

ASX RELEASE

13 November 2019

KAZIA ANNUAL GENERAL MEETING MATERIALS

Sydney, 13 November 2019 – Kazia Therapeutics Limited (ASX: KZA; NASDAQ: KZIA), an Australian oncology-focused biotechnology company, is pleased to provide the Chairman’s Address and CEO presentation which will be discussed at our Annual General Meeting at 10am this morning.

[ENDS]

About Kazia Therapeutics Limited

Kazia Therapeutics Limited (ASX: KZA, NASDAQ: KZIA) is an innovative oncology-focused biotechnology company, based in Sydney, Australia. Our pipeline includes two clinical-stage drug development candidates, and we are working to develop therapies across a range of oncology indications.

Our lead program is GDC-0084, a small molecule inhibitor of the PI3K / AKT / mTOR pathway, which is being developed to treat glioblastoma multiforme, the most common and most aggressive form of primary brain cancer in adults. Licensed from Genentech in late 2016, GDC-0084 entered a phase II clinical trial in 2018. Initial safety data was released in May 2019, and further data is expected in 2H 2019. GDC-0084 was granted orphan designation for glioblastoma by the US FDA in February 2018.

TRX-E-002-1 (Cantrixil), is a third-generation benzopyran molecule with activity against cancer stem cells and is being developed to treat ovarian cancer. TRX-E-002-1 is currently undergoing a phase I clinical trial in Australia and the United States. Interim data was presented at the ESMO Congress in September 2019, and the study remains ongoing. Cantrixil was granted orphan designation for ovarian cancer by the US FDA in April 2015.

Board of Directors

Mr Iain Ross Chairman, Non-Executive Director

Mr Bryce Carmine Non-Executive Director

Mr Steven Coffey Non-Executive Director

Dr James Garner Chief Executive Officer, Managing Director

**KAZIA ANNUAL GENERAL MEETING
13 NOVEMBER 2019**

CHAIRMAN'S ADDRESS

Ladies and Gentlemen,

It is my pleasure once again to welcome you to the Annual General Meeting for Kazia Therapeutics Limited. This is my third AGM as Chairman of Kazia, and I can say with confidence that 2019 has been one of the most exciting years in our company's short history.

The reason for that excitement is, in a word, data. The lifeblood of any drug development company is the data that it is able to generate from its clinical trials. That data represents economic value for shareholders and it represents hope for patients. There is no real room for gloss or hype or spin – objective data provides the hard facts on which professional investors and potential partners will ultimately judge us.

We have had three important data read-outs this year. Perhaps the most important one, however, is coming in just over a week from today.

In May, we announced that GDC-0084 had achieved a higher maximum tolerated dose – MTD – in newly-diagnosed patients than in the original Genentech phase I study. This is a very encouraging indication that the drug is well tolerated in the precise patient group that we are targeting for commercialisation. Our ability to administer a higher dose can only bode well for our prospects of demonstrating clinical benefit.

In September, our colleagues at St Jude Children's Research Hospital achieved a comparable MTD in childhood brain cancer. It is very positive to know that the drug is also tolerable in children, and the St Jude team are currently recruiting additional patients to look for potential efficacy signals. I would remind everyone that there are no approved drug treatments for this form of brain cancer, and the average survival from diagnosis is approximately nine months. It would be remarkable if we are able to offer benefit to patients and their families.

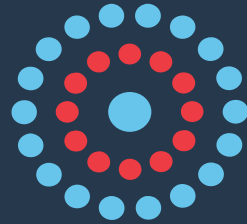
Also in September, we presented interim data from our ongoing Cantrixil study in ovarian cancer at the prestigious ESMO conference. The data suggested a potential increase in progression-free survival for patients treated with Cantrixil. Given that these are very late stage patients who are very resistant to treatment, this is a tremendous result. I had the pleasure of meeting with our lead investigator yesterday, and his excitement at the emerging data was quite palpable.

In short, we find ourselves in a very strong position. However, we have perhaps saved the best for last. Next week, we will present the first preliminary efficacy data from the ongoing GDC-0084 phase II study in glioblastoma. The study is still ongoing, and so this will only be an early glimpse, but I know that a wide range of stakeholders will be watching with great interest. The median progression-free survival for the patients we are targeting is only around five months, so any preliminary indication that we are able to prolong this duration is likely to be of very high impact.

To see these projects through to their completion, your Board chose to capitalise on growing investor interest and conduct a modest share placement to strengthen the company's balance sheet. As always, our overriding concern has been to ensure that we are able to deliver value from our pipeline while safeguarding the interests of existing investors. We have once again raised only what is needed to drive the next round of data generation. Despite a very challenging environment, our placement was conducted without the need for options or warrants, and has brought additional high-quality institutional investors on to the registry. I am pleased to take this opportunity to welcome them to Kazia.

Looking ahead, we aspire to take GDC-0084 into a pivotal study next year, and we will be examining every option to determine the best way to deliver a high-quality program within our means. Kazia has demonstrated an incredibly innovative approach to partnering for clinical development, and we hope that these capabilities will allow us to bring something novel, efficient, and world-class to the next chapter of GDC-0084's development. I look forward to sharing more with you in due course.

In the meantime, I must thank you again, on behalf of my fellow directors, for your ongoing support of the company. I recommend today's resolutions to you, and invite you to continue shaping the future success of Kazia.



KAZIA
THERAPEUTICS



Presentation to Annual General Meeting of Shareholders

Dr James Garner
Chief Executive Officer

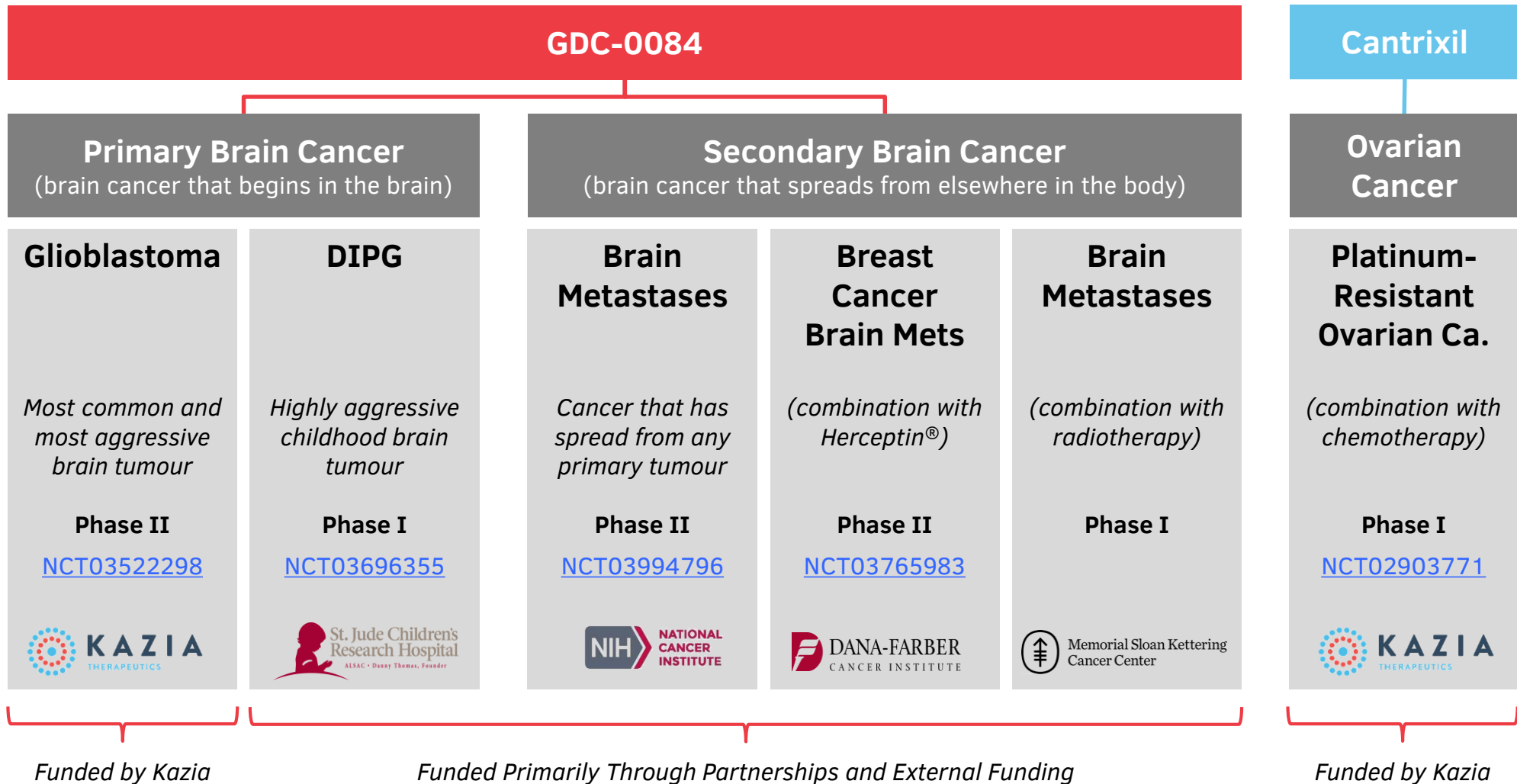
Sydney, NSW
13 November 2019

Agenda

2019 in Review

Looking Forward

Six ongoing clinical trials across two assets, lead program covers full range of brain cancers



Kazia's phase 2 study in newly-diagnosed GBM is ongoing, with new data coming in November 2019

Step 1: Dose Optimisation

6 – 24 patients
12 months

Primary objective is to determine the appropriate dose for newly-diagnosed patients (phase 1 was in end-stage patients)

Complete



- Top-line data reported May 2019
- Dose of 60mg determined (higher than 45mg dose found in phase I)

Step 2: Expansion Cohort

20 patients
6 months

Primary objective is to generate supportive data for FDA and to provide confirmatory signals of efficacy in newly-diagnosed population

Ongoing

- Data unlikely to be rate-limiting for pivotal study

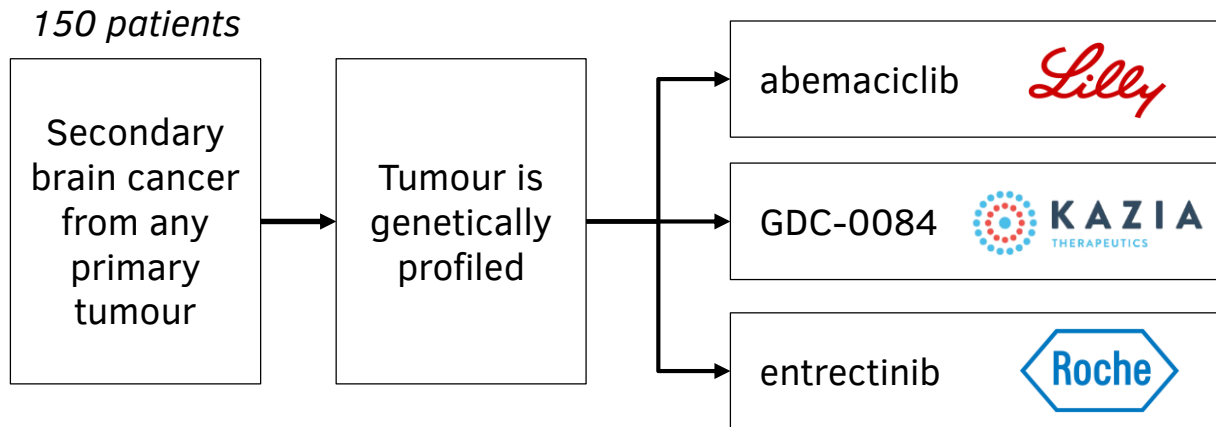
- Newly-diagnosed patients with the unmethylated MGMT promotor (i.e. resistant to temozolomide)
- GDC-0084 administered once daily, orally, as monotherapy in place of temozolomide
- Primary objective is dose determination (Step 1) and time to progression (Step 2)



Note: timelines are estimated and subject to periodic revision based on recruitment performance and treatment effect



The Alliance study in brain metastases is a cutting-edge, multi-drug clinical trial



- 'Precision medicine' study in which treatment is guided by the specific genetic make-up of each individual patient's tumour
- Accepts patients with brain metastases from any primary tumour (estimated to be ~200,000 patients per annum in US)

Funded by
US National Cancer Institute



Executed by Alliance for Clinical
Trials in Oncology



Led by Dr Priscilla Brastianos, a
world expert on brain mets



The St Jude study in DIPG has the potential for breakthrough designation and early approval

Step 1: Dose Escalation

6 – 24 patients

Primary objective is to determine the appropriate dose for pediatric use (mg/kg dosing)

Complete

- Top-line data reported Sept. 2019
- Dose of 27 mg/m² determined for paediatric use (comparable to adult doses)

Step 2: Expansion Cohort

12 patients

Primary objective is to provide initial evidence of clinical efficacy

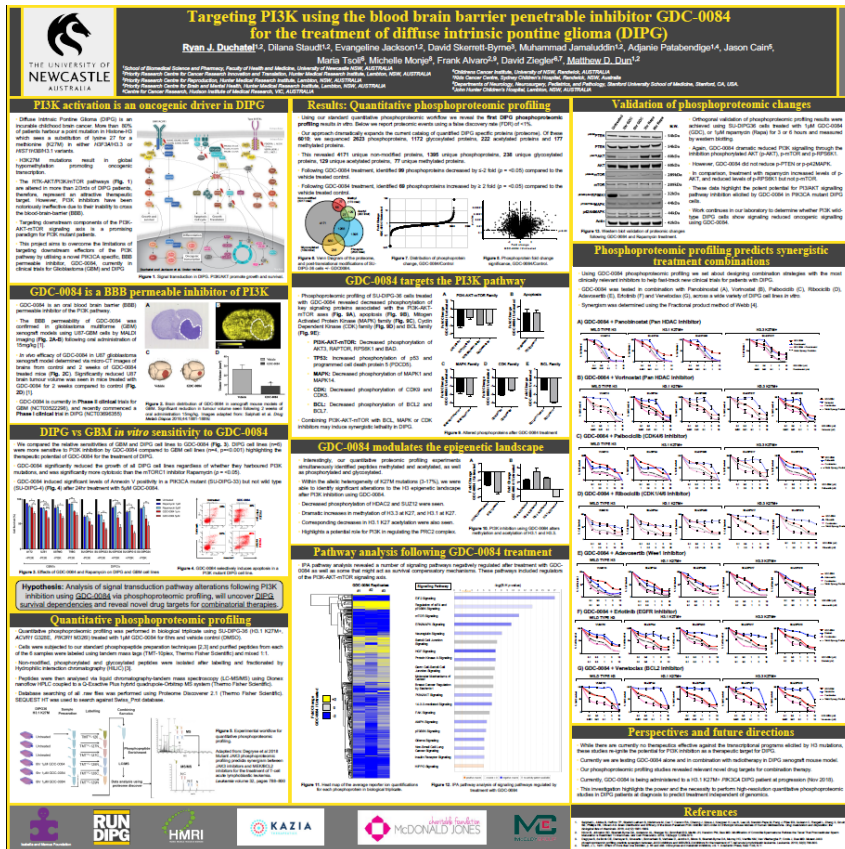
Ongoing

- All patients with DIPG or high-grade gliomas (2 – 22 years of age), following radiotherapy
- GDC-0084 given once daily, orally, as monotherapy
- Primary objective is dose determination (Step 1) and time to progression (Step 2)
- Given no FDA-approved therapies for DIPG, a successful result could lead to discussion of early approval

Important new preclinical data has also been reported during the year

DIPG

Breast Cancer Brain Metastases



References: Duchatel et al. *Neuro-Oncology* (2019). 21(Suppl. 2):ii68; Ippen et al. *Clin Cancer Res.* (2019). 25(11):3374-83

The PI3K class has been further validated by the approval of Novartis' Piqray (alpelisib)



Zydelig (idelalisib)



FDA Approved **July 2014** ✓
(blood cancers)
[accelerated approval]

Does not cross blood-brain barrier ✗

Potentially fatal liver toxicity and diarrhoea ✗



Aliqopa (copanlisib)



FDA Approved **September 2017** ✓
(blood cancers)
[accelerated approval]

Does not cross blood-brain barrier ✗

Potentially fatal infections ✗



Copiktra (duvelisib)



FDA Approved **October 2018** ✓
(blood cancers)
[accelerated approval]

Does not cross blood-brain barrier ✗

Potentially fatal infections & diarrhoea ✗



Piqray (alpelisib)



FDA Approved **May 2019** ✓
(breast cancer)
[accelerated approval]

Does not cross blood-brain barrier ✗

Limited toxicities to date ✓



GDC-0084



In phase II human trials under US FDA oversight (brain cancer)

Does cross blood-brain barrier ✓

Appears generally safe and well-tolerated thus far ✓

Our efforts continue to be recognised in the public sphere



proactive



The Sydney Morning Herald

THE AUSTRALIAN 

STOCKHEAD



YAHOO!
FINANCE

A range of content, from academic papers to media interviews, helps investors grasp our story

ADVERTISING FEATURE

Development in biotechnologies



Shift in focus delivers global success

Australia's \$100 billion biotechnology – or life sciences – sector enjoys an international reputation, making its mark in key segments such as medical technology, ag-tech and foodtech, therapeutics and regenerative medicine.

In 2016, Scientific American Workview ranked Australia No. 5 for biotechnology innovation behind New Zealand, Denmark, Singapore and the United States at No. 1.

According to the industry's peak body, AusBiotech, the ASX-listed Australian life sciences industry employs 40,000 Australians and is expected to reach an aggregate revenue of \$262 billion by 2023. Such figures are a far cry from the uncertainty of Australia's fledgling biotechnology sector at the turn of the century.

An investment sheet from 2001 noted the difficulties facing potential investors in blue-sky biotech stocks with "intellectual property based on unproven science, no current earnings, no products on the market in the immediate future and long-term projections of sales in the regularly mentioned 'billion-dollar' markets".

"The science is still complicated but Australia's biotechnology industry is no longer a novelty investment and biotechs such as Kazia Therapeutics, Sirix Medical, Viralitycs, Mesoblast and Starpharma are leading players on the world life-sciences stage.

Capital markets partner at MinterEllison, James Hutton, says there are "clear opportunities" for Australian biotechnology companies looking to secure overseas investors for funding and collaboration partners for research and commercialisation, particularly in Asia.

Investors and trade players are attracted by the quality of Australia's scientific research and potential clinical outcomes, according to Hutton. As a result, Chinese and other regional players are actively courting Australian biotech companies.

Deals struck in 2018 include the \$187 billion acquisition of liver cancer treatment company Sirix Medical by Chinese private equity house CDH Investments and China Grand Pharmaceutical & Healthcare and the \$29.6 million investment in oncology immunotherapies company Viralitycs by China's Lepu Medical Technology.

Hutton also cites two recent ASX-listed players with late-stage products securing offshore investors: regenerative medicine company Mesoblast, its partnership with China pharmaceutical company Tasy and Japan's JCR Pharmaceuticals and dendrimer product maker Starpharma has just been picked up by diversified Chinese group Shenyang Shy & Land Latex Co and Japan's Daiichi Sankyo.

Deloitte's Global 2019 Life Sciences Outlook notes "accelerating change in life sciences" as biotechs adopt new business models to remain competitive.

"Trends in the life sciences industry typically take place over decades rather than years, but the pace of change now feels like it is moving faster than ever," the report states.

The continuous search for the next generation of market-leading medicines and decreasing returns on R&D make external deals attractive sources of investment for biotechs, either through licensing, M&A and/or joint ventures, according to Deloitte.

Over the next few years, major pharmaceutical companies are expected to shift from

"We focus on the things we do well, which includes working closely with a very rich network of partners and collaborators."
James Garner

managing the approvals and trials stage of drug development – the critical middle part between discovery and commercialisation – which it does under the strict oversight of the US Food and Drug Administration.

"We consider that a more viable business model. We focus on the things we do well, which includes working closely with a very rich network of partners and collaborators," he says.

"We don't aspire to the commercialisation side of the business. The actual implementation, execution and funding of bringing a product to market is what the big pharma do best."

Kazia's pipeline includes its lead GDC-0084 program, which is being developed to treat glioblastoma multiforme, the most common and most aggressive form of primary brain cancer in adults.

Kazia licensed GDC-0084 from US biotechnology company Genentech in 2016 after a successful Phase I trial. The drug entered a phase II clinical trial in 2018. (New drugs must pass through various stages of regulatory approval and three main phases of clinical research before making it to commercialisation.)

In July, Kazia announced that one of the world's leading cancer treatment hospitals, Memorial Sloan Kettering Cancer Centre (MSK) in New York, will investigate the potential use of GDC-0084 in combination with radiotherapy in a clinical trial for cancer that has spread to the brain.

The MSK study will investigate whether GDC-0084 has the potential to enhance the effects of radiotherapy, which remains the current standard of care in most cases.

The two-year study is one of five ongoing clinical studies involving GDC-0084.

Dr James Garner
CEO and Managing Director

Dr James Garner
CEO and Managing Director

Looking back over the past progress has been made here, as we build forward to seeing further ahead and is now closer to the half of next year. New data conference in late September insight into the potential gains these many achieve. Kazia team is final our national seminar and Executive Leadership Forum (EMLF) Jerome Anders, and Austin This award testifies to the AND I am proud to work with

KAZIA THERAPEUTICS



Dr MATT DUN
Cancer Researcher

FOR MORE VIDEOS > sunrise.com.au



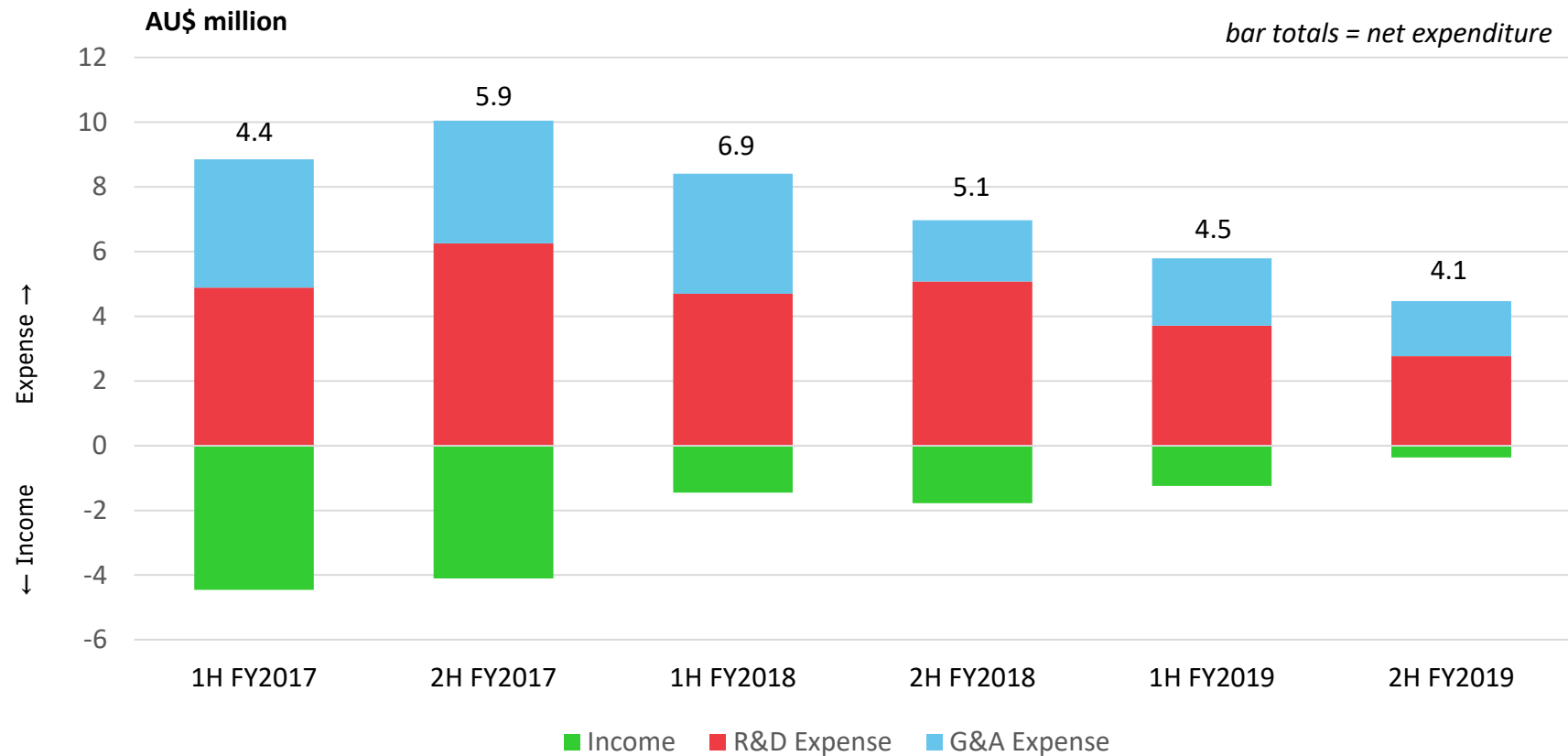
CommSec

The Trans-Tasman Innovation and Growth Award was a powerful recognition of Kazia's achievements



Trans-Tasman
Innovation &
Growth Awards
WINNER 2019

These milestones have been achieved with tight operational management and financial economy



G&A % 44.9% 37.8% 44.1% 27.1% 36.0% 38.0%

Agenda

2019 in Review

Looking Forward

From 2020 onwards, GDC-0084 will be known as 'paxalisib'

Internal compound code

Selected by company once drug begins journey to clinical trials



International Non-proprietary Name (INN)

Awarded by WHO, usually around phase 1 / 2 clinical trials



Commercial Brand Name

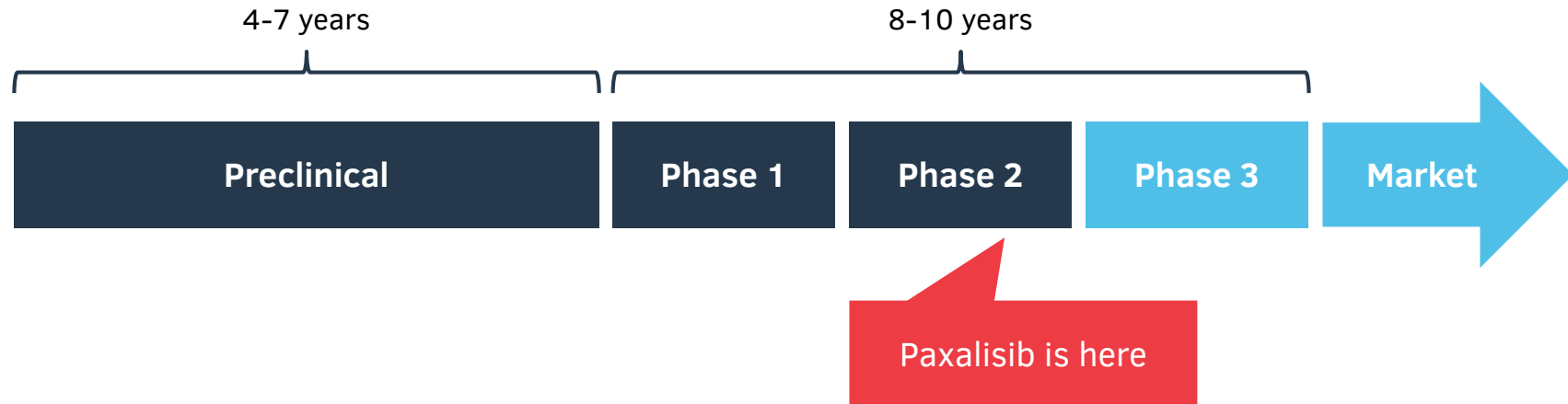
Selected by FDA after recommendation from company at time of marketing application

GDC-0084

paxalisib

The award of an INN is an important milestone in the development of a drug and provides an industry-standard, recognisable name for the drug moving forward

Next step for paxalisib is a pivotal study for registration



- Upcoming SNO data read-out will be a key check-point before committing to phase 3
- Kazia expects to share more detail on phase 3 plans early in CY2020, pending ongoing partnering discussions

In the meantime, important new data will be presented at the upcoming SNO conference



2019 Annual Meeting

Phoenix, AZ, USA
20 – 24 November 2019

1

Phase II Trial in Glioblastoma

poster presentation

Lead Author:
Professor Patrick Wen
Dana-Farber Cancer Institute

*Initial interim efficacy data from
Kazia's ongoing phase 2 study of
paxalisib in glioblastoma*

2

Phase I Trial in Advanced Glioma

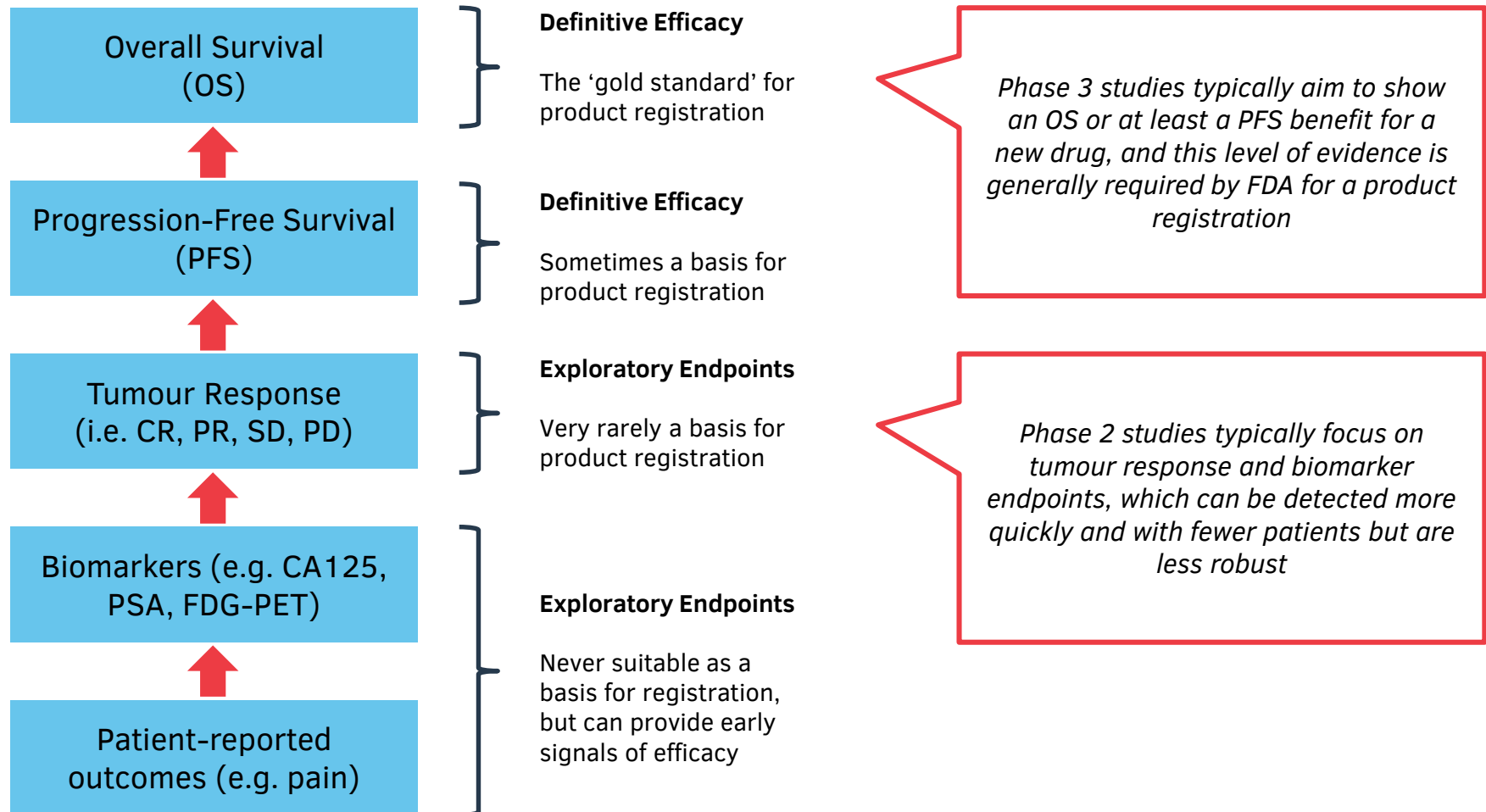
oral presentation

Lead Author:
Professor Ben Ellingson
UCLA Imaging Laboratory

*Cutting edge re-analysis of
imaging data from Genentech's
phase 1 study in 2016*

This data is a critical read-out for the program

Early-stage studies such as the ongoing phase 2 typically provide less mature efficacy endpoints



Paxalisib data will ultimately be compared against several key benchmarks

Genentech Phase I Study

GDC-0084

26%

Of patients with a metabolic partial response on FDG-PET

GDC-0084

40%

Of patients with stable disease (SD) on MRI

Existing Standard of Care

Temozolomide

**From 4.4
to 5.3
months**

Improvement in progression-free survival (PFS)
(unmethylated MGMT)

Temozolomide











**From 11.8
to 12.7
months**

Improvement in overall survival (OS)
(unmethylated MGMT)









Source: PY Wen et al. Poster Presentation at ASCO (2016); ME Hegi et al. (2008) *J Clin Oncol.* 26:4189-4199

The partnering market for new oncology drugs is active and driven by emerging data

Select CY2019 Licensing Transactions

Licensee	Licensor	Stage	Asset(s)	Deal Value (US\$)
 GILEAD	 CARINA BIOSCIENCES	Discovery	Lipid kinase inhibitors	\$470M
 Johnson & Johnson	 Genmab	Preclinical	Anti-CD38 antibody	\$275M
 Jazz Pharmaceuticals	 RedX Pharma	Preclinical	RAS-RAF-MAPK inhibitors	\$207M
 Boehringer Ingelheim	 LUPIN	Clinical	MEK inhibitor	\$700M
 Mallinckrodt Pharmaceuticals	 SILENCE THERAPEUTICS	Discovery	Complement modulator	\$2.0B

Select CY2019 M&A Transactions

Acquirer	Target	Stage	Asset(s)	Deal Value (US\$)
 Pfizer	 ARRAY BIOPHARMA	Commercial	BRAF inhibitors	\$11.0B
 MERCK	 Peloton Therapeutics	Clinical	HIF-2 α inhibitors	\$2.2B
 AMGEN	 NUEVOLUTION	Discovery	Discovery platform	\$167M
 Boehringer Ingelheim	 AMAL THERAPEUTICS	Clinical	Cancer vaccine platform	\$367M

The next six months will be an exciting period for Kazia, and a crucial inflection point for our programs

November 2019	Initial interim data from ongoing phase 2 study of paxalisib in glioblastoma
December 2019	Extraordinary General Meeting (EGM) of shareholders
February 2020	Half-Year Report
1Q CY2020	Completion of patient dosing in Cantrixil phase 1 study
1Q CY2020	Announcement of phase 3 strategy for paxalisib
2Q CY2020	Potential initial efficacy data from St Jude paxalisib DIPG study
2Q CY2020	Potential initial efficacy data from Dana-Farber paxalisib breast cancer mets study
2Q CY2020	Further efficacy data from ongoing phase 2 study of paxalisib in glioblastoma

Note: all milestones are indicative and subject to periodic revision in light of operational factors and emerging data



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