ASX RELEASE
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PHASE II STUDY OF PAXALISIB IN GLIOBLASTOMA ACHIEVES FINAL COMPLETION; DATA TO BE PRESENTED AT UPCOMING CONFERENCE

Sydney, 21 April 2022 – Kazia Therapeutics Limited (NASDAQ: KZIA; ASX: KZA), an oncology-focused drug development company, is pleased to announce that its phase II study of paxalisib in glioblastoma (NCT03522298) has been successfully completed.

A final clinical study report has been received by Kazia, and an abstract summarizing the results of the study has been accepted for presentation at an upcoming international clinical oncology conference.

Key Points

- The study recruited 30 patients with newly diagnosed glioblastoma and unmethylated MGMT promotor status, a genetic profile which confers primary resistance to temozolomide, the only existing FDA-approved drug treatment for first line treatment.
- 60mg once daily was identified as the maximum tolerated dose (MTD) and selected for future studies.
- Median overall survival (OS) in the intent-to-treat (ITT) population (n=30) was 15.7 months (11.1 – 19.1), which compares very favourably to 12.7 months historically reported with temozolomide in this patient group.[1]
- Median progression-free survival (PFS) in the ITT population was 8.4 months (6.6 – 10.2), representing a substantial increment over the comparable figure of 5.3 months associated with temozolomide.
- In the modified ITT (mITT) population (n=27), which includes only those patients evaluable for efficacy, OS increased to 15.9 months (12.8 – 19.1).
- The safety profile of paxalisib was highly consistent with previous clinical studies: hyperglycaemia, oral mucositis, and skin rash were among the most common drug-related toxicities.

[1] ME Hegi et al. (2005) *N Engl J Med*. 352:997-1003

Kazia CEO, Dr James Garner, commented, “we are very pleased to have successfully completed this last step in the phase II study of paxalisib, and we look forward to sharing detailed data with clinicians and investors over coming months. This study has greatly expanded our understanding of paxalisib, and the insights it has provided have informed all our subsequent work with the drug. We are grateful to the clinicians and patients that have participated. Paxalisib is now the subject of an ongoing pivotal study in glioblastoma, GBM AGILE, and we hope to see results from that study confirm the very positive signals seen in this phase II trial.”

Patrick Wen, MD, Principal Investigator at Dana-Farber Cancer Institute, commented, “we look forward to presenting the final data from this phase II study and continuing our investigations in the multi-drug GBM AGILE study. Glioblastoma is a devastating diagnosis and we are encouraged by the prospect of providing new hope to this patient community”

Pursuant to an agreement entered into by Novogen Limited, Kazia’s predecessor company, in November 2013, completion of this study satisfies the criteria for the third and final conversion event associated with a convertible note issued to certain shareholders of Triaxial Pty Ltd. The company will notify the issuance of shares under this agreement to ASX at the appropriate time.

Next Steps

The GBM AGILE pivotal study in glioblastoma commenced recruitment to the paxalisib arm in January 2021. At present, recruitment to the paxalisib arm is ongoing in the United States and Canada, and the study is expected to open in Europe and China during Q2 or Q3 of CY2022. Final data from the study is expected in 2H CY2023.

Seven other studies of paxalisib are ongoing in glioblastoma, in other forms of primary brain cancer, and in various forms of cancer that has metastasized to the brain. The upcoming conference presentation for the glioblastoma phase II trial will expand on the top-line data released in December 2021.

For More Information, Please Contact:-

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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 glioblastoma, the most common and most aggressive form of primary brain cancer in adults. Licensed from Genentech in late 2016, paxalisib commenced recruitment to GBM AGILE, a pivotal study in glioblastoma, in January 2021. Seven additional studies are active in various forms of brain cancer. 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.

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 www.kaziatherapeutics.com or follow us on Twitter @KaziaTx.

This document was authorized for release to the ASX by James Garner, Chief Executive Officer, Managing Director.