Kazia Therapeutics Ltd

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

Kazia Therapeutics Ltd (ASX:KZA) (NASDAQ:KZIA) has confirmed a higher maximum tolerated dose (MTD) of 60 milligrams in new safety data from its ongoing phase-IIa clinical study of GDC-0084 in newly-diagnosed patients with glioblastoma (GBM).

Licensed from Genentech in October 2016, GDC-0084 is a novel targeted therapy that inhibits the PI3K pathway, important in many forms of cancer and activated in 85-90% of GBM cases.

Glioblastoma 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.

Kazia chief executive officer James Garner said this was an important milestone and the company was encouraged by the results.

The MTD of 60 milligrams is substantially higher than the 45-milligram dose found during Genentech's phase-I study in patients with recurrent disease.

Dose-limiting toxicities in this phase-IIa study included oral mucositis (mouth ulcers) and hyperglycemia (elevated blood sugar), both of which are expected effects of the PI3K inhibitor class of drugs.

READ: Kazia Therapeutics studies evaluate therapeutic candidates in ovarian cancer and brain tumours

Garner said: "Genentech's original phase-one study examined GDC-0084 in very advanced patients, who are often less able to tolerate therapy.

"They reached an MTD of 45 milligrams which is expected to be within the therapeutic range.

"When we licensed the drug from Genentech, we recognised the opportunity to refocus around newly-diagnosed patients, who are often in generally better health.

"The fact that the drug appears better tolerated here than in the previous study validates our strategy for GC-0084 and bodes well for the clinical efficacy of the drug."

Price: 0.445

Market Cap: $32.11 m

1 Year Share Price Graph

Share Information

Code:		KZA
Listing:		ASX
52 week	**High**	**Low**
	0.8	**0.32**
Sector:		**Pharma & Biotech**
Website:		**www.kaziatherapeutics.com**

Company Synopsis:

Kazia Therapeutics (ASX: KZA, NASDAQ: KZIA) pipeline includes two clinical-stage drug development candidates.

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Kazia's phase-IIa study of GDC-0084 is designed in two parts, the first of which began dosing in September last year and is now complete.

This was a dose optimisation component designed to determine if newly-diagnosed patients could tolerate a higher dose of GDC-0084 than advanced recurrent patients.

The second part is the dose expansion cohort, designed to provide confirmatory efficacy signals, for which Kazia expects to report initial data in the fourth quarter of calendar year 2019.

Kazia will recruit a further 20 patients for the dose expansion cohort, on top of the eight already recruited in the dose optimisation component.

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Garner continued: "The total clinical experience with GDC-0084 is now approaching 70 patients.

"The side effects that we have seen to date have all been very typical for this type of drug: mouth ulcers, high blood sugar, etc.

"Critically, we have not seen any of the more serious side effects that have sometimes been observed with other drugs in the class, such as infections, liver toxicity, or gastrointestinal problems.

"This is very reassuring as we prepare to take the drug forward into the next phase of development."

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