ASX RELEASE

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WORLD HEALTH ORGANISATION PUBLISHES PROPOSED INTERNATIONAL NONPROPRIETARY NAME FOR KAZIA'S BRAIN CANCER DRUG, GDC-0084

Sydney, 23 August 2019 – Kazia Therapeutics Limited (ASX: KZA; NASDAQ: KZIA), an Australian oncology-focused biotechnology company, is pleased to announce that the World Health Organisation (WHO) has selected '**paxalisib**' as the proposed international nonproprietary name (INN) for Kazia's investigational new drug GDC-0084.

Kazia is developing GDC-0084 for the treatment of various forms of brain cancer. The lead indication is glioblastoma, the most common and most aggressive form of primary brain cancer. Four clinical studies are currently underway in different forms of brain cancer, with data expected during the second half of calendar 2019.

The selection of paxalisib as an international nonproprietary name (INN) for GDC-0084 represents an important regulatory milestone on its pathway to becoming a commercial drug. It provides a more identifiable name for clinicians and researchers to use in relation to the drug and follows standard naming conventions laid down by WHO. Selection of an INN is usually a necessary step before a new drug can be submitted for commercial registration.

The name has been published by WHO in the 121st list of Proposed International Nonproprietary Names on 21 August 2019. The proposed name is subject to a four-month period for comment before paxalisib can be confirmed as the INN. Subject to completion of the selection procedure, the name will be formalised by the end of calendar 2019.

The selection of paxalisib as the proposed INN for GDC-0084 is consistent with other approved drugs in the PI3K inhibitor class, which includes idelalisib, copanlisib, duvelisib, and alpelisib. The suffix '-lisib' is used to denote drugs in the PI3K inhibitor class.

Subject to successful completion of WHO's confirmation procedure, Kazia will begin including the name paxalisib in documentation and communications relating to GDC-0084 and will eventually discontinue public use of the GDC-0084 code number.

Background

New drugs typically receive at least three names during their development. The first name is a company code number, which is used primarily for internal administration purposes during the early stages of development. This code number is chosen by the company that is developing the drug, according to their internal naming conventions. GDC-0084 is an example of such a code number and was selected by Genentech, who originally developed the drug.

The international nonproprietary name (INN) is usually selected around the time of phase II clinical trials. INNs are chosen by the World Health Organisation (WHO) or, for the United States, by the United States Adopted Names Council (USAN), based on recommendations and information supplied by the sponsor company. There are strict guidelines regarding the format of INNs and they are not finally determined by the sponsor company. The INN cannot be trademarked and is not owned by the sponsor company. The INN is used to refer to any product that contains that active drug, regardless of manufacturer. An example of an INN is paracetamol, which is used in the description of any product containing that drug as an active ingredient.

At the time of a product registration, or New Drug Application (NDA) in the US, a drug is given its third name, which is a commercial brand name. This is chosen by the sponsor company, remains trademarked as the exclusive property of that company, and is approved in each country by national regulatory agencies such as FDA and TGA. An example of a brand name is Panadol®, which is exclusively used by the pharmaceutical company GlaxoSmithKline to refer to their range of products containing paracetamol.

By convention the commercial brand name is usually capitalized, whereas the INN is not. When both are used, the INN is typically placed in brackets after the commercial brand name, for example: Zantac® (ranitidine), Prozac® (fluoxetine), Viagra® (sildenafil), Herceptin® (trastuzumab), or Zydelig® (idelalisib).

The commercial brand name of GDC-0084 has not yet been chosen and will be developed as the drug nears a commercial registration, in accordance with guidelines from FDA and other national regulatory agencies.

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About Kazia Therapeutics Limited

Kazia Therapeutics Limited (ASX: KZA, NASDAQ: KZIA) is an innovative oncology-focused biotechnology company, based in Sydney, Australia. Our pipeline includes two clinical-stage drug development candidates, and we are working to develop therapies across a range of oncology indications.

Our lead program is GDC-0084, a small molecule inhibitor of the PI3K / AKT / mTOR pathway, which is being developed to treat glioblastoma multiforme, the most common and most aggressive form of primary brain cancer in adults. Licensed from Genentech in late 2016, GDC-0084 entered a phase II clinical trial in 2018. Initial safety data was released in May 2019, and efficacy data is expected in 2H 2019. GDC-0084 was granted orphan designation for glioblastoma by the US FDA in February 2018.

TRX-E-002-1 (Cantrixil), is a third-generation benzopyran molecule with activity against cancer stem cells, and is being developed to treat ovarian cancer. TRX-E-002-1 is currently undergoing a phase I clinical trial in Australia and the United States. Initial data was presented at the AACR annual conference in April 2019 and the study remains ongoing. Cantrixil was granted orphan designation for ovarian cancer by the US FDA in April 2015.