

ASX RELEASE
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MANUFACTURING PATENTS GRANTED FOR PAXALISIB IN KEY TERRITORIES; EXTEND EFFECTIVE PATENT PROTECTION TO 2036

Sydney, 24 June 2021 – Kazia Therapeutics Limited (NASDAQ: KZIA; ASX: KZA), an oncology-focused drug development company, is pleased to announce the grant of patents by the respective agencies of the United States and India in respect of the manufacturing process for paxalisib. A similar patent has been accepted in Australia and is expected to proceed to grant in 3Q CY2021. Further patents remain pending in the EU, China, Canada, and other strategic territories and are expected to also be approved in due course.

Key Points

- Existing ‘composition of matter’ patents for the chemical structure of paxalisib generally expire in 2031 but are likely to be eligible for a five-year patent term extension in key territories.
- These newly granted manufacturing patents provide an additional layer of protection by covering the process by which paxalisib is manufactured. Any generic competitor would need to develop an alternative method of chemical synthesis, which is technically challenging and hence a costly exercise. The new patents expire in 2036.

Kazia CEO, Dr James Garner, commented, “as we move towards commercialisation, we have worked closely with our IP counsel to ensure we achieve the maximum possible degree and duration of protection for the intellectual property embodied in paxalisib. The original patents for paxalisib protect its chemical structure and have been granted in almost all relevant territories. The new suite of patents additionally covers the process by which paxalisib is manufactured and, together with the original composition of matter patents, provide exceptionally robust protection. The manufacturing patents are now granted in the US and India, and are also expected to be granted in other key territories after review by the respective patent agencies.”

Next Steps

GBM AGILE, the pivotal study for registration of paxalisib, is currently underway in the United States and is expected to open in Europe during 2H CY2021.

Board of Directors

Mr Iain Ross Chairman, Non-Executive Director

Mr Bryce Carmine Non-Executive Director

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About Kazia Therapeutics Limited

Kazia Therapeutics Limited (NASDAQ: KZIA; ASX: KZA) is an oncology-focused drug development company, based in Sydney, Australia.

Our lead program is paxalisib, a brain-penetrant inhibitor of the PI3K / Akt / mTOR pathway, which is being developed to treat glioblastoma, the most common and most aggressive form of primary brain cancer in adults. Licensed from Genentech in late 2016, paxalisib commenced recruitment to GBM AGILE, a pivotal study in glioblastoma, in January 2021. Eight additional studies are active in various forms of brain cancer. Paxalisib was granted Orphan Drug Designation for glioblastoma by the US FDA in February 2018, and Fast Track Designation for glioblastoma by the US FDA in August 2020. In addition, paxalisib was granted Rare Pediatric Disease Designation and Orphan Designation by the US FDA for DIPG in August 2020.

Kazia is also developing EVT801, a small-molecule inhibitor of VEGFR3, which was licensed from Evotec SE in April 2021. Preclinical data has shown EVT801 to be active against a broad range of tumour types and has provided compelling evidence of synergy with immuno-oncology agents. A phase I study is expected to begin in CY2021.

For more information, please visit www.kaziatherapeutics.com or follow us on Twitter @KaziaTx.

This document was authorized for release to the ASX by James Garner, Chief Executive Officer, Managing Director.