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ASIA EDITION

Australia's Kazia enrolls its investigational drugs in glioblastoma clinical study

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The company announced its agreement with the Global Coalition for Adaptive Research (GCAR) to commence Kazia's participation in the GBM AGILE pivotal study in glioblastoma

Kazia Therapeutics Limited, an Australian oncology-focused biotechnology company, announced that it has executed a definitive agreement with the Global Coalition for Adaptive Research (GCAR) to commence Kazia's participation in the GBM AGILE pivotal study in glioblastoma. The study will open a new arm with Kazia's investigational new drug, paxalisib (formerly GDC-0084), and will now move into an operational phase with recruitment of patients to the paxalisib arm expected to begin in Q1 CY2021.

- GBM AGILE (NCT03970447) is intended to serve as the pivotal study for registration of paxalisib in key markets
- Dr Ingo Mellinghoff (Memorial Sloan Kettering Cancer Center) and Dr Eudocia Q Lee (Dana-Farber Cancer Institute) have been named as Principal Investigators for the paxalisib arm; Dr Timothy Cloughesy (UCLA) is the Principal Investigator for the overall study
- Kazia will pay an initial fee of US$ 5 million to GCAR, with further milestone payments payable throughout the course of the study
- The duration of paxalisib's enrollment period in GBM AGILE is expected to total approximately 30 – 36 months, plus follow-up, but will depend on emerging study data, recruitment rates, and other variables

GBM AGILE (Glioblastoma Adaptive Global Innovative Learning Environment) is an international platform study that has been established specifically to facilitate the approval of new medicines for glioblastoma.

The paxalisib arm of GBM AGILE will recruit newly diagnosed patients with unmethylated MGMT promotor status, which is the same population that has been investigated in Kazia's ongoing phase II study. In addition, GBM AGILE will recruit recurrent patients to the paxalisib arm. The drug may ultimately be considered efficacious in either or both of these patient groups, and Kazia will frame any future application for regulatory approval on the basis of this data.