21 March 2024

Kazia Therapeutics licenses paxalisib to Sovargen for intractable seizures in rare central nervous system diseases

Sydney, March 21, 2024 – Kazia Therapeutics Limited (NASDAQ: KZIA), a biotechnology company specialising in oncology, is pleased to announce that it has entered into an exclusive licensing agreement with Sovargen Co., Ltd, a biotechnology company specializing in central nervous system (CNS) diseases, to develop, manufacture and commercialise paxalisib as a potential treatment of intractable epilepsy in focal cortical dysplasia type 2 (FCD T2) and tuberous sclerosis complex (TSC) disease. The underlying cause of FCD T2 and TSC can be traced back to somatic mutations in the PI3K/Akt/mTOR pathway or mutations in the TSC1 or TSC2 genes, which lead to the overactivation of the mTOR pathway. Paxalisib is an oral dual inhibitor targeting both PI3K and mTOR within this pathway, and it is distinguished by its ability to penetrate the brain. Although FCD T2 and TSC are rare orphan diseases, they represent a high medical unmet need with significant market opportunity. There are currently no approved drugs for patients with FCD T2.

Under the agreement, Kazia will receive an upfront payment of US$1.5 million, potential milestone payments of up to US$19 million upon the achievement of development and regulatory milestones, and a percentage of sub-licensing revenues and royalties on net sales of products incorporating paxalisib. The licensing agreement includes all countries worldwide, excluding mainland China, Hong Kong, Macao and Taiwan, which Kazia retains.

Kazia CEO Dr. John Friend said: “We are pleased to announce we have exclusively licensed the development, manufacture and commercialization of paxalisib to Sovargen for its potential use in select CNS diseases that are associated with mTORopathy. Kazia’s primary focus of paxalisib continues to be oncology, with multiple studies ongoing. Our license with Sovargen provides us the ability to explore the impact of paxalisib outside of our area of expertise where there is substantial patient need and market opportunity. We are enthusiastic about seeing paxalisib’s potential explored in these patient populations.”

Sovargen CEO Cheolwon Park shared his excitement about the collaboration: "The dual inhibition mechanism of paxalisib, coupled with its observed safety profile from previous oncology studies, positions us to anticipate initiation of a Phase 2 clinical trial for patients with FCD T2 and TSC in the latter half of 2024. Sovargen has played a pioneering role in identifying the critical link between mTOR hyperactivation due to mTORopathy somatic mutations and epileptic seizures in FCD T2 patients and we have an unwavering dedication to developing effective treatments for these patients.”

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.

About Sovargen

Sovargen Co., Ltd. is a biotechnology company focused on the discovery and development of drugs to treat rare and incurable neurological disorders that are caused by brain somatic mosaicism. Sovargen's platform technology is associated with ASO (Antisense Oligonucleotide) development for undruggable targets in CNS disease including technology for target discovery (SovarIN™), ASO drug discovery & optimization (SovarON™), and target validation & efficacy evaluation platform using disease-specific animal model and human organoid system (SovarUP™).

For more information, please visit www.sovargen.com

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: expansion of paxalisib into other indications including intractable epilepsy in focal cortical dysplasia type 2 (FCD T2) and tuberous sclerosis complex (TSC) disease, expectations regarding whether milestones will be met, expectations on market opportunities for paxalisib in FCD T2 and TSC, plans to initiate clinical trials for paxalisib in FCD T2 and TSC, 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.