ASX RELEASE
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KAZIA PRESENTS PHARMACOKINETIC DATA FROM PAXALISIB PHASE II STUDY AT AACR ANNUAL MEETING

Sydney, 9 April 2021 – Kazia Therapeutics Limited (ASX: KZA; NASDAQ: KZIA), an Australian oncology-focused drug development company, is pleased to share new data from its ongoing phase II study of paxalisib in glioblastoma, the most common and most aggressive form of primary brain cancer.

The data is the subject of a poster presentation at the American Association of Cancer Research (AACR) Annual Meeting, which is being held virtually from 10-15 April 2021, and from 17-21 May 2021.

Key Points

- Pharmacokinetic (PK) data, which shows how long paxalisib remains in the human body, strongly supports 60mg once daily dosing, confirming planned administration schedule for commercial launch.
- Analysis of food effect shows no significant difference between taking paxalisib with food versus on an empty stomach, allowing for a less restrictive administration schedule in commercial use.
- Study remains ongoing, with a number of patients still in follow-up. Final data is now expected in 2H CY2021.

Kazia CEO, Dr James Garner, commented, “this is extremely useful and encouraging data, as we begin to compile regulatory documentation for paxalisib and give shape to its potential commercial approval. These results give us great confidence that we are administering the drug at the right dose, at the right frequency, and under the correct conditions. Moreover, the data helps to confirm the approach that we have taken in the GBM AGILE pivotal study.”

He added, “a lot of our efforts at present are focused on assembling the complex package of scientific information that is required to secure FDA approval for any new drug. Today’s data provides one more piece in that jigsaw. More broadly, the phase II study is drawing to a conclusion, and we expect to be able to share final data in the second half of this year.”

The poster can be viewed on the Company’s website at
https://www.kaziatherapeutics.com/researchpipeline/paxalisib

Background

The phase II study of paxalisib (NCT03522298) opened to recruitment in May 2018. It was designed to establish the most appropriate dose for use in newly-diagnosed patients, and to seek initial indications of potential clinical efficacy.

The study had previously determined a maximum tolerated dose (MTD) of 60mg, administered once daily. This determination was based primarily on safety findings, which suggested increased toxicity at a higher dose. Today's PK data corroborates this finding, and shows that increased doses provide limited additional benefit in terms of drug exposure. In effect, these two independent variables both point to a dose of 60mg, giving a high degree of confidence that this is appropriate for future studies and for commercialisation.

Interim analyses of efficacy data from this study have previously shown encouraging signals of clinical efficacy, with a median overall survival (OS) of 17.5 months and a median progression-free survival (PFS) of 8.4 months reported at the most recent data cut. These figures compare very favourably to historical controls for temozolomide, which provide an OS of 12.7 months and a PFS of 5.3 months.

The phase II study remains ongoing, with a number of patients in follow-up, and is expected to deliver final data in 2H CY2021.

In January 2021, paxalisib opened to recruitment in the GBM AGILE pivotal study, which is expected to provide the basis for registration in the US and other territories.

About Kazia Therapeutics Limited

Kazia Therapeutics Limited (ASX: KZA, 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 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 other 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. In March 2021, Kazia licensed Greater China rights for paxalisib to Simcere Pharmaceutical Company.

For more information, please visit www.kaziatherapeutics.com.

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