13 March 2024

Kazia announces presentation of new data at AACR Annual Meeting

Sydney, March 13, 2024 – Kazia Therapeutics Limited (NASDAQ: KZIA), a biotechnology company specialising in oncology, is pleased to announce the presentation of new data for both its pipeline molecules, paxalisib and EVT801, at the upcoming Annual Meeting of the American Association of Cancer Research (AACR) in San Diego, California, from 5-10 April 2024.

There will be three presentations in total at AACR, including data from the phase 1 study of EVT801 in advanced solid cancers. The data being presented will outline initial clinical data from the phase 1 study and provides support and direction for the next stage of the study.

In addition, data will be presented on the results of the combination therapy of paxalisib and gemcitabine for patients with relapsed/recurrent atypical teratoid/rhabdoid tumors AT/RT. Based on these findings, the Pacific Pediatric Neuro-Oncology Consortium (PNOC) is planning to include this therapy in its next AT/RT international clinical trial.

Summary of Abstracts

Session PO.CL01.15 - Early Detection Biomarkers 1
April 7, 2024 – 1:30pm-5:00pm
Abstract 1059 / 7: Biomarkers analysis on samples from patients in EVT801 clinical trial: Patient characterization and immunomonitoring
Evotec International GmbH, Toulouse, France, Kazia Therapeutics, Sydney, Australia, Institut Universitaire du Cancer Toulouse-Oncopole, Toulouse, France, Centre Léon Bérard, Lyon, France

Session PO.CTP01.01 - Phase I Clinical Trials in Progress 1
April 8, 2024 – 9:00am-12:30pm
Abstract CT088 / 15: EVT801, a novel selective VEGFR-3 inhibitor targeting tumor angiogenesis, is pursuing dose escalation stage of phase I first-in-human study

Session MS.CL08.01 - Novel Approaches for Targeted Therapies
April 9, 2024 – 2:50pm-3:05pm
Abstract 6565 - Improving survival of atypical teratoid/rhabdoid tumor orthotopic xenografts through the combination of PI3K inhibitor paxalisib and nucleoside analog gemcitabine

T. Findlay, K. Malebranche, A. Geethadevi, C. Eberhart, J. Rubens, E. Raabe
Johns Hopkins University School of Medicine, Baltimore, MD

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, is ongoing, with final data expected in 1H2024. 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 FDA in February 2018, and 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 is ongoing and preliminary data is anticipated in CY2024.

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 investigator-initiated trials of Kazia's product candidates, and Kazia's strategy and plans with respect to its programs, including paxalisib and EVT801. 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 United States Securities and Exchange Commission (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 announcement.

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