ASX:NRT
NASDAQ:NVGN

Novogen Ltd
(Company)

ABN 37 063 259 754

Capital Structure

Ordinary Shares on issue:

483 M

Board of Directors

Mr Iain Ross
Chairman
Non-Executive Director

Mr Bryce Carmine
Non-Executive Director

Mr Steven Coffey
Non-Executive Director

Dr James Garner
Chief Executive Officer
Managing Director

ASX RELEASE

25 SEPTEMBER 2017

GDC-0084 PROGRESS UPDATE: PHASE II STUDY REMAINS ON TRACK TO START BY END OF 2017 AFTER FDA CONSULTATION

Sydney, 25 September 2017 – Novogen Ltd (ASX: NRT; NASDAQ: NVGN), an Australian oncology drug development company, is pleased to provide an update on progress with its clinical-stage drug development candidate, GDC-0084. GDC-0084 was in-licensed from Genentech, Inc in October 2016, after it had completed a phase I clinical trial in advanced glioma. Novogen is taking GDC-0084 into a phase II clinical trial in the treatment of glioblastoma multiforme (GBM).

Key Highlights

- Highly constructive meeting held with US Food and Drug Administration (FDA) on 21 September in relation to the proposed phase II clinical study of GDC-0084; key features of study design remain substantially as proposed
- Phase II study in adult GBM patients remains on track to launch before the end of 2017
- Independently of FDA feedback, study design has been refined to include a lead-in component which aims to optimize dosing in the target population, leading to an earlier preliminary data read-out approximately 12-15 months after commencement, and substantial de-risking of the overall program
- Letter of Intent (LOI) signed with Chiltern Oncology, a leading international contract research organization, as part of study initiation activity

Novogen CEO, Dr James Garner, commented on recent progress, "We are grateful to FDA for their careful evaluation and considered advice and we are encouraged by their engagement with the program. The study remains on track for commencement by the end of calendar 2017, and we are confident that our approach is optimized for success."

Outcome of FDA Consultation

Novogen conducted a Type B meeting with FDA on Thursday 21st September at the FDA's Center for Drug Evaluation and Research in Maryland, in order to discuss the proposed clinical development plan for GDC-0084 in adult patients with GBM.

It is anticipated that written minutes of the meeting will be received in due course. However, Novogen is confident following the meeting that the study remains on schedule to commence by the end of calendar 2017, and that the key design features remain substantially unchanged.

Novogen looks forward to working with the FDA, and with the clinician community, throughout this development program in order to rapidly understand the potential benefit of GDC-0084 for patients with GBM.

Study Design Refined to Accommodate Lead-In Dose Optimisation Component

Independently of FDA feedback, and in consultation with its clinician advisors, Novogen has elected to include a lead-in component in the phase II study that will seek to optimize dosing in the intended patient population.

The phase I study conducted by Genentech was performed in patients with high-grade gliomas (WHO Grade III-IV), including glioblastoma, and all patients had progressed during or after treatment with at least one prior line of therapy. Novogen intends to conduct the phase II study only in patients with glioblastoma, and in a first-line setting, so it considers that there may be potential to deliver a higher dose or to improve the dosing regimen.

The staged approach, with the inclusion of a lead-in component, will help to substantially de-risk the overall phase II program, and will provide an initial data read-out approximately 12-15 months after commencement.

Letter of Intent Signed with Chiltern Oncology

Novogen announced in August 2017 that it had entered into a Master Services Agreement (MSA) with Chiltern Oncology, a leading international Contract Research Organization (CRO). Further to that MSA, Novogen has now signed a Letter of Intent (LOI) with Chiltern Oncology, which provides for initiation of set-up activities for the study.

[ENDS]

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. PI3K inhibitors have shown evidence of clinical activity in a broad range of tumor types, and one product in the class has reached market for several hematological malignancies. GDC-0084 was developed by Genentech, who completed a phase I study in patients with recurrent glioma, and was licensed to Novogen in October 2016. A phase II clinical trial is slated to begin in the fourth quarter of calendar 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 development candidates, diversified across several distinct technologies, with the potential to yield first-in-class and best- in-class agents in 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. A second clinical program, TRX-E-002-01 (Cantrixil) commenced a phase I clinical trial in ovarian cancer in December 2016. In addition, the company has several preclinical programs in active development, the largest of which is substantially funded by a CRC-P grant from the Australian Federal Government.

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