Kazia Therapeutics

Clinical trial expansion

PNOC022 trial expanded

Pharma and biotech

Kazia Therapeutics has announced the expansion of the PNOC022 (NCT05009992) trial to two new sites in Australia. The Phase II trial is investigating the combination of ONC201 (a dopamine D2 receptor antagonist) and paxalisib (Kazia's brain penetrant PI3K inhibitor) in the treatment of diffuse midline glioma (DMG) and diffuse intrinsic pontine glioma (DIPG). Importantly, the PNOC022 trial, which is sponsored by the Pacific Pediatric Neuro-Oncology Consortium, uses an adaptive platform design, meaning new arms of the trial can be opened or closed based on the data gathered. Considering this, we see the expansion of PNOC022 as encouraging support for the paxalisib/ONC201 combination; however, we will wait to see initial clinical data (expected in CY23) before drawing more material conclusions.

Year end	Revenue (US$m)	PTP* (US$m)	EPADR* (US$)	DPADR (US$)	P/E (x)	Gross yield (%)
06/21	10.5	(3.1)	(0.25)	0.0	N/A	N/A
06/22	0.0	(14.6)	(1.08)	0.0	N/A	N/A
06/23e	0.0	(18.6)	(1.23)	0.0	N/A	N/A
06/24e	10.6	(16.8)	(1.11)	0.0	N/A	N/A

Note: *Converted at A$1.45/US$. Dividend yield excludes withholding tax. Investors should consult their tax advisor regarding the application of any domestic and foreign tax laws.

As a reminder, DIPG and DMG are particularly aggressive and invasive high-grade (Grade IV) glioma that mostly affect young children. DIPG is predominantly diagnosed in children aged five to 10 and rarely occurs in the adult population. While the incidence of DIPG is low (one to two per 100,000 in the United States, ~300 new pediatric cases per year), most patients will survive less than one year after diagnosis (median overall survival rate 9–11 months). Paxalisib has previously demonstrated, in our view, encouraging clinical and preclinical effects in these indications (for more detail see our Deep dive into childhood brain cancer).

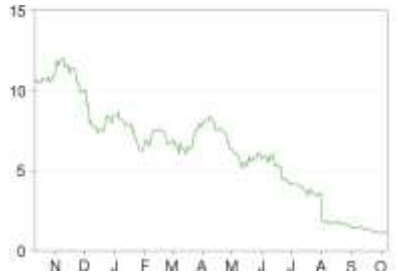
The PNOC022 trial is enrolling children and young adults with DMGs (including DIPG) and will include newly diagnosed and pretreated (with radiotherapy) patients. The adaptive platform design will see all patients administered a combination of paxalisib and ONC201. As such, the newly announced Australian sites will see the first clinical trial of paxalisib in this region. Kazia has communicated that recruitment for the trial has been robust, hence initial primary endpoint data (six-month progression-free survival and overall survival at seven months) is expected to be reported in CY23.

We value Kazia Therapeutics at US$146.6m or US$9.79 per basic ADR.

10 October 2022

Price	**$1.23**
Market cap	**$18m**
	ADR/Ord conversion ratio 1:10
Pro forma net cash (US$m) including $2.5m raised after 30 June 2022	7.6
ADRs in issue	14.96
ADR code	KZIA
ADR exchange	Nasdaq
Underlying exchange	ASX
Depository	BNY

ADR share price performance



Business description

Kazia Therapeutics is a late-stage clinical pharmaceutical company with lead asset paxalisib (a PI3K inhibitor that can cross the blood-brain barrier, licensed from Genentech) in a pivotal study for GBM and in early-stage studies in childhood brain cancers, DIPG and AT/RT. The other asset is the Phase I drug EVT801, an inhibitor of VEGFR3.

Next events

Interim data from EVT801 Phase I study	H1 CY23
Phase III GBM AGILE top-line data	H2 CY23
Interim data from Phase II PNOC022	CY2023

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Australia

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