ASX RELEASE

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EVT801 PHASE I STUDY RECEIVES FULL REGULATORY APPROVAL

Sydney, 2 September 2021 – Kazia Therapeutics Limited (ASX: KZA; NASDAQ: KZIA), an oncology-focused drug development company, is pleased to inform stakeholders that the planned phase I study for EVT801 has received full approval from L'Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM), the French regulatory agency. The study is on track to open to recruitment by the end of CY2021.

Key Points

- Kazia licensed EVT801 from Evotec SE, an international drug discovery alliance and development partnership company, in April 2021.
- EVT801 is a small molecule inhibitor of VEGFR3, and inhibits lymphangiogenesis, the formation of new lymphatic vessels within and around a tumour. The drug modulates the activity of the immune system, creating the possibility for synergistic combination with immuno-oncology therapies.
- The phase I study will be performed in France. It is planned to recruit patients with advanced tumours at two leading cancer hospitals: Oncopole in Toulouse and Centre Léon Bérard in Lyon. Recruitment is expected to start by end of CY2021.

Kazia CEO, Dr James Garner, commented, "since concluding our license agreement with Evotec in April, we have made very swift progress in bringing EVT801 to the clinic. We have been grateful for the exceptional efforts of the Evotec team, working closely with Kazia colleagues to drive the project forward. The study that we have designed is highly innovative, which befits the rich potential of EVT801, and we look forward to commencing recruitment in the near future."

EVT801 is a novel inhibitor of vascular endothelial growth factor receptor 3 (VEGFR3), which is central to lymphangiogenesis, the formation of new lymphatic vessels within and around a tumour. A number of highly successful cancer drugs have targeted angiogenesis, the formation of new blood vessels, and these include Avastin (bevacizumab), Sutent (sunitinib) and Nexavar (sorafenib). However, anti-angiogenic agents are limited by treatment resistance and some agents are associated with substantial toxicity. Compelling preclinical evidence suggests that the novel mechanism of EVT801 may circumvent these challenges and provide lasting benefit to patients with lower toxicity.

In addition, EVT801 has shown the ability to enhance the activity of the immune system within the tumour, offering the potential for combination with immuno-oncology agents. It is expected that this combination approach will play a substantial and early role in the clinical development plan for EVT801.

Next Steps

Kazia expects to provide full details regarding the design and implementation of the study around the time that it commences recruitment. In the meantime, the company will work closely with the Evotec team and with the participating investigators to activate the study.

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 other 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.