Kazia Therapeutics has two novel classes of anti-cancer drugs: Edison Investment Research

Kazia Therapeutics Ltd (ASX:KZA) (NASDAQ:KZIA) has identified a higher maximum tolerated dose (MTD) from a Phase IIa study of its brain-penetrant phosphoinositide 3-kinase (PI3K) inhibitor GDC-0084 in glioblastoma (GBM), which may lead to improved efficacy in the ongoing expansion cohort and planned Phase IIb study.

READ: Kazia Therapeutics' ongoing study confirms higher drug tolerability in newly-diagnosed glioblastoma patients

GBM multiforme is the most common and aggressive form of primary brain cancer, with chemotherapy treatment temozolomide only effective in one-third of patients.

Furthermore, the median survival rate is 12-15 months from diagnosis, meaning there is demand in the market for superior treatments.

Edison Investment Research has assigned an indicative valuation range of $84-135 million or $1.35-2.17 per share for Kazia.

Following is an extract from Edison's pipeline update on Kazia:

Kazia Therapeutics is an Australian biotechnology company focused on oncology drug development, listed on both the ASX (KZA) and Nasdaq (KZIA).

It is developing GDC-0084, a brainpenetrant PI3K inhibitor licensed from Genentech, and a third-generation benzopyran drug, Cantrixil.

A new collaboration with the Alliance for Clinical Trials in Oncology (Alliance) means Kazia will soon have four clinical trials of GDC-0084 underway in primary or secondary brain cancers.

It also expects further preliminary efficacy data from its Cantrixil Phase I study in ovarian cancer in H219.

Higher MTD for GDC-0084 in target population

Kazia's Phase I study showed that recently diagnosed GBM patients were able to tolerate a higher (and therefore potentially more efficacious) dose of its oral PI3K inhibitor GDC-0084 than Genentech had reported from its prior study in patients with late-stage disease. A 20-patient expansion cohort is expected to report top-line efficacy data in Q419.

GDC-0084 is targeting an unmet need in GBM

The GBM trials will test GDC-0084 in patients who have an unmethylated MGMT promotor. This subgroup (~61% of GBM patients) obtains little benefit...
from standard temozolomide chemotherapy. Kazia may seek to position the planned Phase IIb study in GBM as a pivotal study designed to support filing for approval for this patient population who have no effective treatments. If this strategy is accepted, Kazia could be in a position to file for approval in this indication in 2023.

New collaboration targeting brain metastases

Kazia’s collaboration with the Alliance will target brain metastases that have genetic alterations of the PI3K pathway. The Phase II study will target brain metastases from a wide range of solid tumour types, allowing Kazia to fully capitalise on the capacity of GDC-0084 to penetrate the brain. The trial is expected to be completed in 2021.

Cantrixil expansion cohort data in H219

Potential efficacy signals from the 12-patient expansion cohort of the Phase I study of Cantrixil in ovarian cancer are expected to read out in H219. We expect Kazia to seek a partner to support the further development of Cantrixil in this indication.

Valuation: Adjusted to A$84-135m in two scenarios

We adjust our indicative valuation range to A$84-135m or A$1.35-2.17/share (vs A$84-146m, A$1.36-2.34/share), due to revised timelines for post-Phase III approval or single-pivotal-study approval scenarios for GDC-0084. Kazia had A$5.4m cash at 31 December 2018 and will likely need to raise funds in H219. We estimate ~A$15-20m will be needed to fully fund the GDC-0084 Phase IIb study.