

## Kazia to use drug with radiotherapy for brain cancer treatment

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Kazia Therapeutics Limited, an Australian oncology-focused biotechnology company, is pleased to announce that Memorial Sloan Kettering Cancer Center (MSK) in New York, NY will investigate the potential use of Kazia's investigational new drug, GDC-0084, in combination with radiotherapy in a phase I clinical trial for cancer that has spread to the brain (brain metastases and leptomeningeal metastases). This research will explore a new use of GDC-0084 and will run concurrently with other ongoing studies in different forms of brain cancer.

MSK will initiate a phase I clinical trial of GDC-0084 in combination with radiotherapy for patients with solid tumor brain metastases (cancer that has spread to the brain) and leptomeningeal metastases that harbors a genetic alteration in the PI3K pathway.

The trial is expected to recruit 18-30 patients and will take about two years to complete. The trial will be led by MSK, with Kazia providing support including study drug and a financial grant. Initiation of this study brings to five the total number of ongoing clinical trials with GDC-0084, each in different forms of brain cancer.

Up to 30% of patients with metastatic cancer will develop secondary tumors (metastases) in the brain. Radiotherapy remains the standard of care, but 30-50% of patients will progress within one year, despite best available treatment. In animal models of certain cancers, activation of the PI3K pathway has been shown to contribute to radiotherapy resistance. GDC-0084 is a PI3K inhibitor that can cross the blood-brain barrier, and as such it may be able to reduce the problem of resistance to radiotherapy. This clinical trial has been developed to test that hypothesis.

The study will be conducted under an 'investigator IND' with the US FDA, in which the primary regulatory responsibilities for the study will be assumed by MSK. Implementation of the study is conditional upon approval from the Institutional Review Board at MSK, and this approval has yet to be obtained.