Kazia Therapeutics Ltd

10:15 16 Oct 2020

Kazia Therapeutics executes agreement to begin GBM Agile pivotal study

Kazia Therapeutics Ltd (ASX:KZA) has executed a definitive agreement with the Global Coalition for Adaptive Research (GCAR) to begin participation in the GBM AGILE pivotal study in glioblastoma.

The study is set to open a new arm with Kazia's investigational new drug, paxalisib, and will now move into an operational phase with recruitment of patients to the paxalisib arm expected to begin in the first quarter of 2021.

"Ground-breaking clinical trial"

Chief executive officer James Garner said: "We have spent the last nine months or so working closely with the GCAR team to plan paxalisib's entry into GBM AGILE and we are very gratified to now be moving into the operational phase of the study.

"GBM AGILE is truly a ground-breaking clinical trial, driven by some of the world's leading experts in the field, and we are proud to be a part of it.

"We expect GBM AGILE to provide definitive clinical evidence for the approval of paxalisib by regulatory agencies in key markets.

"This is a faster, more cost-effective, and higher quality study than any company of our size could mount independently, and we are confident that it will provide the best possible opportunity for paxalisib to demonstrate its potential in this very challenging disease."

Costs and timeline

Kazia will initially pay a fee of US$5 million to GCAR in consideration for paxalisib joining GBM AGILE.

Additional payments will be due throughout the duration of the study, dependent on the attainment of key milestones.

The full financial terms of the agreement between Kazia and GCAR are considered commercially confidential.

Additionally, the total cost of the study will depend on the number of patients ultimately recruited and other operational variables.

Kazia and GCAR expect that necessary regulatory filings and submissions to institutional review boards will be actioned during the current quarter.

The first patient in to the paxalisib arm is anticipated to occur early in 2021.

Principal investigators

GCAR chief executive officer Dr Meredith Buxton said: "We are pleased to welcome paxalisib into GBM AGILE.

Price: 0.81

Market Cap: $93.27 m

1 Year Share Price Graph

Share Information

Code:	KZA	
Listing:	ASX	
52 week	**High**	**Low**
	1.18354	**0.354583**
Sector:	**Pharma & Biotech**	
Website:	**www.kaziatherapeutics.com**	

Company Synopsis:

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

action@proactiveinvestors.com.au

"Our mission is to help drive the development of new therapies for glioblastoma, by creating an efficient model for testing and confirming new potentially beneficial treatments for patients with GBM.

"We look forward to continuing to work closely with the Kazia team to bring paxalisib into the study and support its evaluation."

Dr Ingo Mellinghoff and Dr Eudocia Q Lee will serve as principal investigators for the paxalisib arm while Dr Timothy Cloughesy is principal investigator for the overall study.

Dr Mellinghoff is the chair of the Department of Neurology at Memorial Sloan Kettering Cancer Center in New York, NY.

He is a highly experienced neuro-oncologist with an extensive track record of published research in brain tumours and is a professor at the Gerstner Sloan Kettering Graduate School of Biomedical Sciences and the Graduate School of Medical Sciences at Weill Cornell University.

Enriching understanding

Dr Lee is a neuro-oncologist at Dana-Farber Cancer Institute in Boston, MA, Director of Clinical Research at the Center for Neuro-Oncology at Dana-Farber, and an Assistant Professor of neurology at Harvard Medical School.

She is a widely published clinical researcher, with a primary research interest in tumours of the brain and spinal cord, and their neurologic complications.

Dr Lee said: "GBM AGILE has been designed to provide a definitive assessment of the efficacy of new drugs for glioblastoma.

"Paxalisib has already been evaluated in two clinical trials in this disease, and GBM AGILE will now greatly enrich our understanding of how best to use it for the benefit of patients."

GBM AGILE

GBM AGILE is an adaptive study where the number of patients recruited, and their allocation within the study, will be continuously adjusted in the light of emerging results.

It is expected that between 50 and 200 patients will receive paxalisib, depending on the safety and efficacy of the drug.

Data from these patients will be compared against data from an estimated several hundred patients in a shared control arm, allowing for considerable operational efficiency.

The primary endpoint of GBM AGILE is overall survival (OS), which is considered the gold standard endpoint for the assessment of new cancer therapies.

Proactive Investors facilitate the largest global investor network across 4 continents in 4 languages. With a team of analysts journalists & professional investors Proactive produce independent coverage on 1000's of companies across every sector for private investors, private client brokers, fund managers and international investor communities.

Contact us +61 (0)2 9280 0700 action@proactiveinvestors.com.au

No investment advice

The Company is a publisher. You understand and agree that no content published on the Site constitutes a recommendation that any particular security, portfolio of securities, transaction, or investment strategy is suitable or advisable for any specific person. You understand that the Content on the Site is provided for information purposes only, and none of the information contained on the Site constitutes an offer, solicitation or recommendation to buy or sell a security. You understand that the Company receives either monetary or securities compensation for our services. We stand to benefit from any volume which any Content on the Site may generate.

You further understand that none of the information providers or their affiliates will advise you personally concerning the nature, potential, advisability, value, suitability or profitability of any particular security, portfolio of securities, transaction, investment, investment strategy, or other matter.

You understand that the Site may contain opinions from time to time with regard to securities mentioned in other products, including Company-related products, and that those opinions may be different from those obtained by using another product related to the Company. You understand and agree that contributors may write about securities in which they or their firms have a position, and that they may trade such securities for their own account. In cases where the position is held at the time of publication and such position is known to the Company, appropriate disclosure is made. However, you understand and agree that at the time of any transaction that you make, one or more contributors may have a position in the securities written about. You understand that price and other data is supplied by sources believed to be reliable, that the calculations herein are made using such data, and that neither such data nor such calculations are guaranteed by these sources, the Company, the information providers or any other person or entity, and may not be complete or accurate.

From time to time, reference may be made in our marketing materials to prior articles and opinions we have published. These references may be selective, may reference only a portion of an article or recommendation, and are likely not to be current. As markets change continuously, previously published information and data may not be current and should not be relied upon.

The Site does not, and is not intended to, provide investment, tax, accounting, legal or insurance advice, and is not and should not be construed as providing any of the foregoing. You should consult an attorney or other relevant professional regarding your specific legal, tax, investment or other needs as tailored to your specific situation.

In exchange for publishing services rendered by the Company on behalf of Kazia Therapeutics Ltd named herein, including the promotion by the Company of Kazia Therapeutics Ltd in any Content on the Site, the Company receives from said issuer annual aggregate cash compensation in the amount up to Twenty Five Thousand dollars ($25,000).