

Kazia Therapeutics Ltd

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Kazia Therapeutics to collaborate with Dana-Farber Cancer Institute in paxalisib clinical trial for primary CNS lymphoma

Kazia Therapeutics Ltd (ASX:KZA) (NASDAQ:KZIA) is collaborating with Dana-Farber Cancer Institute (DFCI) in the US to investigate the use of Kazia's investigational new drug paxalisib (formerly GDC-0084) in primary central nervous system lymphoma (PCNSL).

DFCI will initiate an open-label phase II clinical trial of paxalisib in PCNSL and this study is expected to recruit up to 25 patients, taking up to two years to complete.

This study will be the sixth ongoing clinical trial of paxalisib in brain cancer and Kazia will provide support including study drug and a financial grant.

Kazia chief executive officer Dr James Garner said: "This is an exciting new opportunity for the paxalisib program.

"We are delighted to support the team at Dana-Farber to explore the potential for paxalisib to benefit patients with PCNSL.

"Dana-Farber is one of the world's leading centres of excellence in this disease, so we are immensely fortunate to be working with them.

"We are pleased also to see a new and important target added to the broader paxalisib clinical program, and we look forward to seeing the project commence."

Clinical trial design

Dana Farber Cancer Institute will launch a single-arm phase II clinical trial in patients with relapsed or refractory PCNSL, who are resistant to existing treatments.

The primary endpoint will be to assess efficacy via overall response rate (ORR), which measures the ability of paxalisib to shrink tumours.

Safety and other efficacy endpoints will also be captured.

The study will also examine tissue and cerebrospinal fluid samples to identify potential predictors of response.

Commencement of recruitment to the study is expected in early 2021 but is subject to receiving necessary approvals from FDA and from institutional review boards.

Kazia will provide financial support to the study using a portion of the funds contributed by shareholders in the share purchase plan conducted in May 2020.

Price: 1.34

Market Cap: \$126.8 m

1 Year Share Price Graph



November 2019 June 2020 November 20

Share Information

Code: KZA

Listing: ASX

52 week High Low
1.78 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.

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Primary CNS Lymphoma

Lymphoma is a haematological malignancy (blood cancer) that originates from lymphocytes, a type of white blood cell involved in the immune system and PCNSL is a specific form of the disease that originates in the brain and central nervous system.

Three of the four PI3K inhibitors approved by the US Food and Drug Administration (FDA) are treatments for various forms of lymphoma, provide a strong validation for PI3K as a target in this disease.

Paxalisib is the only PI3K inhibitor in mainstream development with the ability to penetrate the blood-brain barrier, and as such has a unique rationale for development in PCNSL.

Next steps

The initiation of this trial in PCNSL brings the number of ongoing clinical studies of paxalisib in brain cancer to six.

Kazia completed recruitment to a phase II clinical trial of paxalisib in newly-diagnosed glioblastoma in February 2020, and interim clinical data was presented at the AACR Virtual Annual Meeting II in June 2020.

Overall survival was calculated at 17.7 months, which compares favourably to an historical figure of 12.7 for temozolomide, the existing FDA approved standard of care.

Kazia expects to present further data from this study before the end of this year and to conclude the study in early 2021.

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