

ASX RELEASE 9 November 2022

#### KAZIA TO PRESENT TO HCW BIOCONNECT INVESTOR CONFERENCE

**Sydney, 9 November 2022** – Kazia Therapeutics Limited (NASDAQ: KZIA; ASX: KZA), an oncology-focused drug development company is pleased to provide the presentation due to be delivered by the CEO, Dr James Garner, to the Bell Potter Healthcare Conference in Sydney, Australia on Wednesday 9 November 2022.

#### About Kazia Therapeutics Limited

Kazia Therapeutics Limited (NASDAQ: KZIA; ASX: KZA) is an oncology-focused drug development company, based in Sydney, Australia.

Our lead program is paxalisib, a brain-penetrant inhibitor of the PI3K / Akt / mTOR pathway, which is being developed to treat multiple forms of brain cancer. Licensed from Genentech in late 2016, paxalisib is or has been the subject of ten clinical trials in this disease. A completed phase II study in glioblastoma reported promising signals of efficacy in 2021, and a pivotal study for registration, GBM AGILE, is ongoing, with final data expected in 2H CY2023. Other clinical trials are ongoing in brain metastases, diffuse midline gliomas, and primary CNS lymphoma, with several of these having reported encouraging interim data.

Paxalisib was granted Orphan Drug Designation for glioblastoma by the US FDA in February 2018, and Fast Track Designation for glioblastoma by the US FDA in August 2020. In addition, paxalisib was granted Rare Pediatric Disease Designation and Orphan Designation by the US FDA for DIPG in August 2020, and for atypical teratoid / rhabdoid tumours (AT/RT) in June 2022 and July 2022, respectively.

Kazia is also developing EVT801, a small-molecule inhibitor of VEGFR3, which was licensed from Evotec SE in April 2021. Preclinical data has shown EVT801 to be active against a broad range of tumour types and has provided compelling evidence of synergy with immuno-oncology agents. A phase I study commenced recruitment in November 2021.

For more information, please visit <u>www.kaziatherapeutics.com</u> or follow us on Twitter @KaziaTx.

This document was authorized for release to the ASX by Dr James Garner, CEO and Managing Director.

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

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Presentation to Bell Potter Healthcare Conference

9 November 2022



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### **Forward-Looking Statements**

This presentation contains **forward-looking statements** within the meaning of the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. Such statements involve substantial risks and uncertainties, not all of which may be known at the time. All statements contained in this presentation, other than statements of historical fact, including statements regarding our strategy, research and development plans, collaborations, future operations, future financial position, future revenues, projected costs, prospects, plans, and objectives of management, are forward-looking statements. Not all forward-looking statements in this presentation are explicitly identified as such.

Many factors could cause the actual results of the Company to differ materially from the results expressed or implied herein, and you should not place undue reliance on the forward-looking statements. Factors which could change the Company's expected outcomes include, without limitation, our ability to: advance the development of our programs, and to do so within any timelines that may be indicated herein; the safety and efficacy of our drug development candidates; our ability to replicate experimental data; the ongoing validity of patents covering our drug development candidates, and our freedom to operate under third party intellectual property; our ability to obtain necessary regulatory approvals; our ability to enter into and maintain partnerships, collaborations, and other business relationships necessary to the progression of our drug development candidates; the timely availability of necessary capital to pursue our business objectives; and our ability to attract and retain qualified personnel; changes from anticipated levels of customer acceptance of existing and new products and services and other factors.

Although the Company believes that the expectations reflected in such forward-looking statements are reasonable, there can therefore be no assurance that such expectations will prove to be correct. The Company has no obligation as a result of this presentation to clinical trial outcomes, sales, partnerships, future international, national or regional economic and competitive conditions, changes in relationships with customers, access to capital, difficulties in developing and marketing new products and services, or marketing existing products.

In addition, the extent to which the COVID-19 outbreak continues to impact our workforce and our discovery research, supply chain and clinical trial operations activities, and the operations of the third parties on which we rely, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration and severity of the outbreak, additional or modified government actions, and the actions that may be required to contain the virus or treat its impact.

Any forward-looking statements contained in this presentation speak only as of the date this presentation is made, and we expressly disclaim any obligation to update any forward-looking statements, whether because of new information, future events or otherwise.



### **Company Overview**

# A late-clinical-stage oncology drug development company





# **Lead Program – Paxalisib** *Strategic focus on brain cancer*

#### **Brain Metastases**

Cancer that has spread to the brain from elsewhere in the body

- 200,000 new cases pa in US
- 3 ongoing trials of paxalisib

#### Glioblastoma

Most common and most aggressive primary brain cancer

- 13,000 new cases pa in US
- 2 ongoing trials of paxalisib

#### **Diffuse Midline Gliomas**

Most lethal cancer of childhood with no FDA-approved drug therapy

- 800 new cases pa in US
- 2 ongoing trials of paxalisib

#### **Primary CNS Lymphoma**

Non-Hodgkin's Lymphoma that occurs in the brain

- 2,000 new cases pa in US
- 1 ongoing trial of paxalisib

#### Low-Grade Glioma

Less aggressive form of brain cancer, mainly in younger adults

- 3,000 new cases pa in US
- Area of research interest

#### Melanoma

Most lethal form of skin cancer

- 100,000 new cases pa in US
- Ongoing research with paxalisib

#### **Breast Cancer**

Most common cancer of female patients

- 290,000 new cases pa in US
- Area of research interest

#### AT/RT

Rare form of childhood brain cancer with no FDA-approved drug therapy

- 200 new cases pa in US
- Ongoing research with paxalisib



# **Paxalisib History** *Asset licensed from Genentech in 2016*





## **Competitive Landscape**

Brain cancer is very poorly served by existing therapies





## **Paxalisib Mechanism of Action**

Only brain-penetrant drug in well-proven PI3K inhibitor class





## **Paxalisib – Potential Paths to Registration** *Multiple opportunities to become a marketed product*





## **Paxalisib in Diffuse Midline Gliomas**

Case studies from compassionate use suggest activity

### Patient 1

- Commenced ON201 + paxalisib immediately following re-irradiation
- At 5 months, MRI showed continued regression of primary tumour and clinical improvement
- Patient succumbed unexpectedly of pneumonia, with autopsy showing no evidence of new tumour growth or tumour-related mortality



### Patient 2

- Commenced ONC201 + paxalisib following radiotherapy after diagnosis
- Tumour size has decreased by 80% (versus diagnosis) or 68% (versus post-RT)
- Patient has returned to school with marked reduction of DIPG-associated symptoms, and dramatic and continued tumour regression





### **Paxalisib in Glioblastoma**

Phase II study suggests efficacy superior to existing treatment



Note: figures for existing therapy are for temozolomide, per Hegi et al. (2005); comparison between different studies is never perfectly like-for-like



# Paxalisib in Glioblastoma

### Safety profile is favorable for a drug in advanced cancer

Term	Gr 1	Gr 2	Gr 3	Gr 4	Total (%)
Fatigue	3	13	2		18 (60%)
Stomatitis	4	7	3		14 (47%)
Decreased appetite	6	6	1		13 (43%)
Hyperglycemia	3	1	6	2	12 (40%)
Nausea	4	6	1		11 (37%)
Rash, maculo-popular	1	1	7		9 (30%)
Diarrhea	7	1			8 (27%)
Vomiting	4	2	1		7 (23%)
Rash	2	4	1		7 (23%)
Neutrophils decreased	3	3		1	7 (23%)
Platelets decreased	6	1			7 (23%)
Weight decreased	5	2			7 (23%)
Lymphocytes decreased	2	3			5 (17%)
Dehydration		4	1		5 (17%)
Dysgeusia		4			4 (13%)
Cholesterol increased	4				4 (13%)
ALT increased	1		2		3 (10%)
Triglycerides increased	1	2			3 (10%)
Malaise	2	1			3 (10%)

Number of Patients at Any Dose (n=30) Experiencing AEs 'Possibly' or 'Likely' Related to Paxalisib (affecting ≥10% of patients)



## **Second Drug in Clinical Trials**

EVT801 has potential in a wide range of cancers





# **Board and Management Team** Extensive experience in drug development

### **Board of Directors**



Iain Ross Chairman of the Board



**Bryce Carmine** Independent Director Lilly



**Steven Coffey** Independent Director VA 1



**Dr James Garner** Managing Director





### Management Team

**Dr James Garner** 

**Chief Executive Officer** 

Takeda





SANOFI **Karen Krumeich** Chief Financial Officer

Bristol Myers Squibb SOLIGENIX







Kate Hill **Company Secretary** 

Deloitte.





Priscilla Brastianos, MD



MASSACHUSETTS GENERAL HOSPITAL



John de Groot, MD

UCSF School of Medicine

MDAnderson Cancer Center



Alan Olivero, PhD

Genentech

HARVARD



Patrick Y Wen, MD





# **Financial Metrics** *Lean operating model drives high level of cash efficiency*



Source: Company ASX Appendix 4C Filings



# CY2022-23 Milestones and Newsflow

## Multiple catalysts across two clinical programs

Commence recruitment to paxalisib phase II GBM study at Weill Cornell	1H CY2022	$\checkmark$
Preclinical data for paxalisib in AT/RT presented at AACR (April 2022)	1H CY2022	$\checkmark$
Preclinical data for paxalisib in DIPG presented at ISPNO (June 2022)	1H CY2022	$\checkmark$
Final data from Kazia's paxalisib phase II study in GBM presented at ASCO (June 2022)	1H CY2022	$\checkmark$
Initial data from paxalisib phase II brain metastases study with Alliance for Clinical Trials in Oncology	1H CY2022	$\checkmark$
Paxalisib granted orphan drug designation and rare pediatric disease designation in AT/RT by FDA	1H/2H CY2022	$\checkmark$
Initial interim data from paxalisib + radiotherapy phase I brain mets study at Memorial Sloan-Kettering	2H CY2022	$\checkmark$
Preclinical data for paxalisib in melanoma presented at SMR (October 2022)	2H CY2022	$\checkmark$
Initial interim data from paxalisib phase II PCNSL study at Dana-Farber	1H CY2023	
Initial interim data from paxalisib phase II DIPG study with PNOC	1H CY2023	
Further interim data from paxalisib brain metastases trials	1H CY2023	
Initial interim data from Kazia's EVT801 phase I trial	1H CY2023	
Final data from GBM AGILE pivotal study of paxalisib	2H CY2023	

Italics – updated guidance

Note: all guidance is indicative, and subject to amendment in light of changing conference schedules, operational considerations, etc.





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