

Kazia Therapeutics

Pivotal phase 3 study underway

Kazia Therapeutics (ASX:KZA) is an oncology focused drug development company with lead candidate paxalisib targeting multiple forms of brain cancer. Paxalisib is a brain-penetrant PI3K inhibitor with a lead indication in glioblastoma, the most common and aggressive brain cancer in adults with few treatment options and no new drug approvals since 2009. KZA began recruiting for a pivotal phase 3 trial in January 2021 with the primary endpoint overall survival. The phase 3 is an innovative “platform” study evaluating multiple drugs at the same time and is fully funded. Orphan Drug and Fast Track designation have been granted for the candidate/indication, promising a quicker path to commercialisation should the phase 3 study be successful. The other clinical studies include two phase 1 trials in DIPG, a phase 2 in CNS Lymphoma and three phase 2 trials in Brain Metastases that promise multiple data readouts over the next 12 to 24 months. KZA has recently added another licensed drug to their portfolio in the form of EVT801, a small molecule VEGFR3 inhibitor licensed from Evotec targeting lymphangiogenesis, with a phase 1 study due to commence 2HCY21. The group’s cash burn ex recent license fees received from Simcere in China for paxalisib was A\$4.3m per quarter, representing 6 quarters of cash before the costs of EVT801 are taken into consideration.

Business model

KZA’s business model is to license drugs/technology under development and assume the rights and responsibility for the development, manufacturing and commercialisation of the drug. This model avoids the time consuming and often expensive pre-clinical development, and typically comprises an initial upfront payment, development milestones, commercial milestones and royalties. The first drug acquired under this model was paxalisib, a brain-penetrant PI3K inhibitor of the PI3K/Akt/mTOR pathway developed by Genentech. KZA recently licensed EVT801, a small molecule VEGFR3 inhibitor from Evotec targeting lymphangiogenesis.

Paxalisib has eight clinical studies underway in brain cancers

Securing a pathway for a notoriously difficult indication or “unmet need” such as glioblastoma typically allows the developer to examine the suitability of the drug in other indications, and KZA has followed this model. Indications for paxalisib have been extended to DIPG, a highly aggressive childhood brain cancer, CNS lymphoma an uncommon form of non-Hodgkin’s lymphoma and brain metastases, which spreads from elsewhere in the body to the brain. In total KZA will have nine trials at various stages underway by the end of CY21 and a further trial of EVT801 in advanced solid tumours.

Domestic listed peers but difficult indications

Comparing biotech stocks with different technologies across different indications is complex. Addressable markets, stage of development, strength and terms of patents, licensing terms, ability to manufacture at commercial scale and potential partners are just some of the considerations. Companies that have adopted similar models to KZA with difficult indications and at an early to mid-stage of development include Immunet (ASX:IMM), Paradigm (ASX:PAR), Antisense Therapeutics (ASX:ANP) and Actinogen (ASX:ACW).

Biotechnology

10th September 2021

Share details

ASX Code	KZA
Share price	\$1.42
Market Capitalisation	\$186.0M
Shares on issue	131.0M
Net cash at 30/06/2021	\$27.5M
Free float	80.8%

Share performance (12 months)



Upside Case

- Successful pivotal phase 3 GBM study
- Multiple readouts from (8) other studies
- Further on-licensing of technology

Downside Case

- Phase 3 overall survival rates <12-months
- Patient recruitment disruptions
- Ability to access funding for trial progression

Catalysts/upcoming events

- Continued dosing of patients (ongoing)
- Phase 1 trial result readout

Comparable companies (Aust/NZ)

Immunet (ASX:IMM), Paradigm (ASX:PAR), Antisense Therapeutics (ASX:ANP), Actinogen (ASX:ACW)

Top 5 shareholders*

Willoughby Capital	11.7%
Quest Asset Partners	8.4%
Platinum Asset Mgt	5.6%
UniSuper	4.5%
MNA Family Holdings	1.6%

*Source: Refinitiv Eikon

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