ASX:NRT
NASDAQ:NVGN

Novogen Ltd
(Company)

ABN 37 063 259 754

Capital Structure

Ordinary Shares on issue:

450 M

Board of Directors

Mr John O'Connor
Chairman
Non-Executive Director

Mr Bryce Carmine
Deputy Chairman
Non-Executive Director

Dr James Garner
Chief Executive Officer
Managing Director

Mr Ian Phillips MNZM
Non-Executive Director

Mr Iain Ross
Non-Executive Director

Mr Steven Coffey
Non-Executive Director

MARKET RELEASE
31 October 2016

NOVOGEN LICENSES PHASE II-READY MOLECULE FROM GENENTECH FOR DEVELOPMENT IN GLIOBLASTOMA

- **Licensing of GDC-0084, a small molecule phosphoinositide-3-kinase (PI3K) inhibitor developed by Genentech, is ready to enter a phase II clinical trial in glioblastoma multiforme (GBM)**

Sydney, 31st October 2016 – Australian oncology-focused biotechnology company, Novogen Ltd (ASX: NRT; NASDAQ: NVGN) today announced that it has entered into a worldwide licensing agreement with Genentech, a member of the Roche Group, to develop and commercialise GDC-0084, a small molecule inhibitor of the phosphoinositide-3-kinase (PI3K) pathway.

The lead indication for GDC-0084 is glioblastoma multiforme (GBM), which is the most aggressive form of brain cancer, accounting for approximately 15% of primary brain tumours. Median overall survival is considered to be approximately 12 – 15 months from the time of diagnosis.[1]

Therapies targeting the PI3K pathway have been under development by a number of pharmaceutical and biotechnology companies for several years, in various types of cancer. GDC-0084 is distinguished from most molecules in the class by its ability to cross the blood-brain barrier, potentially making it suitable for cancers of the central nervous system.

Genentech has completed a phase I study of GDC-0084 in patients with recurrent GBM, and data was presented at the American Society of Clinical Oncology (ASCO) annual meeting in Chicago, IL in June 2016[2]. The study recruited 47 patients at five centres in the United States and Spain, including UCLA, Dana-Farber Cancer Institute, and Massachusetts General Hospital. In addition, GDC-0084 has an open Investigational New Drug (IND) application with the United States Food and Drug Administration (FDA),

[1] World Health Organisation. *World Cancer Atlas 2014*
[2] PY Wen, T Cloughesy, A Olivero, *et al*. (2016). Poster Presentation 2012, Annual Meeting of the American Society for Clinical Oncology (Chicago, IL)

and the transaction includes a quantity of pre-manufactured drug substance that is expected to be sufficient to support a proposed phase II clinical trial.

Novogen CEO, Dr James Garner, commented, “We are excited that Genentech has entrusted us to take forward this promising investigational medicine in one of the most challenging areas of cancer treatment.

This is a transformative step for Novogen, and the addition of GDC-0084 to our portfolio strengthens our position as an emerging oncology biotech company. Our pipeline is now diversified across three distinct technology platforms, and we anticipate it will provide a rich flow of value-driving milestones as the company progresses.”

He added, “The PI3K inhibitor class is well-validated and is of considerable interest to larger pharmaceutical companies. While a number of development candidates are in clinical trials across a range of cancer types, we believe GDC-0084 is well differentiated and represents an important opportunity to contribute to the treatment of patients with glioblastoma.”

Under the terms of the agreement, Novogen will pay Genentech an upfront payment of US$ 5 million and performance-related consideration linked to regulatory and commercial outcomes. In addition, Genentech will receive royalty payments in-line with industry benchmarks.

Genentech will immediately initiate transfer of the IND for GDC-0084 to Novogen, as well as key manufacturing and analytical processes. Novogen anticipates being able to provide an update to the market in the design, project cost, and timelines of the proposed phase II study early in the new year.

[ENDS]

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About the GDC-0084 development candidate

GDC-0084 is a small molecule inhibitor of the PI3K / AKT / mTOR pathway, which is distinguished from other molecules in the class by its ability to penetrate the blood-brain barrier. The molecule was developed by Genentech, who completed a phase I study in recurrent glioblastoma patients, and was licensed to Novogen in October 2016. A phase II clinical trial is slated to begin in 2017.

About Novogen Limited

Novogen Limited (ASX: NRT; NASDAQ: NVGN) is an emerging oncology-focused biotechnology company, based in Sydney, Australia. Novogen has a portfolio of four development candidates, diversified across three distinct technologies, with the potential to yield first-in-class and best-in-class agents across a range of oncology indications.

The lead program is GDC-0084, a small molecule inhibitor of the PI3K / AKT / mTOR pathway, which is being developed to treat glioblastoma multiforme. Licensed from Genentech in late 2016, GDC-0084 is anticipated to enter phase II clinical trials in 2017. Three further molecules have been developed in-house from two proprietary drug discovery platforms (superbenzopyrans and anti-tropomyosins) to treat ovarian cancer and a range of solid tumours. Cantrixil, the most advanced of these, is slated to enter clinical trials in late 2016, while Anisina and Trilexium are in preclinical development.

For more information, please visit: www.novogen.com