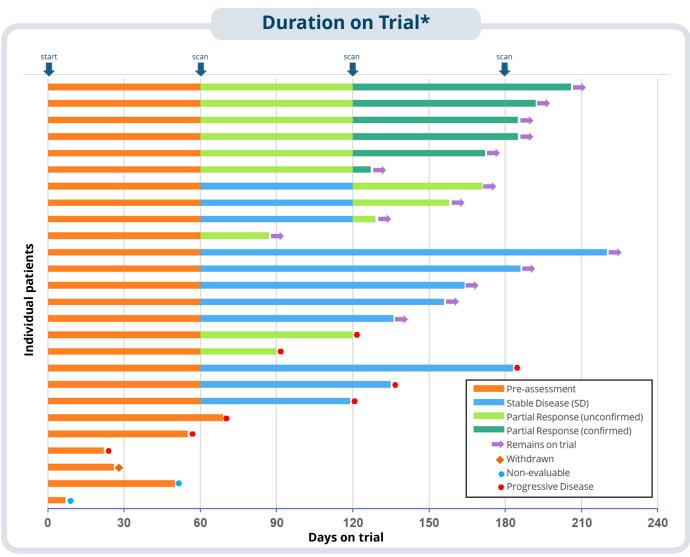
Developing data-set sufficiently positive, compared to historical data, to continue trial and complete recruitment of 50 patients



# High-level data as of 27 September 2024\*

Trial is ongoing - dataset is developing

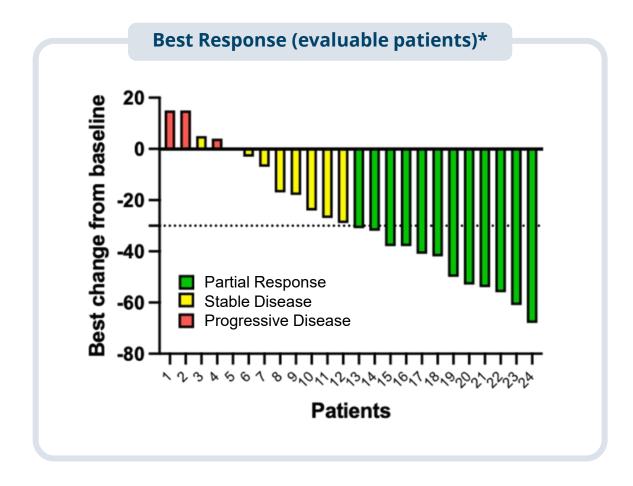
- 15 patients remain on study
- 6 confirmed PRs (= PR sustained over 2 or more months)
- 4 PRs yet to be confirmed
- 7 SDs for 2 or more months
- 8 patients whose disease has progressed
- 3 patients that have withdrawn or were considered ineligible for assessment





# 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%



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



# 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%) <sup>†</sup>	23%
Stable Disease (SD)	8 (31%)	27%
Progressive Disease (PD)	3 (12%)	20%
Not evaluable (NE)	3 (12%) <sup>‡</sup>	30%
Median Duration on Treatment	136 days	117 days

<sup>\*</sup> Based on data available in trial database on Sep 27; responses are investigator read; analysis may change as data matures

<sup>\*\*</sup> Confirmed data from MPACT trial (independent review); NEJM 2013: 369; 1691-1703

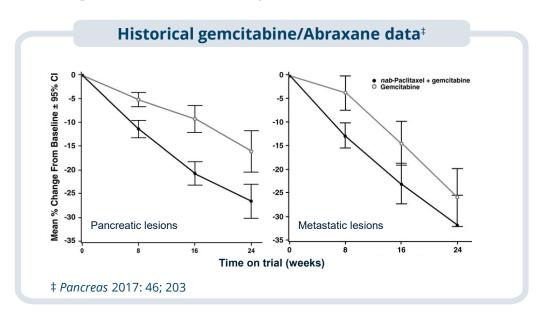
<sup>†</sup> Partial response as best response includes 6 confirmed PRs, 4 unconfirmed PRs, 2 PRs that converted to PD

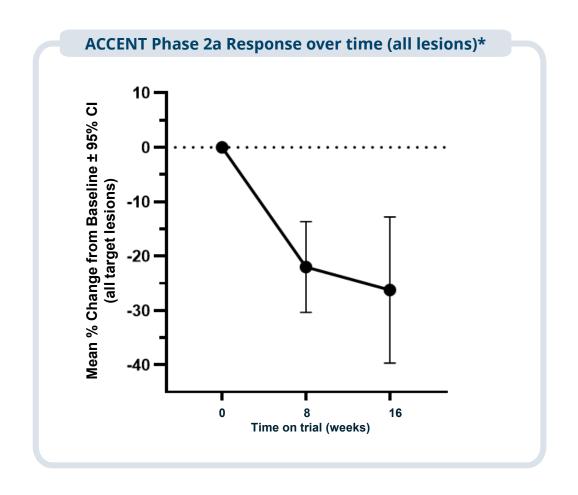
<sup>‡</sup> Includes one patient who withdrew



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

- Faster response
- Longer/sustained response





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



#### **FOLFIRINOX COMBINATION STUDY**



#### Narmafotinib + FOLFIRINOX in advanced pancreatic cancer

#### Daily dosing of narmafotinib + fortnightly mFOLFIRINOX\*

- First-line therapy/newly diagnosed patients
- Cleared IND from FDA for US-based trial
- Open label study in 2 parts
  - Part A: (i) Dose escalation; (ii) Identification of RP2D<sup>†</sup> to Project Optimus<sup>‡</sup> guidance
  - Part B: Safety and efficacy at RP2D

#### Part A (i) – estimated 20 patients

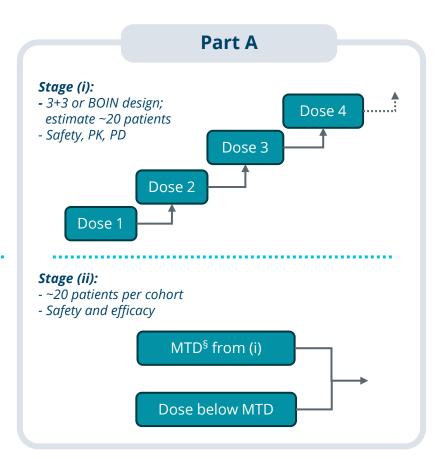
- Funding for this stage included in use-of-funds
- Drug product already in-hand

#### Part A (ii) – estimated 40 patients

• Drug substance costs for this stage included in use-of-funds

#### Part B – estimated 100 patients

• No costs for this stage currently sought



- \* Modified FOLFIRINOX
- † Recommended Phase 2 Dose
- ‡ www.fda.gov/about-fda/oncology-center-excellence/project-optimus
- § Maximum tolerated dose

#### **OVARIAN CANCER OPPORTUNITY**



#### Narmafotinib + SOC\* therapy in resistant ovarian cancer

#### Strong FAK involvement in ovarian cancer

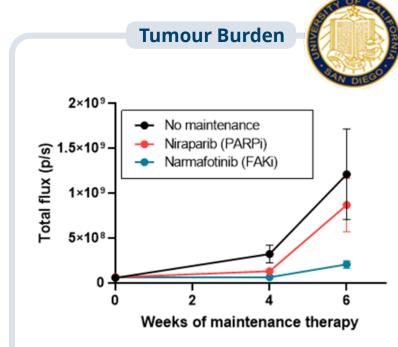
- FAK is overexpressed in ovarian cancer
- FAK levels increase post-chemotherapy
- FAK activity drives tumour growth and resistance to therapies

#### Promising preclinical data with narmafotinib

Demonstrated activity against ovarian cancer cells in vitro and in vivo

# Significant interest from clinicians in Australia and US in our program

Positive clinical data from ovarian cancer studies by competitors
 Verastem (in LGSOC<sup>‡</sup>) and Inxmed (in HGSOC<sup>†</sup>) further justify clinical work in this space



Mice bearing mouse ovarian cancer cells show minimal tumour growth (measured as flux) when treated with narmafotinib while standard-of-care drug niraparib is largely ineffective.

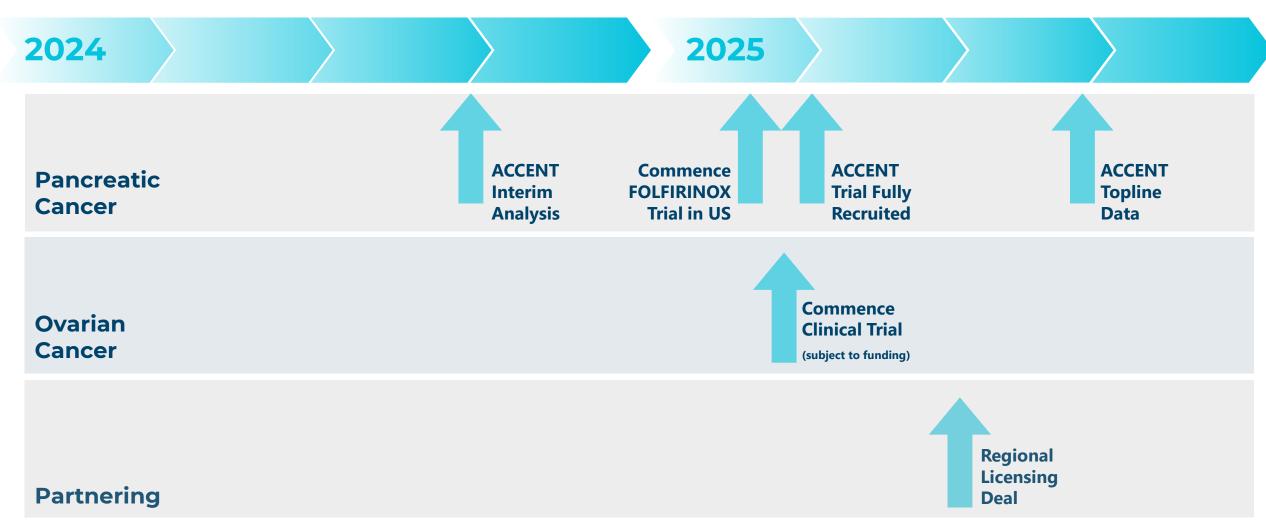
<sup>\*</sup> Standard of care

<sup>‡</sup> Low Grade Serous Ovarian Cancer

<sup>†</sup> High Grade Serous Ovarian Cancer

#### **FUTURE MILESTONES**





#### **OPPORTUNITY SUMMARY**





# 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 in other solid tumors

Bile duct, oesophageal, head and neck cancer

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

Other fibrotic cancers (e.g. liver cancer)



# Capital Raising Overview

#### **CAPITAL RAISING OVERVIEW**

**Managers** 



#### Amplia is undertaking a capital raising (the "Offer") of up to approximately A\$13.0m comprising: - a 1 for 6.45 pro-rata accelerated non-renounceable entitlement offer to eligible Amplia shareholders to raise up to approximately A\$4.9 million ("Entitlement Offer"); **Offer Structure** - an institutional placement ("Placement") to raise up to approximately A\$7.8m million utilising Amplia's existing placement capacity under Listing Rules 7.1 and 7.1A; and - a placement to Amplia's Directors to raise a total of \$0.32 million, subject to shareholder approval. • Up to approximately 113.2 million new fully paid ordinary shares in Amplia ("New Shares") to be issued under the Offer, representing approximately 41.2% of Amplia's current shares on issue. • New Shares issued under the Offer will be issued at a price of A\$0.115 (11.5 cents) per New Share ("Offer Price"), representing a: - 14.8% discount to the last close price on 29 October 2024 of \$0.135; **Offer Price** - 18.6% discount to 5 trading day VWAP on 29 October 2024 of \$0.141; and - 22.3% discount to 10 trading day VWAP on 29 October 2024 of \$0.148. **Institutional** • The institutional component of the Entitlement Offer ("Institutional Entitlement Offer") and the Placement will be conducted by way of a bookbuild process on Wednesday, 30 October 2024. Offer Entitlements under the Institutional Entitlement Offer that are not taken up and entitlements of ineligible institutional shareholders will also be offered in the bookbuild process. • The retail component of the Entitlement Offer ("Retail Entitlement Offer") is expected to open on Wednesday, 6 November 2024 and close at 5.00pm on Friday, 22 November 2024. **Retail Offer** Eligible existing retail shareholders in Australia and New Zealand will have the opportunity to apply for additional New Shares under a 'Top up Facility'. • New Shares will be offered under the Placement, Director Placement and Entitlement Offer with three (3) free attaching options for every four (4) New Shares issued ("Attaching Options"). • The Attaching Options will have an exercise price of \$0.1725 and will expire on 31 October 2027. **Attaching Options** Amplia will apply for quotation of the Attaching Options on the ASX. Quotation of the Attaching Options is subject to the Company satisfying ASX's quotation requirements. • The offer of Attaching Options to Placement participants is conditional on Amplia shareholder approval at a General Meeting to be held on or around Monday, 9 December 2024. • Amplia's directors have committed to subscribe for \$325,000 worth of New Shares pursuant to the Director Placement, as follows (subject to shareholder approval): - Dr Warwick Tong- \$80,000 worth of New Shares (being 695,6215 New Shares and 521,739 Attaching Options); Director - Ms Jane Bell - \$80,000 worth of New Shares (being 695,6215 New Shares and 521,739 Attaching Options); **Placement** Dr Robert Peach - \$125,000 worth of New Shares (being 1,086,957 New Shares and 815,218 Attaching Options); and - Dr Chris Burns - \$40,000 worth of New Shares (being 347,826 New Shares and 260,869 Attaching Options). **Record Date** The record date for the Entitlement Offer is 7.00pm (Sydney, Australia time) on Friday, 1 November 2024. **Prospectus** • The Entitlement Offer and the offer of Attaching Options to Placement participants will be undertaken pursuant to a transaction-specific prospectus dated Wednesday, 30 October 2024. All New Shares issued under the Offer will rank equally with existing Amplia shares from the date of issue (save that the New Shares offered under the Offer will be issued with Attaching **Ranking** Options). **Joint Lead** Bell Potter Securities Limited ("Bell Potter") and Taylor Collison Limited ("Taylor Collison") are acting as Joint Lead Managers and Bookrunners to the Offer. The Offer is not underwritten.

#### **SOURCES AND USE OF FUNDS**



SOURCES OF FUNDS	AMOUNT (A\$M)		
Cash Balance <sup>1</sup>	\$4.6		
Anticipated R&D Rebate <sup>2</sup>	\$4.0		
Capital Raising Proceeds <sup>3</sup>	\$13.0		
Total Sources	\$21.6		

PURPOSE	AMOUNT (A\$M)
ACCENT • Trial Costs	\$5.9
FOLFIRINOX	\$6.3
CMC (Follow-on studies)	\$1.9
Operations, Pre-clinical, Working Capital	\$6.7
Offer Costs	\$0.8
Total Uses	\$21.6

<sup>1</sup> Cash balance as at 30 Sep 2024. 2 Subject to approval – see 'R&D Tax Rebate' in the Key Risks section below. 3 Assumes that the Offer is fully subscribed (before Offer costs) – see 'Risks associated with the Offer' in the Key Risks section below.

#### **OFFER TIMETABLE**

Allotment of Attaching Options to Placement participants (subject to Shareholder approval)

Commencement of trading of Attaching Options (subject to satisfaction of quotation conditions)

The timetable is indicative only and dates and times are subject to change without notice.
Trading halt and announcement of Offer Prospectus lodged with ASIC and released to ASX
Placement & Institutional Entitlement Offer opens
Placement & Institutional Entitlement Offer closes
Announcement of results of Placement and Institutional Entitlement Offer and trading halt lifted
Record date for Entitlement Offer (7.00pm Sydney time)
Settlement of New Shares issued under the Placement and Institutional Entitlement Offer
Entitlement and acceptance forms made available to Eligible Shareholders and Retail Entitlement Offer opens
Issue of New Shares under the Placement and Institutional Entitlement Offer and Attaching Options under the Entitlement Offer
Retail Entitlement Offer closes (5.00pm Sydney time)
Announcement of results of Retail Entitlement Offer
Settlement of Retail Entitlement Offer
Issue of New Shares and Attaching Options under the Retail Entitlement Offer
Commencement of trading of New Shares issued under the Retail Entitlement Offer
EGM to approve issue of Attaching Options to Placement participants



Wednesday, 30 October 2024

Wednesday, 30 October 2024

Thursday, 31 October 2024

Friday, 1 November 2024

Friday, 1 November 2024

Wednesday, 6 November 2024

Wednesday, 6 November 2024

Thursday, 7 November 2024

Friday, 22 November 2024

Wednesday, 27 November 2024

Thursday, 28 November 2024

Friday, 29 November 2024

Monday, 2 December 2024

On or around Monday, 9 December 2024

On or around Tuesday, 10 December 2024

On or around Thursday, 12 December 2024



# Appendix

#### **ACCENT PHASE 1b TRIAL**



#### Key trial read-outs following industry standard criteria

- Primary endpoint Safety and Tolerability
- Secondary endpoint PK and preliminary efficacy

#### Objective Response Rate categorised as:

- Complete Response (CR) Disappearance of all tumour lesions; no new lesions
- Partial Response (PR) >30% decrease in tumour lesions; no new lesions
- **Stable Disease (SD)** Tumour lesions have reduced in size by less than 30% or have shown either no growth or minimal growth (<20%)
- **Progressive Disease (PD)** At least a 20% increase in tumour lesions; or new lesions

#### **ACCENT PHASE 1b DATA**



Narmafotinib in combination with standard of care gemcitabine and Abraxane®

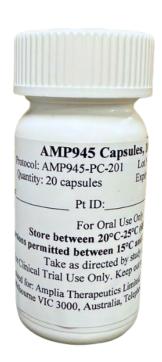
Orally-dosed narmafotinib in the days preceding weekly chemotherapy

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\*: nausea > 72h
- Fatigue (Grade 3 or below) in more than 1 patient likely drug related



## **ACCENT PHASE 1b DATA**



#### **Preliminary signs of efficacy observed**

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

Average treatment time at top dose ~2x longer

# Best Response (all patients)

Classification	ACCENT Best 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%

<sup>\*</sup> Investigator reviewed

<sup>\*\*</sup> Confirmed data from MPACT trial (independent review); *NEJM* 2013: 369; 1691-1703 NB. Phase 1b trial not powered for efficacy

## **ACCENT PHASE 1b DATA**



#### **Preliminary signs of efficacy observed**

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

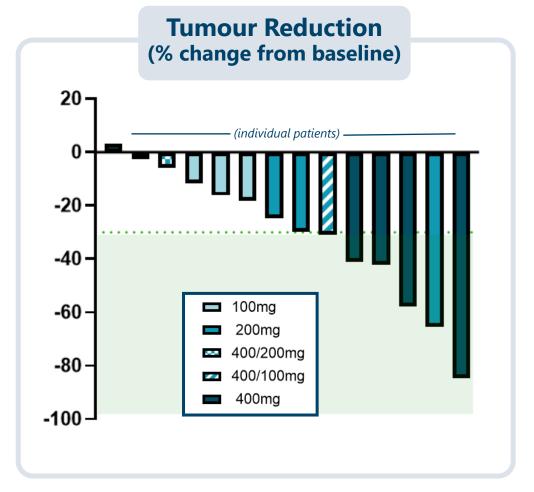
Comparison to pivotal trial (2013)\*\*

# Better objective response (tumour reduction) at higher doses

4 of 6 PRs with top dose narmafotinib

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## **ACCENT PHASE 1b DATA**



#### **Preliminary signs of efficacy observed**

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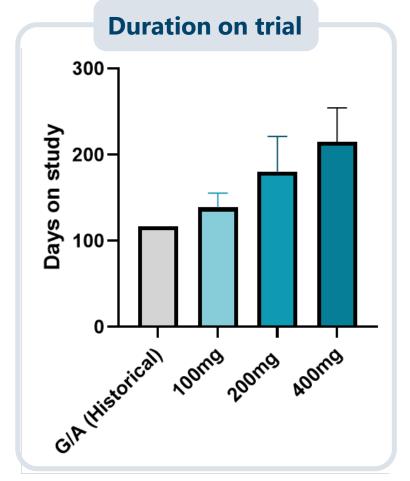
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4 of 6 PRs with top dose narmafotinib

# Duration on trial significantly improved vs gemcitabine/Abraxane alone

Average treatment time at top dose ~2x longer



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<sup>\*\*</sup> Independent review as part of MPACT trial (NEJM 2013: 369; 1691-1703)

NB. Phase 1b trial not powered for efficacy



# **Key Risks**

# **KEY RISKS**



RISK	DESCRIPTION
Risks associated with the Offer	The Offer is not underwritten. Accordingly, the amount that will be raised under the Offer is uncertain and as such could be insufficient to meet all of the objectives outlined in the "Sources and Uses of Funds" slide above. If the Offer raises less than the targeted amount, the Company may need to raise additional capital to fund the objectives specified in the "Uses of Funds" outlined in this presentation. See also the "Additional requirements for capital" risk below.
	The Offer includes New Shares being offered under the Placement with three (3) free attaching option for every four (4) New Shares issued ("Attaching Options"). The issue of Attaching Options to Placement participants is conditional on the approval of Amplia shareholders for the purposes of Listing Rule 7.1 at a general meeting to be held in early December 2024.
	Amplia has applied or will apply for quotation of the Attaching Options within seven days of the Prospectus being lodged with ASIC. ASX requires certain conditions to be met for quotation of the Attaching Options as a new class on ASX, including 'minimum spread' requirements. There is a risk that the ASX's quotation requirements are not met in respect of the Attaching Options, in which case the offer of Attaching Options may have to be voided in accordance with the Corporations Act. This may also have implications on any outstanding offer of New Shares under the Prospectus.
	If Amplia's application for the Attaching Options to be quoted on ASX is granted, the trading price of the Attaching Options may be affected by the ongoing performance and financial position of Amplia. The liquidity of trading of in the Attaching Options may be limited at times and may affect an eligible participant's ability to buy or sell Attaching Options. In addition, Amplia's share price may not exceed the exercise price of the Attaching Options during the exercise period. In such circumstances, the Attaching Options would lapse without any value being realised.
	Investors who do not participate in the Offer, or do not take up all of their entitlement under the Entitlement Offer, will have their percentage shareholding in Amplia diluted (in addition to the dilution arising from the Placement). In addition, the exercise of Attaching Options, and/or the future issue of equity capital, may result in dilution in the future.
Clinical development risk	The nature of clinical drug development has inherent risks, with many drug candidates entering clinical trial failing to be successfully developed into marketable products. The Company is currently undertaking a clinical trial with its lead drug narmafotinib in advanced pancreatic cancer patients. Clinical trials have many associated risks which may impact commercial potential and therefore future profitability. Such trials may fail to recruit patients at a sufficient rate, and a slower than expected recruitment will mean slower than expected data points so a longer period incurring overheads and personnel costs. Clinical trialling may reveal drug candidates to be unsafe or poorly tolerated in the patient population being tested. The drugs may also be shown to be only modestly effective, thereby limiting commercial potential, or ineffective. Any of these outcomes will likely have a significant adverse effect on the Company, the value of its securities and the future commercial development of its drug candidates, including narmafotinib. Clinical trials might also potentially expose the Company to product liability claims in the event its products in development have unexpected effects on clinical subjects.
Regulatory approvals necessary for clinical trials	The Company may be unable to secure and maintain necessary approvals from regulatory agencies and institutional bodies (clinics and hospitals) to conduct its clinical trials. Using funds raised in the Offer, the Company plans to initiate a Phase 2 clinical trial (as an Investigator Initiated Trial) in advanced ovarian cancer patients. There is no assurance that regulatory bodies and local ethics committees will approve the Company's plans to recruit these patients.

# **KEY RISKS**



RISK	DESCRIPTION
Regulatory and reimbursement approvals	The research, development, manufacture, marketing and sale of products developed by the Company are subject to varying degrees of regulation by a number of government authorities in Australia and overseas. Pharmaceutical products under development, such as drug candidate narmafotinib, must undergo a comprehensive and highly regulated development and review process before receiving approval for marketing. The process includes the provision of clinical data relating to the quality, safety and efficacy of the products for their proposed use. There is no guarantee that such regulatory approvals will be granted. Products may also be submitted for cost reimbursement approval. The availability and timing of that reimbursement approval may have an impact upon the uptake and profitability of products in some jurisdictions. There is no guarantee that such approvals will be granted.
Chemistry, manufacturing and controls	The ACCENT clinical trial currently underway requires supply of narmafotinib drug product (capsules). There are risks to production of drug substance in a timely manner should supply chains be affected. There are also risks associated with shipment, storage and handling of drug product that may render the material unavailable or inappropriate for clinical usage. For clinical trial sites in South Korea, supplies of the chemotherapies gemcitabine and Abraxane are also required. There are risks in the supply, shipment, storage and handling of drug product that may delay delivery or render the material unavailable or inappropriate for clinical usage.
Commercialisation of products and potential market failure	The Company has not yet commercialised any products and as yet has no revenues. The Company is also dependent on commercially attractive markets remaining available to it during the commercialisation phase and there is a risk that, once developed and ready for sale, commercial sales may not be achieved.  Furthermore, any products developed by the Company may prove to be uneconomical to market or compete with alternative products marketed by third parties, or not be as attractive or efficacious as alternative treatments.
Competition and regulation	The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant change. A number of companies, both in Australia and abroad, may be pursuing the development of products that target the same markets and/or diseases that the Company is targeting. The Company's products may compete with existing products that are already available to customers. The Company may face competition from parties who have substantially greater resources than the Company. Competing products may be superior to the Company's products, which would adversely impact the commercial viability of the Company's products.
Dependence upon key personnel	The Company's ability to attract and retain personnel will have a direct impact on its ability to deliver its project commitments. The Company depends on the talent and experience of its personnel as an important asset. There may be a negative impact on the Company if any of its key personnel leave. It may be difficult to replace them, or to do so in a timely manner or at comparable expense. Additionally, any key personnel of the Company who leave to work for a competitor may adversely impact the Company.  Additionally, increases in recruitment fees, wages and contractor costs may adversely impact upon the financial performance of the Company.

# **KEY RISKS**



RISK	DESCRIPTION
Research & Development (R&D) Tax Rebate	The Company is currently entitled to receive an R&D rebate on part of its expenditure in research and development. There is a risk that the Australian Government may make material changes to the rebate scheme, which may adversely impact the funding available to the Company to fund its operations. In order to obtain an R&D rebate on that part of its expenditure that is incurred out of Australia the Company must first gain approval for that expenditure from the Australian Government. Such an approval is called an Advanced Finding. The Company has received Advanced Findings for R&D work which is planned for its lead assets narmafotinib and AMP886.
Growth	There is a risk that the Company may be unable to manage its future growth successfully. The ability to hire and retain skilled personnel as outlined above may be a significant obstacle to growth.
Commercial partners	The Company's growth strategy may be impacted if it is unable to find suitable commercialisation partners. The Company's due diligence processes may not be successful and a commercial partnership may not perform to the level expected.
Intellectual property	The Company's ability to commercialise any product depends upon its ability to protect its intellectual property and any improvements to it. The intellectual property may not be capable of being legally protected, it may be the subject of unauthorised disclosure or be unlawfully infringed, or the Company may incur substantial costs in asserting or defending its intellectual property rights.
Revenues and profitability	The Company does not currently generate revenue from product sales nor are revenues anticipated in the short to medium term. The Company's ability to achieve both revenues and profitability is dependent on a number of factors, including its ability to complete successful clinical trials, obtain regulatory approval for its products and successfully commercialise those products. There is no guarantee that the Company's products (including the drug narmafotinib) will be commercially successful.

## **GENERAL RISKS**



RISK	DESCRIPTION
Economic	General economic conditions, movements in financial markets, interest and inflation rates and currency exchange rates may have an adverse effect on the Company's business and production activities, as well as on its ability to fund those activities.
Market conditions	Share market conditions may affect the value of the Company's quoted shares (and options to acquire quoted shares) regardless of the Company's operating performance. Share market conditions are affected by many factors such as:  a) general economic outlook;  b) introduction of tax reform or other new legislation;  c) interest rates and inflation rates;  d) changes in investor sentiment toward particular market sectors;  e) the demand for, and supply of, capital; and  f) terrorism or other hostilities.  The market price of securities can fall as well as rise and may be subject to varied and unpredictable influences on the market for equities in general and pharmaceutical stocks in particular. Neither the Company nor the Directors warrant the future performance of the Company or any return on an investment in the Company.
Litigation	There is a risk that the Company may in future be the subject of or required to commence litigation. There is, however, no litigation, mediation, conciliation or administrative proceeding taking place, pending or threatened against the Company.
Tax risks	Changes to the rate of taxes imposed on the Company (including in overseas jurisdictions in which the Company operates now or in the future) or tax legislation generally may affect the Company and its shareholders. In addition, an interpretation of Australian tax laws by the Australian Taxation Office that differs to the Company's interpretation may lead to an increase in the Company's tax liabilities and a reduction in shareholder returns. Personal tax liabilities are the responsibility of each individual investor. The Company is not responsible either for tax or tax penalties incurred by investors.
Additional requirements for capital	The Company's capital requirements depend on numerous factors. The Company may require further financing in addition to amounts raised under the capital raising. Any additional equity financing will dilute shareholdings, and debt financing, if available, may involve restrictions on financing and operating activities. If the Company is unable to obtain additional financing as needed, it may be required to reduce the scope of its operations, its production levels, or scale back its research and development and/or clinical trials as the case may be. There is no guarantee that the Company will be able to secure any additional funding or be able to secure funding on terms favourable to the Company.



# International Selling Restrictions

## INTERNATIONAL SELLING RESTRICTIONS



This document does not constitute an offer of New Shares and Attaching Options in any jurisdiction in which it would be unlawful. In particular, this document may not be distributed to any person, and the New Shares and Attaching Options may not be offered or sold, in any country outside Australia except to the extent permitted below.

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WARNING: This document has not been, and will not be, registered as a prospectus under the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong, nor has it been authorised by the Securities and Futures Commission in Hong Kong pursuant to the Securities and Futures Ordinance (Cap. 571) of the Laws of Hong Kong (the "SFO"). Accordingly, this document may not be distributed, and the New Shares and Attaching Options may not be offered or sold, in Hong Kong other than to "professional investors" (as defined in the SFO and any rules made under that ordinance).

No advertisement, invitation or document relating to the New Shares and Attaching Options has been or will be issued, or has been or will be in the possession of any person for the purpose of issue, in Hong Kong or elsewhere that is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to New Shares and Attaching Options that are or are intended to be disposed of only to persons outside Hong Kong or only to professional investors. No person allotted New Shares and Attaching Options may sell, or offer to sell, such securities in circumstances that amount to an offer to the public in Hong Kong within six months following the date of issue of such securities.

The contents of this document have not been reviewed by any Hong Kong regulatory authority. You are advised to exercise caution in relation to the offer. If you are in doubt about any contents of this document, you should obtain independent professional advice.

#### **New Zealand**

This document has not been registered, filed with or approved by any New Zealand regulatory authority under the Financial Markets Conduct Act 2013 (the "FMC Act").

The New Shares and Attaching Options are not being offered to the public within New Zealand other than to existing shareholders of the Company with registered addresses in New Zealand to whom the offer of these securities is being made in reliance on the Financial Markets Conduct (Incidental Offers) Exemption Notice 2021.

Other than in the entitlement offer, the New Shares and Attaching Options may only be offered or sold in New Zealand (or allotted with a view to being offered for sale in New Zealand) to a person who:

- is an investment business within the meaning of clause 37 of Schedule 1 of the FMC Act;
- meets the investment activity criteria specified in clause 38 of Schedule 1 of the FMC Act;
- is large within the meaning of clause 39 of Schedule 1 of the FMC Act;
- is a government agency within the meaning of clause 40 of Schedule 1 of the FMC Act; or
- is an eligible investor within the meaning of clause 41 of Schedule 1 of the FMC Act.

### INTERNATIONAL SELLING RESTRICTIONS



#### Singapore

This document and any other materials relating to the New Shares and Attaching Options have not been, and will not be, lodged or registered as a prospectus in Singapore with the Monetary Authority of Singapore. Accordingly, this document and any other document or materials in connection with the offer or sale, or invitation for subscription or purchase, of New Shares and Attaching Options, may not be issued, circulated or distributed, nor may the New Shares and Attaching Options be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore except pursuant to and in accordance with exemptions in Subdivision (4) Division 1, Part 13 of the Securities and Futures Act 2001 of Singapore (the "SFA") or another exemption under the SFA.

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#### **United Kingdom**

Neither this document nor any other document relating to the offer has been delivered for approval to the Financial Conduct Authority in the United Kingdom and no prospectus (within the meaning of section 85 of the Financial Services and Markets Act 2000, as amended ("FSMA")) has been published or is intended to be published in respect of the New Shares and Attaching Options.

The New Shares and Attaching Options may not be offered or sold in the United Kingdom by means of this document or any other document, except in circumstances that do not require the publication of a prospectus under section 86(1) of the FSMA. This document is issued on a confidential basis in the United Kingdom to "qualified investors" within the meaning of Article 2(e) of the UK Prospectus Regulation. This document may not be distributed or reproduced, in whole or in part, nor may its contents be disclosed by recipients, to any other person in the United Kingdom.

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This document does not constitute an offer to sell, or a solicitation of an offer to buy, securities in the United States. The New Shares and Attaching Options, and the underlying ordinary shares, have not been, and will not be, registered under the US Securities Act of 1933 or the securities laws of any state or other jurisdiction of the United States. Accordingly, the New Shares and Attaching Options may not be offered or sold in the United States except in transactions exempt from, or not subject to, the registration requirements of the US Securities Act and applicable US state securities laws.



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