PRESS RELEASE
21 November 2023

KAZIA PROVIDES OVERVIEW OF PAXALISIB RELATED PRESENTATIONS FROM THE SOCIETY OF NEURO-ONCOLOGY 2023 ANNUAL MEETING

21 November 2023 – Kazia Therapeutics Limited (NASDAQ: KZIA), an oncology-focused drug development company, is pleased to provide key highlights of the clinical and preclinical paxalisib related presentations given by key thought leaders at the Society of Neuro-Oncology 2023 Annual Meeting. "The 2023 SNO Annual Meeting was another successful event with the latest advances in clinical trials, diagnosis and treatment of pediatric and adult patients with CNS malignancies," stated Dr. John Friend, CEO Kazia. "We are highly encouraged with the preliminary overall survival data from the PNOC022 clinical study that we believe will provide an alternative to the current therapies considered as standard of care."

Key paxalisib highlights from the meeting:
Friday, November 17th
Combining ONC201 and paxalisib for the treatment of diffuse midline glioma (DMG); the preclinical results underpinning the international Phase II clinical trial (NCT05009992).
Presenter: Evangeline R. Jackson; University of Newcastle, NSW, Australia

- The mechanism of action of both paxalisib and ONC201 were reviewed as well as the synergistic effects of their combination in DMG preclinical models
    - Specifically, the authors observed how ONC201 over activates the PI3K-AKT pathway, which is the target pathway for paxalisib
    - Consistent and statistically significant improvements were observed with the combination of paxalisb and ONC201 in DMG preclinical mouse models
- Two patient case studies were discussed; each receiving the combination of paxalisib and ONC201 through compassionate access
    - 16-year old female with advanced and relapsed diffuse intrinsic pontine glioma (DIPG) who demonstrated significant neurological improvements as well as rapid tumour regression after receiving the combination
    - Six-year old female with DIPG who received the combination of paxalisib and ONC201 after upfront radiation therapy. Tumor regression has been maintained for more than two years on paxalisib and ONC201

Exploiting the genetic dependency on PI3K/mTOR signaling for the treatment of H3-altered Diffuse Midline Glioma
Presenter: Ryan Duchatel, PhD; University of Newcastle, NSW, Australia

- PI3K pathway activation is observed in >80% of all DMGs and was shown to be required for DMG cell growth
- The authors stated that the success of a monotherapy in DMG is highly unlikely; therefore they explored several combinations [of other therapies] with paxalisib with the aim of optimizing tolerability and efficacy of such combinations in preclinical

mouse studies
    - Adding metformin to paxalisib was observed to improve hyperglycemia (elevated blood glucose) as well as extend the overall survival rate
    - The combination of paxalisib and enzastaurin (PKC inhibitor) was observed to further extend the overall survival when combined to radiation treatment
    - Authors concluded the triple combination of paxalisib, enzastaurin and metformin warranted further investigation in clinical trials

Phase I study of paxalisib and radiotherapy for CNS disease harboring PI3K pathway mutations: pilot analysis of circulating tumor DNA for patient eligibility confirmation and post-treatment response

Presenter: Brandon Imber, MD, Memorial Sloan Kettering Cancer Center, NYC, USA

- This is a multi-institutional, Phase I trial of concurrent paxalisib and radiation therapy in patients with brain metastases with documented PI3K pathway mutations
- Study has expanded after data from the initial stage identified the maximal tolerated dose (45mg once daily) along with observed signals of clinical activity (100% response rate)
- The authors observed that plasma circulating tumor DNA (ctDNA) was able to accurately confirm the tumor's genetic mutations at baseline and can potentially be used as a biomarker to assess patient treatment response
- The authors presented a representative case from the ongoing Phase I study:
    - 70-year-old woman with metastatic breast cancer with tumor harboring PIK3CA mutation received radiation therapy in combination with paxalisib for brain metastases
    - Her baseline plasma ctDNA test before starting treatment detected the same PIK3CA mutation as her tumor
    - MRI scan three months after treatment demonstrated radiographic response. In addition, a 99% reduction in the amount of ctDNA with PIK3CA mutation compared to baseline was detected, indicating ctDNA can potentially be used as an accurate method to monitor response after radiation therapy in combination with paxalisib
    - This is the first time in this patient population to demonstrate a link between MRI findings and a blood-based measure of tumor burden (ctDNA)

Sunday, November 19

PNOC022: a combination therapy trial using an adaptive platform design for patients with diffuse midline gliomas (DMGs) at initial diagnosis, post-radiation therapy and at time of therapy

Presenter: Sabine Mueller, MD, UCSF, San Francisco, USA

- 30 sites open to enrollment in North America, Europe and Australia
- Total enrollment to date: 137 patients
    - Cohort 1 (newly diagnosed) = 37 patients
    - Cohort 2 (post radiation therapy) = 69 patients (one patient was replaced due to physician preference)
    - Cohort 3 (at the time of recurrence) = 31 patients
- Cohort 2 preliminary analyses (median follow-up time was approximately 9 months)
    - Median Overall Survival rate was 16.5 months

    - Median Progression Free Survival (PFS) was 9.9 months (central review is ongoing)
- Analysis of preliminary data from all cohorts is still ongoing and the protocol is subject to amendment to refine dosing with the aim of improving tolerability and efficacy at which time the enrollment of new patients will start
    - Additional data includes ctDNA, microbiome and quality of life measures

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

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, a brain-penetrant inhibitor of the PI3K / Akt / mTOR pathway, which isbeing 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 clinical activity in 2021, and a pivotal study, GBM AGILE, is ongoing, with final data expected in CY2023. Other clinical trials are ongoing in brain metastases, DMGs, and primary CNS lymphoma, with several of these having reported encouraging interim data.

Paxalisib was granted Orphan Drug Designation for glioblastoma by the US Food and Drug Administration (US FDA) in February 2018, andFast 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 tumors 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 tumor typesand has provided evidence of synergy with immuno-oncology agents. A Phase I study in advanced solid tumors commenced recruitment in November 2021.

For more information, please visit www.kaziatherapeutics.com or follow us on Twitter @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, and Kazia’s strategy and plans with respect to its programs, including paxalisib and EVT801, as well as any potential future indications and timing for the release of interim or final data for such programs. 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

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