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KAZIA ENTERS CLINICAL COLLABORATION TO INVESTIGATE USE OF BRAIN CANCER DRUG GDC-0084 IN BREAST CANCER

The Australian oncology-focused biotech Kazia Therapeutics announced today that it will collaborate with world-leading treatment and research centre Dana-Farber Cancer Institute to investigate the use of Kazia's potential new therapy for brain cancer, GDC-0084, in breast cancer that has spread to the brain.

The phase 2 clinical trial will investigate the effects of GDC-0084 in combination with the current standard of care, Herceptin (trastuzumab), in patients with HER2-positive breast cancer that has metastasised to the brain. About 10-15% of women with stage IV breast cancer develop brain metastases, according to Breastcancer.org.

The study is estimated to recruit between 22 and 49 patients, and will take up to three years to complete.

Kazia is developing GDC-0084 as a potential treatment for the primary form of brain cancer, glioblastoma multiforme). The drug targets the signaling pathway implicated in about 90% of glioblastoma cases, and is differentiated from other brain cancer treatments by its ability to cross the so called 'blood-brain' barrier that prevents many drugs from fully impacting the brain.

Kazia CEO, Dr James Garner said: "We strongly believe in the potential for GDC-0084 to bring benefit to patients with other forms of brain cancer beyond glioblastoma, and it is exciting to be working with the team at Dana-Farber to explore its potential use in this very challenging disease. It is extremely rewarding to be able to work with specialist researchers of this calibre, at a centre held in such high reputation, and we are committed to seeing this important study move forward."

Explaining the rationale behind the investigation of GDC-0084 as a HER2-positive breast cancer treatment, Kazia's GDC-0084 Clinical Program Director Dr Jeremy Simpson said:

"HER2 is a protein that promotes the growth of cancer cells. Approximately 20-30% of early-stage breast cancers show amplification of a gene associated with HER2, and these patients are generally treated with Herceptin, an anti-HER2 monoclonal antibody.

"The efficacy of Herceptin is well established. However, breast cancer can nevertheless spread to other parts of the body, a process described as metastasis, and in about a third of such cases the brain is the site to which it spreads. Such brain metastases are often highly

resistant to Herceptin, in contrast to the primary tumour, and there remains a substantial need for new therapies in this patient population. Recent research suggests that the PI3K pathway may represent an important part of this resistance mechanism, and so there is a sound rationale to explore GDC-0084, a brain-penetrant PI3K inhibitor, as a potential treatment for patients with breast cancer that has metastasized to the brain."

The Dana-Faber study will run alongside an ongoing phase II clinical trial of GDC-0084 in adults with newly-diagnosed glioblastoma. Trial sites are open in the US, with further sites to open in Australia in 2019.

Dana-Farber Cancer Institute is based in Boston, Massachusetts, and is a principal teaching affiliate of Harvard Medical School.

Analysts forecast that the HER2-positive treatment market is estimated to reach $12.7 billion by 2023[1].

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About Kazia Therapeutics Limited

Kazia Therapeutics Limited (ASX: KZA, NASDAQ: KZIA) is an innovative oncology-focused biotechnology company, based in Sydney, Australia. Our pipeline includes two clinical-stage drug development candidates, and we are working to develop therapies across a range of oncology indications.

Our lead program is GDC-0084, a small molecule inhibitor of the PI3K / AKT / mTOR pathway, which is being developed to treat glioblastoma multiforme, the most common and most aggressive form of primary brain cancer in adults. Licensed from Genentech in late 2016, GDC-0084 entered a phase II clinical trial in March 2018. Initial data is expected in early calendar 2019. GDC-0084 was granted orphan designation for glioblastoma by the US FDA in February 2018.

TRX-E-002-1 (Cantrixil), is a third-generation benzopyran molecule with activity against cancer stem cells, and is being developed to treat ovarian cancer. TRX-E-002-1 is currently undergoing a phase I clinical trial in Australia and the United States. Initial data was presented in June 2018 and the study remains ongoing. Cantrixil was granted orphan designation for ovarian cancer by the US FDA in April 2015.

[1] September 2014, Her-2 Positive Breast Cancer Global Drug Forecast and Market Analysis to 2023, Global Data PharmaPoint, GDHC86PIDR