UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of November, 2024

Commission File Number 000-29962

Kazia Therapeutics Limited
(Translation of registrant's name into English)

Three International Towers Level 24 300 Barangaroo Avenue Sydney NSW 2000
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F ☑ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

INFORMATION CONTAINED IN THIS FORM 6-K REPORT

On November 4, 2024, Kazia Therapeutics Limited (the "Company") issued a press release titled, "Kazia Therapeutics Announces Granting of Type C Meeting with FDA to Discuss Potential Next Steps for Paxalisib in the Treatment of Newly Diagnosed Glioblastoma Multiforme." A copy of this release is attached hereto as Exhibit 99.1 and is incorporated herein by reference. The Company also updated its corporate presentation for use in meetings with investors, analysts and others. A copy of the corporate presentation is attached hereto as Exhibit 99.2.

EXHIBIT LIST

Exhibit	Description
99.1	Press Release of Kazia Therapeutics Limited dated November 4, 2024
99.2	Corporate Presentation

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Kazia Therapeutics Limited (Registrant)

/s/ John Friend
John Friend
Chief Executive Officer

Date: November 4, 2024

4 November 2024

Kazia Therapeutics Announces Granting of Type C Meeting with FDA to Discuss Potential Next Steps for Paxalisib in the Treatment of Newly Diagnosed Glioblastoma Multiforme

Company and FDA to meet in December to discuss potential pathways to registration of paxalisib in glioblastoma multiforme (GBM)

Company updates to corporate presentation and participation in upcoming medical meetings

Sydney, November 4, 2024 – Kazia Therapeutics Limited (NASDAQ: KZIA), an oncology-focused drug development company, announced that the U.S. Food and Drug Administration (FDA) has granted a Type C meeting with the Company in December 2024 to discuss the potential pathways to registration of Kazia's blood brain barrier penetrant PI3K/mTOR inhibitor, paxalisib, for the treatment of patients with newly diagnosed GBM.

In July 2024, the Company announced results from the Phase II/III clinical trial, GBM-AGILE, in which newly diagnosed unmethylated patients with glioblastoma treated with paxalisib showed clinically meaningful improvement in a prespecified secondary analysis for overall survival. Full data including secondary endpoints from the paxalisib arm of the GBM-AGILE study is expected to be presented at a scientific meeting later this year.

Paxalisib has previously received orphan drug designation and fast track designation from the FDA for glioblastoma in unmethylated MGMT promoter status patients, following radiation plus temozolomide therapy.

Updated corporate presentation

Today, the Company also announced that it has updated its corporate presentation, which now incorporates preliminary data from the GBM AGILE Phase II/III clinical trial evaluating paxalisib versus the standard of care for the treatment of in patients with glioblastoma. The updated presentation can be found at https://www.kaziatherapeutics.com/site/pdf/ebcc5b2e-29a6-410c-ab9a-c3e722413615/Kazia-Corporate-Presentation-November-2024.pdf

Participation in Upcoming and Recent Medical and Investor Conferences

The company plans on attending the following medical conferences in the fourth quarter of 2024:

- Society for Neuro-Oncology 29th Annual Meeting and Education Day, November 21-24, 2024, in Houston, TX
- San Antonio Breast Cancer Symposium, December 10-13, 2024, in San Antonio, TX

These events provide Kazia with the opportunity to engage with key stakeholders and share the Company's vision to make a difference in the lives of patients by developing innovative cancer treatments. Kazia looks forward to meeting with investors in person at these events and invites discussion regarding partnering and investment opportunities.

Over the last several months, the Company has also participated and presented at a number of medical and investor conferences, including:

- H C Wainwright 26th Annual Global Investment Conference from Sep. 9-11, 2024
- 15th Biennial AACR Ovarian Cancer Research Symposium, Sep. 20 – 21, 2024
- Oppenheimer Oncology Summit, in collaboration with MD Anderson Cancer Center, Sep. 26, 2024
- American Society for Radiation Oncology Annual Meeting, Sep. 29 – Oct. 1, 2024
- Deerfield CEO Conference, Oct. 8-9, 2024
- Maxim Group's 2024 Healthcare Virtual Summit, Fireside Chat, Oct. 15, 2024

About Kazia Therapeutics Limited

Kazia Therapeutics Limited (NASDAQ: KZIA) is an oncology-focused drug development company, based in Sydney, Australia. Our lead program is paxalisib, an investigational 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 2 study in glioblastoma reported early signals of clinical activity in 2021, and a pivotal study in glioblastoma, GBM AGILE, has been completed with presentation of paxalisib arm data expected later in 2024 at a major medical conference. Other clinical trials involving paxalisib are ongoing in brain metastases, diffuse midline gliomas, and primary CNS lymphoma, with several of these trials having reported encouraging interim data. Paxalisib was granted Orphan Drug Designation for glioblastoma by the FDA in February 2018, and Fast Track Designation (FTD) for glioblastoma by the FDA in August 2020. Paxalisib was also granted FTD in July 2023 for the treatment of solid tumour brain metastases harboring PI3K pathway mutations in combination with radiation therapy. In addition, paxalisib was granted Rare Pediatric Disease Designation and Orphan Drug Designation by the FDA for diffuse intrinsic pontine glioma in August 2020, and for atypical teratoid / rhabdoid tumours 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 evidence of synergy with immuno-oncology agents. A Phase I study has been completed and preliminary data was presented at 15th Biennial Ovarian Cancer Research Symposium in September 2024. For more information, please visit www.kaziatherapeutics.com or follow us on X @KaziaTx.

Forward-Looking Statements

This announcement may contain forward-looking statements, which can generally be identified as such by the use of words such as “may,” “will,” “estimate,” “future,” “forward,” “anticipate,” or other similar words. Any statement describing Kazia’s future plans, strategies, intentions, expectations, objectives, goals or prospects, and other statements that are not historical facts, are also forward-looking statements, including, but not limited to, statements regarding: the timing for results and data related to Kazia’s clinical and preclinical trials, Kazia’s strategy and plans with respect to its programs, including paxalisib and EVT801, the potential benefits of paxalisib as an investigational PI3K/mTOR inhibitor, timing for any regulatory submissions or discussions with regulatory agencies, and the potential market opportunity for paxalisib. Such statements are based on Kazia’s current expectations and projections about future events and future trends affecting its business and are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements, including risks and uncertainties: associated with clinical and preclinical trials and product development, related to regulatory approvals, and related to the impact of global economic conditions. These and other risks and uncertainties are described more fully in Kazia’s Annual Report, filed on form 20-F with the SEC, and in subsequent filings with the United States Securities and Exchange Commission. Kazia undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required under applicable law. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this announcement.

This announcement was authorized for release by Dr John Friend, CEO.

Exhibit 99.2

KAZIA THERAPEUTICS

A Diversified Oncology Drug Development Company

Kazia Corporate Overview

November 2024

NASDAQ: KZIA | X: @KaziaTx

Forward Looking Statements

This presentation contains forward -looking statements, which can generally be identified as such by the use of words such as “may,” “will,” “estimate,” “future,” “forward,” “anticipate,” “plan,” “expect,” “explore,” “potential” or other similar words. Any statement describing Kazia's future plans, strategies, intentions, expectations, objectives, goals or prospects, and other statements that are not historical facts, are also forward-looking statements, including, but not limited to, statements regarding: the timing for interim or final results and data related to Kazia’s clinical and preclinical trials, or third-party trials evaluating Kazia’s product candidates, timing and plans with respect to enrolment of patients in Kazia’s clinical and preclinical programs, the potential benefits of paxalisib and EVT801, and Kazia’s strategy and plans with respect to its business and programs, including paxalisib and EVT801. Such statements are based on Kazia’s expectations and projections about future events and future trends affecting its business and are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements, including risks and uncertainties: associated with clinical and preclinical trials and product development, the risk that interim data may not be reflective of final data, related to regulatory approvals, and related to the impact of global economic conditions, including disruptions in the banking industry. These and other risks and uncertainties are described more fully in Kazia’s Annual Report, filed on Form 20-F with the SEC, and in subsequent filings with the SEC. Kazia undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required under applicable law. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this presentation.

Certain information contained in this presentation and statements made orally during this presentation relate to or are based on studies, publications, surveys and other data obtained from third-party sources and our own internal estimates and research. While we believe these third-party studies, publications, surveys and other data to be reliable as of the date of this presentation, it has not independently verified, and makes no representations as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. In addition, no independent source has evaluated the reasonableness or accuracy of our internal estimates or research and no reliance should be made on any information or statements made in this presentation relating to or based on such internal estimates and research.

Company Overview

A late-clinical-stage oncology drug development company

KAZIA THERAPEUTICS

Paxalisib	EVT801
Brain-penetrant pan-PI3K / mTOR inhibitor • Well-validated class with five current FDA-approved therapies • Only brain-penetrant PI3K inhibitor in development	**Selective VEGFR3 inhibitor** • Designed to avoid off-target toxicity of older, non-selective angiokinase inhibitors • Primarily targets lymphangiogenesis
In development for multiple brain cancers • Clinical trials ongoing in brain metastases, childhood brain cancer, glioblastoma, IDH-mutant glioma, and primary CNS lymphoma	**Completed phase I for advanced solid tumors** • Preliminary data from adaptive, biomarker study at 2 leading cancer sites in France to be presented at upcoming 2024 meeting
Unique asset being evaluated in multiple trials • Multiple signals of clinical activity across several cancer types • Fast Track, Orphan Drug, and Rare Pediatric Disease Designations from US FDA	**Potential use in multiple solid tumor types** • Potential indications include: ovarian cancer, renal cell carcinoma, liver cancer, colon cancer, and sarcoma
Rich potential commercial opportunity • Glioblastoma alone sized at US$ 1.5 billion per annum • Commercial licensee in place for China • Licensee for intractable seizures in rare CNS diseases	**Potential combination with immunotherapy** • Strong evidence of synergy in preclinical data supports potential of monotherapy or combination use
Top Line Ph. 3 Data: Reported July CY2024	**Phase 1 Preliminary Data presented Sep CY2024**

Corporate Highlights

Licensing-driven business model focused on high quality, differentiated clinical-stage assets sourced from Genentech (Paxalisib) and Sanofi / Evotec (EVT801)

Lean virtual pharma model, with ~75% of cashflows applied directly to clinical trials

Potential opportunities for non-dilutive income via additional partnering activity

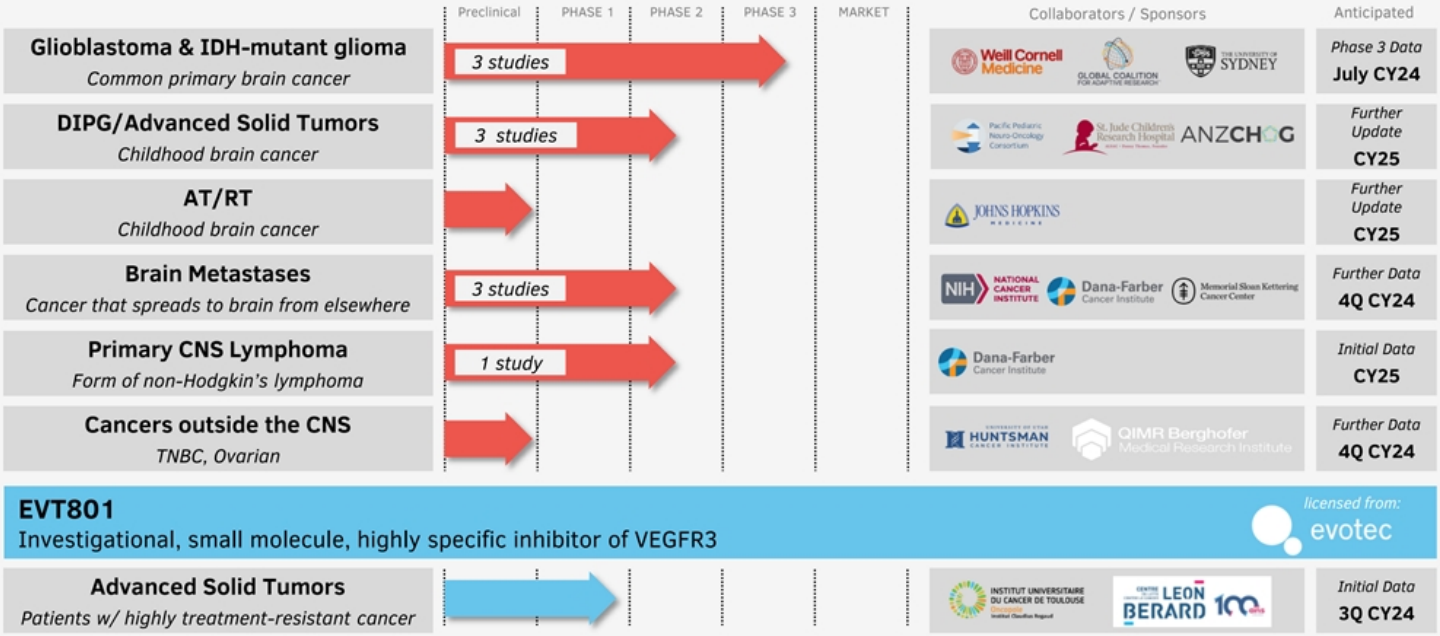
Delisted from Australian Securities Exchange (ASX) in Nov 2023; now solely listed on NASDAQ (KZIA)

Pipeline – Two Differentiated Assets

CY2024 positive clinical data updates driving strong interest in oncology community

Paxalisib *licensed from: Genentech*

Investigational, small molecule, potent, brain-penetrant inhibitor of PI3K / mTOR



EVT801 *licensed from: evotec*

Investigational, small molecule, highly specific inhibitor of VEGFR3

IDH: Isocitrate dehydrogenase, DIPG: Diffuse Intrinsic Pontine Glioma, AT/RT: Atypical Teratoid Rhabdoid Tumor, CNS: central nervous system, TNBC: triple negative breast cancer, VEGFR3: vascular endothelial growth factor receptor 3

Paxalisib Mechanism of Action

Only brain-penetrant drug in development within the PI3K inhibitor class

1 The PI3K pathway is activated in many forms of cancer

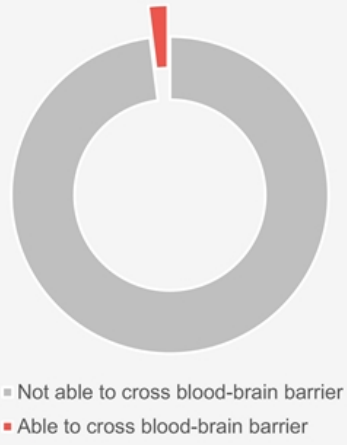
Glioblastoma	**90%**
Breast	**80%**
Lung	**75%**
Endometrial	**60%**
Ovarian	**60%**
Prostate	**45%**

2 Five PI3K inhibitors have already been approved by FDA

Zydelig (idelalisib) tablets	• Chronic lymphocytic leukemia • Follicular lymphoma
Aliqopa (copanlisib)	• Follicular lymphoma
Copiktra (duvelisib)	• Chronic lymphocytic leukemia • Follicular lymphoma
PIQRAY (alpelisib) tablets	• Breast cancer
UKONIQ umbralisib tablets	• Follicular lymphoma

3 Paxalisib is the only brain-penetrant PI3K inhibitor in development

Only 2% of small-molecule drugs are brain-penetrant

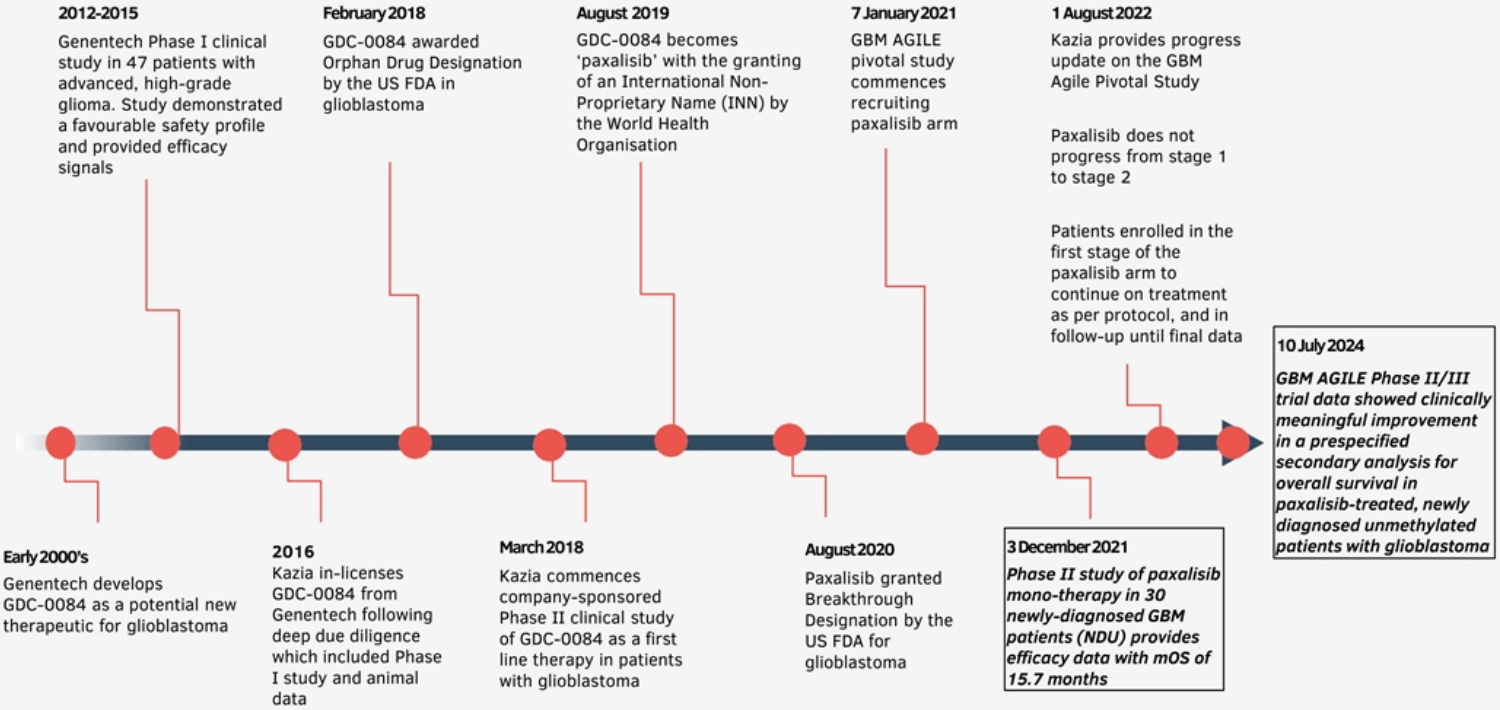


Source: Data on file

KAZIA THERAPEUTICS

Paxalisib – *Development History*

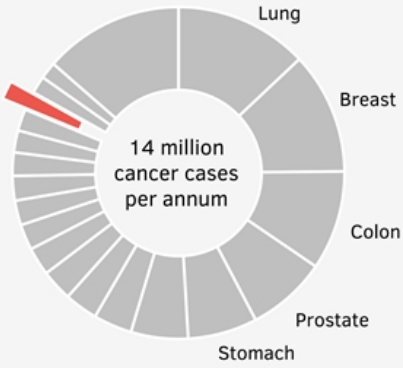
Growing Body of Clinical Evidence Demonstrating Activity in GBM



Glioblastoma
Background & Market potential

Glioblastoma Overview

The most aggressive malignant brain cancer



Glioblastoma Multiforme

133,000 cases per annum worldwide

GBM treatment market size (2022)

US$ 1.5 billion

No clear cause

or strong risk factors

Any age, but most common in

60s

No clear improvement in prognosis for

20 years

3-4 months

Survival, if untreated

Five-year survival

3 – 5%

(breast cancer: 90%)

"Even a few months increase in overall survival makes a huge difference for my patients, so efficacy of an approved therapeutic makes the largest impact."

US Neuro-Oncologist

Source: Data on file. Market research performed 2021

KAZIA THERAPEUTICS

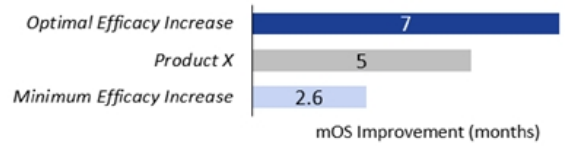
Primary Market Research Outcomes

Physicians indicated a 2-month minimum and 12-month optimum increase in efficacy for newly diagnosed unmethylated GBM treatments, but adoption would be high regardless

Physician receptivity to optimal and minimal mOS efficacy for ND* GBM

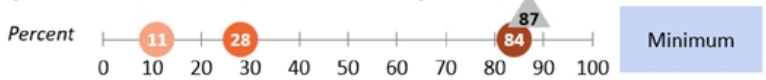
(N=15 Physicians)

Optimal and minimal mOS increase in newly diagnosed GBM patients



Adoption rates of Product X if optimal mOS improvement achieved

Adoption rates of Product X if minimum mOS improvement achieved



ND Unmethylated ND Methylated Recurrent Base Case

Key Takeaway

- Due to the high unmet need for a more efficacious therapy for Newly Diagnosed Unmethylated (NDU) GBM patients, physicians indicated high adoption rates if Product X (paxalisib)* is approved by the FDA and achieved their suggested minimum mOS improvement of 2-3 months for newly diagnosed unmethylated GBM patients

Source: Data on file. Company-sponsored market research performed in 2021

* There is no guarantee that the Paxalisib data generated to date will support an FDA approval for commercial use

KAZIA THERAPEUTICS

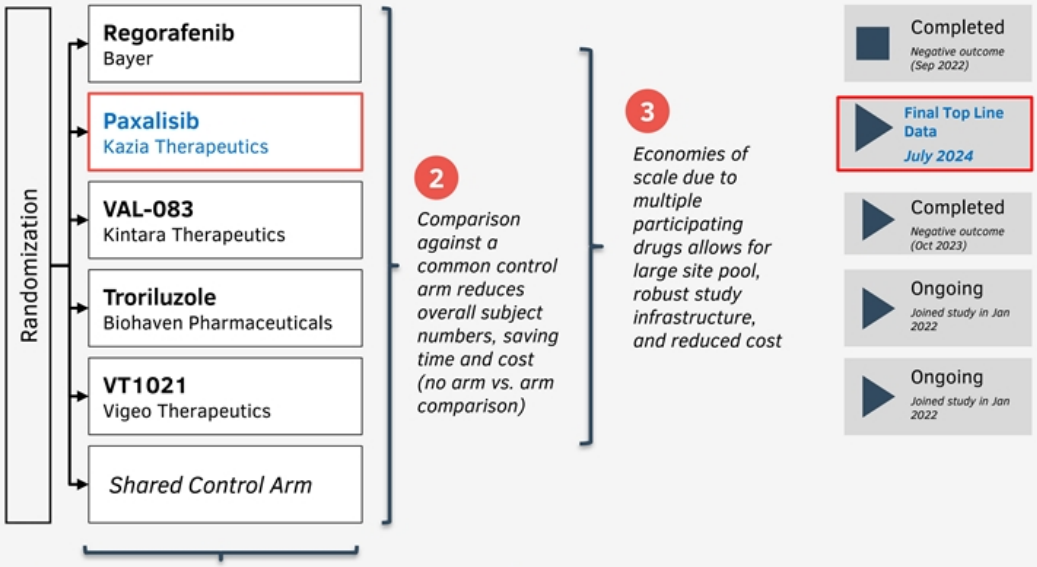
GBM AGILE study data –
Primary and secondary analysis

Paxalisib and GBM-Agile

International, multi-center, adaptive, phase 2/3 study evaluating promising therapeutics in patients with glioblastoma

Key Points

- A 'platform study', sponsored by GCAR run independently of individual companies, designed to expedite the approval of new drugs for glioblastoma
- Multiple drugs are evaluated in parallel, saving time and money
- Not a 'winner-takes-all' approach: multiple drugs can succeed
- Cutting-edge 'adaptive design' avoids redundant recruitment, expediting path to market
- FDA acknowledged that GBM-AGILE data may be suitable for registration



GCAR: Global Coalition for Adaptive Research

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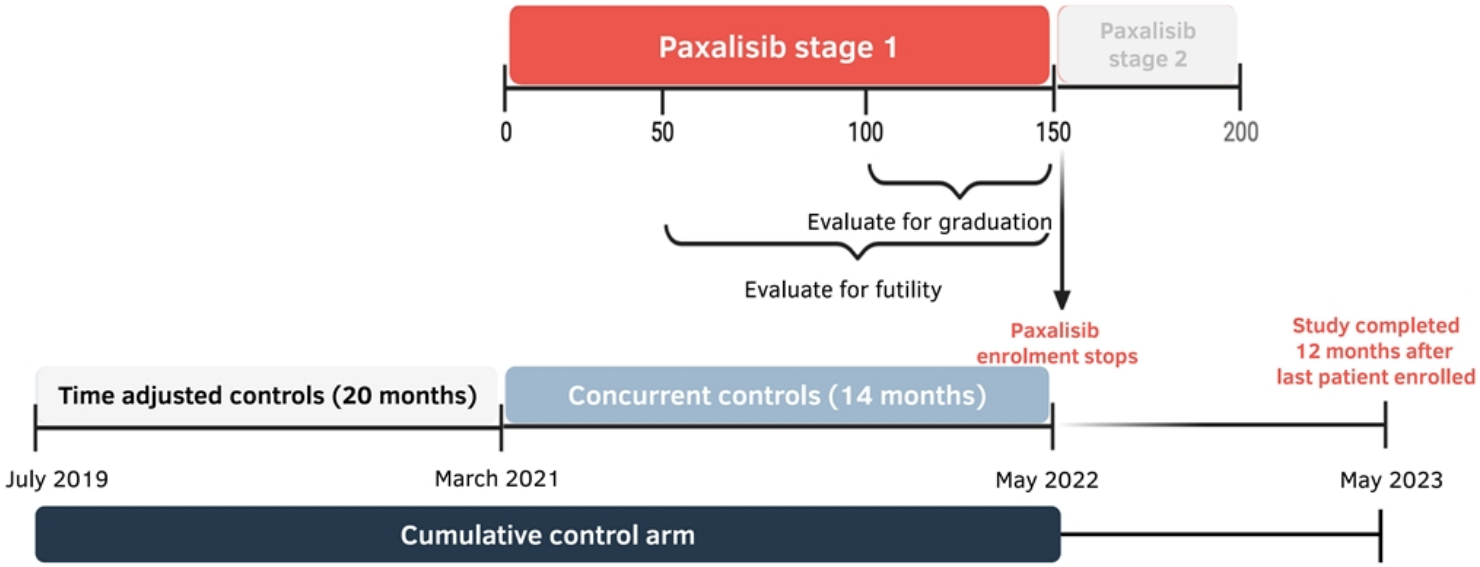
Paxalisib & GBM-Agile

Study schema; Paxalisib arm (n=154) enrolled Newly Diagnosed Unmethylated GBM patients (NDU) and Recurrent GBM patients



Important notes:

- The Cumulative control arm is a combination of Concurrent control patients and the "Time adjusted control" patients that were enrolled in the study before the Paxalisib arm joined the study
- Bayesian Primary Analysis uses data from the Cumulative control arm, while Prespecified Secondary Analysis uses data from the Concurrent Control Arm (i.e.. Compares paxalisib data with standard of care)
- All patients (Paxalisib, concurrent control, and cumulative control) were censored on May 2023 if still alive

Paxalisib and GBM-Agile

Newly Diagnosed Unmethylated GBM patients (NDU)
Primary endpoint: median Overall Survival analyses (ITT)

Bayesian Primary Analysis:
Paxalisib (n=54) vs Standard of Care (n=77)[1]
14.77 months vs 13.84 months

Prespecified Secondary Analysis:
Paxalisib (n=54) vs Standard of Care (n=46)[2]
15.54 months vs 11.89 months

A prespecified sensitivity analysis in NDU patients showed a similar median OS difference between paxalisib treated patients (15.54 months) and concurrent SOC patients (11.70 months)

Important notes:

- The Cumulative control arm is a combination of Concurrent control patients and "Time adjusted control" patients that were enrolled in the study before the Paxalisib arm joined the study
- Primary Analysis comparator is the Cumulative control arm, while Prespecified Secondary Analysis comparator is the Concurrent Control Arm
- An efficacy signal was not detected in the recurrent disease population [median OS of 9.69 months for concurrent SOC (n=113) versus 8.05 months for paxalisib (n=100)]

[1] Cumulative controls. [2] Concurrent controls

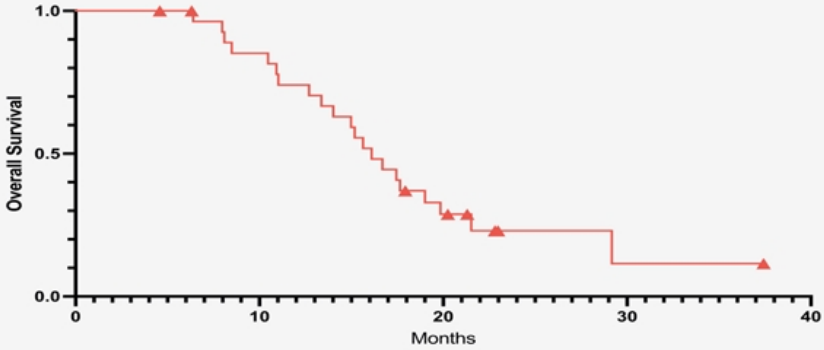
Recap and next steps for Paxalisib in glioblastoma

Paxalisib in Glioblastoma Phase II Clinical Study

Encouraging median OS (mOS) in Newly Diagnosed Unmethylated GBM patients

Overall Survival (OS)

(n=30)



Median OS: **15.7 months** (11.1-19.1)

Historical mOS for existing therapy: **12.7 months** (Hegi et al. 2005)

Note: Figures for existing therapy are for temozolomide, per Hegi et al. (2005); No head-to-head studies have been published

Paxalisib in Glioblastoma Phase II Clinical Study

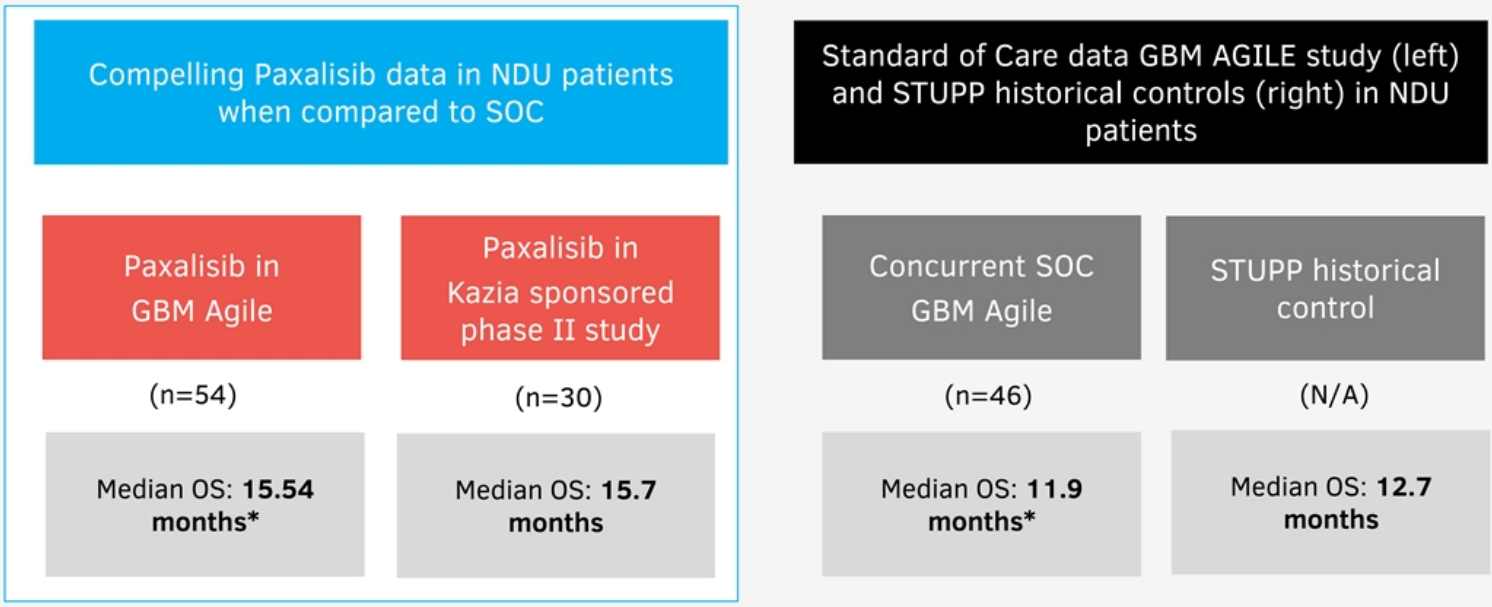
Encouraging safety profile

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

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%)

Paxalisib in Glioblastoma

Consistent median Overall Survival data in two studies of NDU glioblastoma patients



*GBM Agile; Prespecified secondary analysis of median Overall Survival

Paxalisib glioblastoma program highlights

Significant body of clinical evidence from two clinical trials supporting paxalisib's activity in newly diagnosed GBM

- ✓ **GBM AGILE Phase II/III trial data showed improvement in a prespecified secondary analysis for overall survival (15.5 months) in paxalisib-treated, newly diagnosed unmethylated patients with glioblastoma; presentation of data from GBM AGILE anticipated in 4Q CY 2024**

- ✓ **Earlier Phase II study of paxalisib as a mono-therapy in 30 newly-diagnosed GBM patients (NDU) provides additional clinical evidence of activity with mOS of 15.7 months**

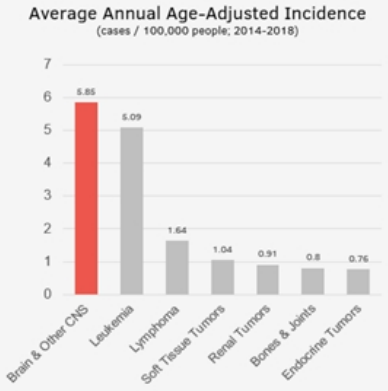
US FDA has granted a December 2024 Type C meeting with Kazia Therapeutics to discuss results and possible pathways to registration

Childhood Brain Cancers

Paxalisib in Childhood Brain Cancer

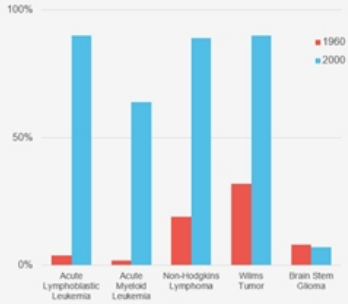
High unmet need especially in patients with diffuse midline gliomas (DMGs)

1 Brain cancer is the most common malignancy of childhood



2 Brain cancer represents about one third of childhood cancer deaths

3 Prognosis of childhood brain cancer, especially DMGs, has improved little in recent decades



FDA-Approved Drug Therapies

Diffuse Midline Gliomas	Nil
Atypical Teratoid / Rhabdoid Tumors	Nil
Medulloblastoma	Nil

Source: CBTRUS; CDC; Ages 0-14 shown; Adamson PC, *CA Cancer J Clin*. 2015;65:212–220

KAZIA THERAPEUTICS

Summary of Paxalisib in Childhood Brain Cancer

Kazia is actively pursuing three forms of childhood brain cancer

	Diffuse Midline Gliomas (DMG, DIPG)	Atypical Teratoid / Rhabdoid Tumors (AT/RT)	Advanced Childhood Cancer (PI3K/mTOR activated)
Preclinical Research	*Positive preclinical data in combination with ONC201*	*Positive preclinical data as monotherapy and in combination (AACR 2022, 2023, 2024)*	*Research proposals under discussion*
Clinical Trials	*Phase I monotherapy clinical trial at St Jude Children's Research Hospital completed*	*Clinical trial design/execution discussions ongoing between PNOC and Kazia*	*Additional clinical trial opportunities under discussion for medulloblastoma and HGG*
	PNOC022, Phase II clinical trial in combination with ONC201, ongoing		*Phase II clinical trial in combination with chemotherapy for treatment of high-risk malignancies commenced 2023*
Regulatory Interaction	*Orphan Drug Designation (ODD) and Rare Pediatric Disease Designation (RPDD) granted by FDA in Aug 2020*	*ODD and RPDD granted by FDA in June and July 2022, respectively*	*Regulatory strategy under discussion*

Paxalisib in Diffuse Midline Gliomas

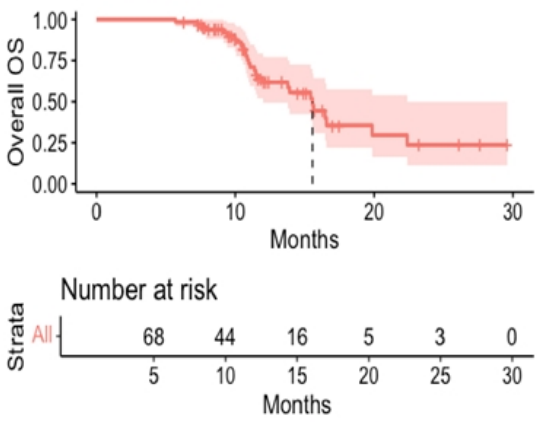
Follow-up Phase II data presented at ISPNO 2024 Annual Meeting

In spite of research that has helped improve treatment for DIPG patients, the prognosis remains poor–with the median survival range being from 8-11 months[1]

- 68 patients with biopsy-proven DMG were enrolled in the PNOC Phase II study between November 2021 and June 2023 (median age 9 years [range 3-37], n=41 female [60%])
- Updated Median OS from time of diagnosis was 15.6 months (Confidence interval (CI) 12.0, 22.4)
- Cohort 3 enrolled 30 recurrent patients (in conjunction with radiation therapy) had median OS 8.7 months [CI 95% 8.5, NA]
- Most common grade 3 and above treatment-related adverse events were decreased neutrophil count (n=4); mucositis (n=3); and colitis, drug reaction with eosinophilia and systemic symptoms, decreased lymphocyte count, hyperglycemia, and hypokalemia (n=2)
- Next Steps: Further PK and biomarker analyses ongoing for subsequent cohorts; anticipate clinical update 1HCY2025

Overall Survival - Cohort 2 (post RT)

Median OS 15.6 months [CI 95%; 12.0, 22.4]



Central imaging review analysis of PFS ongoing

1. Hargrave, D., Bartels, U. & Bouffet, E. Diffuse brainstem glioma in children: critical review of clinical trials. Lancet Oncol 7, 241-8 (2006)

KAZIA THERAPEUTICS

Brain Metastases

Paxalisib in Brain Metastasis

MSKCC-sponsored Phase I trial's interim analysis showed encouraging clinical activity of paxalisib in combination with radiation therapy (NCT04192981)

12-13 August 2022

Data from first stage presented at **2022 Annual Conference on CNS Clinical Trials and Brain Metastases**, Toronto, Canada from 12-13 August 2022

All 9 patients evaluated for efficacy exhibited a clinical response, according to RANO-BM criteria, with breast cancer representing the most common primary tumor

July 2023

Fast Track Designation granted by US FDA for paxalisib in combination with radiation therapy in patients with solid tumor brain metastases and PI3K pathway mutations

Based on the interim Stage 1 data from the MSKCC-sponsored Phase I trial's interim analysis.

February 2024

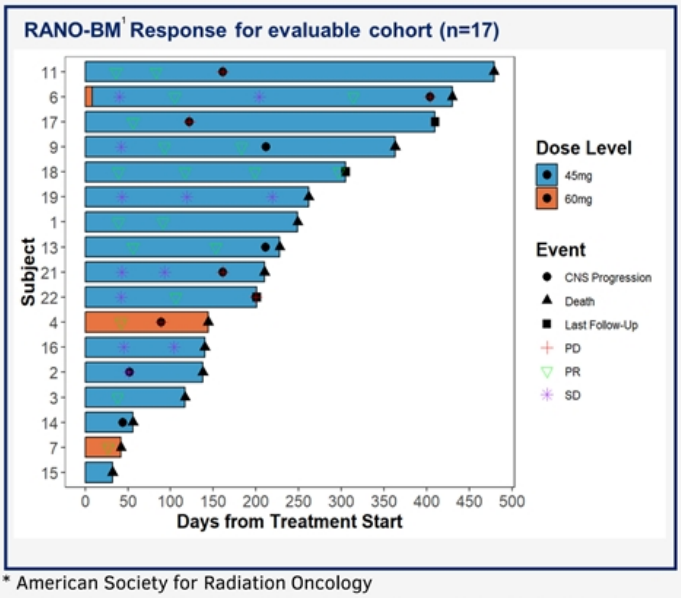
Announced early conclusion, based on Stage 2 positive safety data and **promising clinical response** findings observed to date.

- Data presentation anticipated at upcoming scientific congress in 2H CY2024
- Coordinate and plan next clinical study in conjunction key thought leaders and FDA

Paxalisib in Brain Metastasis

MSKCC-sponsored Phase I trial's interim analysis presented at 2024 ASTRO meeting showed encouraging clinical activity of paxalisib in combination with radiation therapy (NCT04192981)*

Robust response signal seen for concurrent paxalisib and brain RT



* American Society for Radiation Oncology

1. Response assessment in neuro-oncology brain metastases (RANO-BM)
2. Zhou et al. 2021, Kim et al. 2020

Overall Summary

- Primary objective of identifying the maximum tolerated dose (MTD) was met:
  - Concurrent daily administration of paxalisib with brain radiotherapy was generally well-tolerated at a maximum dose of 45 mg per day in advanced solid tumor patients with brain metastases and PI3K pathway mutations
- Over two-thirds of the patients at MTD achieved intracranial response which compares favorably to historical response rates (20-40%)[2] for WBRT alone
- Future goals include:
  - Extending the duration of PI3K inhibition, neoadjuvant, adjuvant and maintenance (ideally with complementary systemic therapy options)
  - Integrating PI3K inhibition with CNS tumor types with relevant pathway driver mutations and potentially SRS

Other Solid Tumors

Paxalisib in Triple Negative Breast Cancer

QIMR Berghofer Medical Institute collaboration

"*In treatment-resistant pre-clinical models of breast cancer, paxalisib (4T1 mouse model, TNBC[1]) has shown encouraging results in inhibiting both the primary tumor burden and metastasis by reinvigorating the immune system within the tumor microenvironment*" – Professor Sudha Rao, Group Leader, QIMR Berghofer

- Leading transcriptional biology and epigenetics expert, Prof Rao identified an entirely novel effect of PI3K inhibition:
  - Immune modulator of the tumor and the surrounding microenvironment
  - Administration of PI3K inhibitors such as paxalisib, at doses and frequencies different to those conventionally used, appears to activate or reinvigorate the immune system in the tumour, making it more susceptive to immunotherapy
- The preliminary data from our collaboration will be presented at an upcoming conference in 4Q CY2024

Combination Paxalisib + KEYTRUDA® (pembrolizumab) data in TNBC[1] preclinical models

Combination Paxalisib + LYNPARZA® (olaparib) data in advanced breast cancer preclinical models

Paxalisib influence on immune system (example, T cells, B cells, NK cells) and within the tumor and its micro-environment

Intellectual Property (IP) update

1. Triple Negative Breast Cancer

Triple Negative Breast Cancer Treatment Landscape

Projected TNBC market to exceed $1.5 Billion by 2030

2.3 million[1]

Cases / year Breast cancer most commonly diagnosed cancer

American Cancer Society says nearly

300,000

new cases of invasive BC in US

Triple negative breast cancer

TNBC

most aggressive form of breast cancer

Characteristics

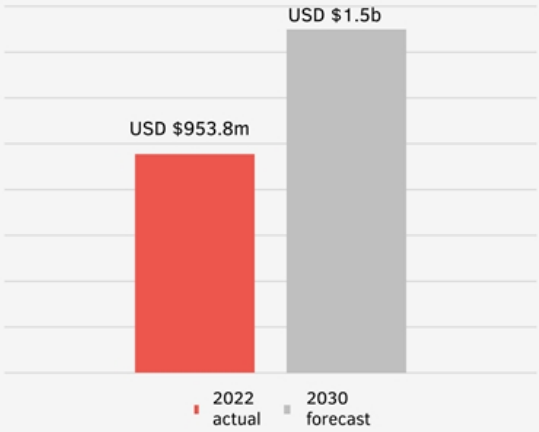
Higher early relapse rate, increased metastases risk and higher mortality rate

15-20%

Of all breast cancers attributed to TNBC

TNBC market valued at USD $953.8m in 2022. Predicted to grow to **USD $1.5b by 2030**[2]

TNBC market growth forecast[2]

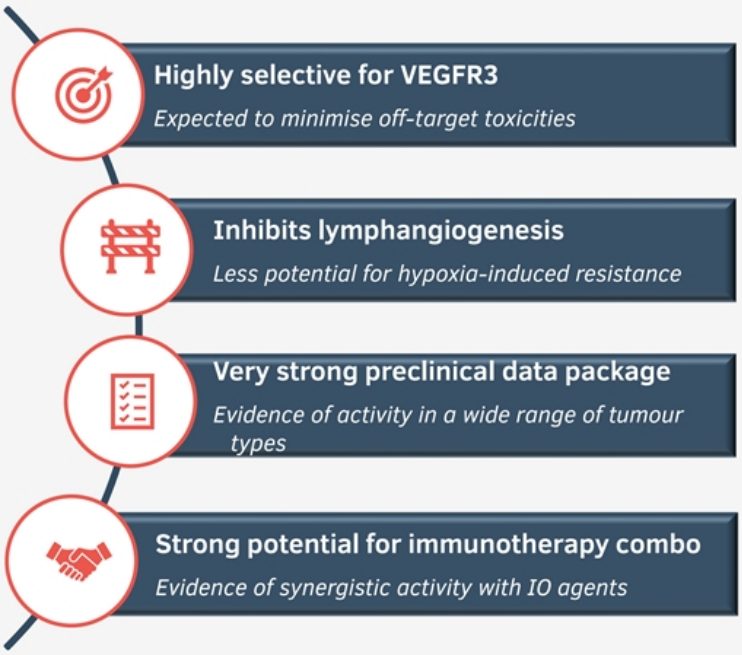


1. National Institutes of Health (NIH): Current and future burden of breast cancer: Global statistics for 2020 and 2040
2. https://www.databridgemarketresearch.com/reports/global-triple-negative-breast-cancer-market

KAZIA THERAPEUTICS

EVT801

EVT801 is a highly selective VEGFR3 inhibitor, primarily inhibiting lymphangiogenesis (formation of new lymphatic vessels)



Oral Presentation
Administered by mouth once or twice daily

Strong IP Protection
Composition-of-matter to 2032 / 2033 in most jurisdictions

Low Cost of Goods
Straightforward manufacture with excellent stability

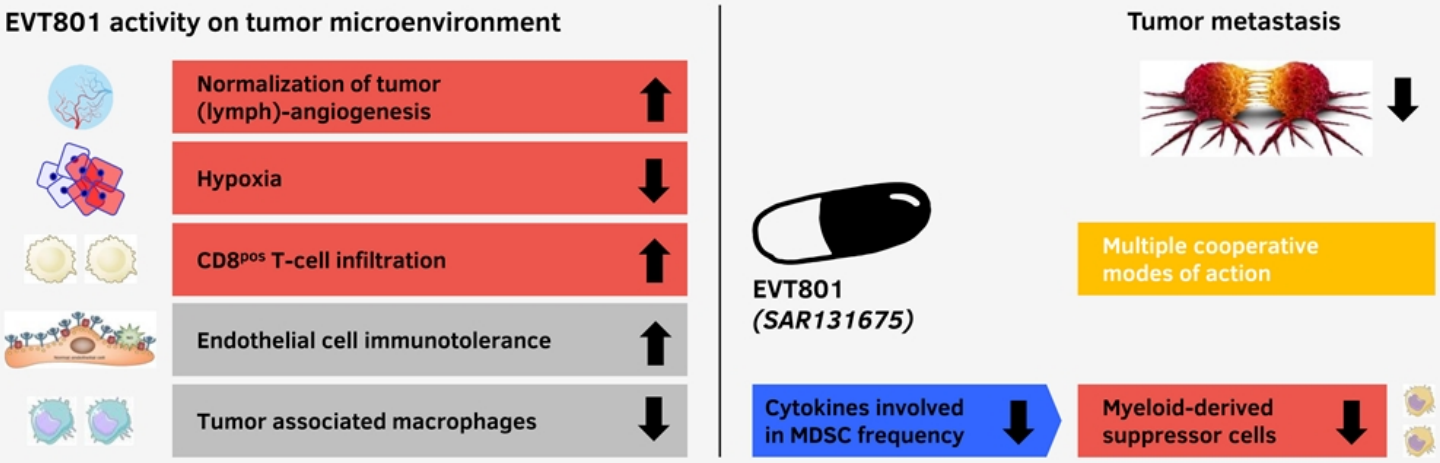
Favourable Preclinical Toxicology
Limited evidence of toxicity in one-month GLP studies

In Clinical Development
Phase 1 clinical trial completed

EVT801 Mechanism of Action

By targeting VEGFR3^{pos} tumor blood vessels, EVT801 may induce tumor blood vessel normalization, reduce hypoxia, and improve CD8 T-cells infiltration

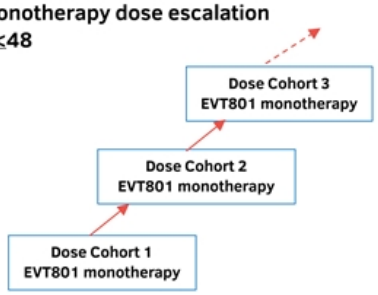
Schematic overview based on pre-clinical data



Data from Tacconi & al. with SAR131675

EVT801: Phase 1 dose-finding trial; KZA 0801-101 (NCT05114668)
Staged development in patients with advanced cancer

STAGE 1
Monotherapy dose escalation
n≤48



- Up to 8 cohorts
- Single-patient cohorts initially, expand to 3+3 when toxicity is encountered
- Mixed population of advanced solid tumors
- Doses from 50mg QD to 800mg BID

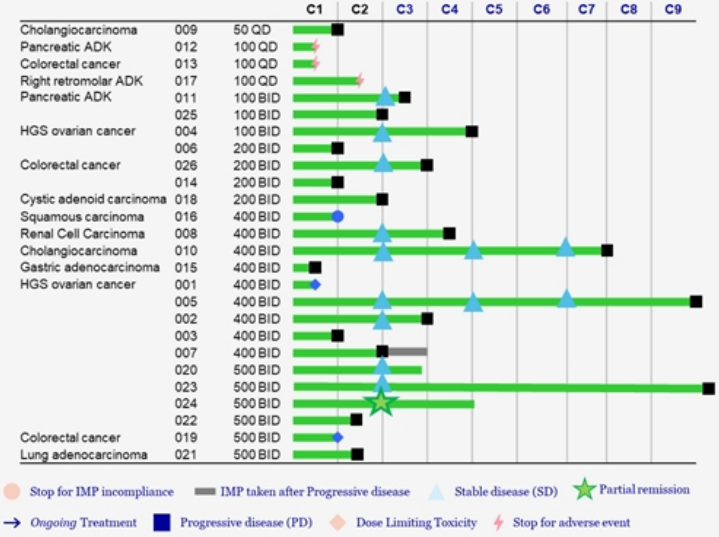
CENTRE LEON BERARD

INSTITUT UNIVERSITAIRE DU CANCER DE TOULOUSE Oncopole

Phase 1 study in advanced cancer patients Completed

- Primary objective of stage one of the study was successfully met:
  - MTD has been reached at 500mg BID
  - The recommended dose for phase 2 is 400 mg BID* in continuous monotherapy administration

Number of cycles of treatment: Status on 11 October 2024



MTD = Maximum Tolerated Dose; RP2D = Recommended Phase 2 Dose
Human active dose prediction based on predicted human clearance of 2.5 mL/min/kg: 375 mg BID

KAZIA THERAPEUTICS

EVT801 Key Points

1. Well-understood mechanism (anti-angiogenesis) with unique differentiating feature (high VEGFR3 selectivity)
2. Strong preclinical data package, with observed activity in multiple tumours and favourable toxicology
3. Potential for combination use with immuno-oncology therapies
4. Phase 1 completed demonstrating encouraging safety and tolerability profile to date:
   - Clinical and biomarker data presented at AACR Ovarian Cancer Research Symposium September 2024
   - Primary and secondary objectives successfully met, with MTD and RP2D identified
   - Encouraging signal of activity observed in High Grade Serous (HGS) ovarian cancer as well as strong VEGFR3 biomarker expression
5. Next clinical trial under discussion with scientific thought leaders:
   - Consolidate safety data at RP2D and our hypotheses on EVT801 mode of action
   - Validate HGS ovarian cancer as indication of choice for clinical trial phase 2 as monotherapy or in combination with standard-of-care (ex. PARPi)

2024 Corporate Update

Paxalisib Licensing and Collaborations

Opportunistic partnering and strategic collaborations continue to add value

Licensing

Summary	Simcere	Sovargen
Territories and responsibilities	To develop and commercialize Paxalisib in Greater China, Hong Kong, Macau, and Taiwan	To develop, manufacture and commercialize Paxalisib as a potential treatment for intractable epilepsy in focal cortical dysplasia type 2 (FCD T2) and tuberous sclerosis complex (TSC) disease
Upfront payment	US$11m, comprising US$7m in cash and a US$ 4m equity investment	US$1.5 million
Milestone payments	Contingent milestone payments of up to US$ 281 million in GBM + further milestones payable in indications beyond GBM	Potential milestone payments of up to US$19 million upon the achievement of development and regulatory milestones
Royalties on net sales	Mid-teen percentage royalties on commercial sales	A percentage of sub-licensing revenues and royalties on net sales of products incorporating paxalisib

Key Collaborations

QIMR Berghofer Medical Research Institute

Cutting edge preclinical program to evaluate Paxalisib in combination with immuno-therapies for Advanced Breast Cancer

Johns Hopkins University

- Paxalisib alone and in combination with other targeted agents is active in preclinical models of AT/RT[1]
- US FDA has awarded Orphan Drug Disease and Rare Pediatric Disease Designations in AT/RT
- If Paxalisib were to be approved, Kazia could be entitled to receive a **pediatric priority review voucher** which are tradeable and have historically commanded prices in excess of USD $100 million.

1. Atypical Teratoid Rhabdoid Tumor

Kazia Therapeutics: 2024-2025 Corporate Focus

Objectives for value creation

Progress paxalisib glioblastoma program	• Compile data from all clinical trials • FDA granted Type C meeting with Kazia in December 2024 • Propose potential pathways to registration
Execute paxalisib pediatric and brain metastasis programs	• PNOC team to complete PK/biomarker data analysis and provide update 1Q CY2025 • Additional data presentation and advance development to evaluate Paxalisib + Radiation Therapy 4Q CY2024
Paxalisib in other key oncology indications	• Advance TNBC[1] program stemming from QIMR collaboration whereby encouraging signals of immune reinvigoration and cancer stem cell activity have been consistently observed in animal models
EVT801 program	• Complete analysis Stage one of EVT801 Phase 1 clinical study • Data presented at AACR Ovarian Cancer Research Symposium, September 2024 • Discuss and plan for Phase 2 study in advanced ovarian cancer patients
Corporate business development	• Continue to be opportunistic in terms of global and regional licensing for paxalisib and EVT801

1. Triple Negative Breast Cancer

KAZIA

THERAPEUTICS

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