ASX:NRT
NASDAQ:NVGN

Novogen Ltd
(Company)

ABN 37 063 259 754

Capital Structure

Ordinary Shares on issue:

483 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
6 December 2016

NOVOGEN ENROLS FIRST PATIENT INTO INTERNATIONAL PHASE I STUDY OF CANTRIXIL™ IN OVARIAN CANCER

- Cantrixil (TRX-E-002-1) is one of Novogen's four oncology development candidates, and is being developed as a therapy for patients with ovarian cancer

- Phase I study is designed primarily to understand the safety and tolerability of Cantrixil in ovarian cancer patients, and will be run at hospitals in US and Australia

- It is anticipated that up to 60 patients will be recruited and the study will run for approximately 18 months

Sydney, 6 December 2016 – Australian oncology-focused biotechnology company Novogen Ltd (ASX: NRT; NASDAQ: NVGN) today announced that it had enrolled the first patient into its first-in-human, phase I clinical study for Cantrixil (TRX-E-002-1) in ovarian cancer. Opening the study represents an important clinical and commercial milestone for Novogen.

Dr Kimberley Lilischkis, Clinical and Regulatory Affairs Director, commented, "the commencement of this trial represents a further step in Novogen's transition to a clinical-stage drug development company, and we are excited to be working with leading clinicians in the US and Australia on this critical project.

"Novogen is focused on developing treatments for patients with the highest unmet medical need and those who are inadequately served by existing therapies. We hope that Cantrixil will have the potential to offer a meaningful new treatment option for patients with ovarian cancer," she said.

The Cantrixil phase I study is designed primarily to assess the appropriate dosage, safety and tolerability of Cantrixil when administered to patients with ovarian cancer who have failed at least two prior lines of chemotherapy.

Although the study is not designed to assess efficacy, patients will also be monitored for radiological evidence of disease response, and exploratory biomarkers will be assessed. In addition, after an initial period of treatment with Cantrixil alone, clinicians will be permitted to add other approved therapies, which will provide useful information regarding the ability of Cantrixil to be used in combination with standard-of-care chemotherapy.

The study will begin by administering Cantrixil at a low dose, and this will be systematically increased as the study progresses until a Maximum Tolerated Dose (MTD) is determined. Cantrixil will be administered via direct infusion into the intraperitoneal cavity, which is a route

that has shown evidence of improved outcomes for some patients with ovarian cancer.[1] Intraperitoneal chemotherapy is recommended for certain patients with ovarian cancer by the National Comprehensive Cancer Network in the United States, based on the results of a phase III study conducted by the Gynaecological Oncology Group and reported in 2006.[2]

Up to 60 patients will be enrolled across approximately six hospitals and research centres in the United States and Australia. The study is expected to take approximately 18 months to complete, although the actual duration and number of patients may be altered by findings observed during the course of the study.

Dr Gordon Hirsch, Chief Medical Officer, added, 'I would like to congratulate the entire Novogen team for achieving this important milestone in Novogen's efforts to develop therapeutic advances for patients suffering cancer. The study has commenced on schedule, in line with the company's prior guidance of a start in the fourth quarter. We look forward to progressing the study, while also moving forward as swiftly as possible with the other molecules in our pipeline.'

Cantrixil is a novel, first-in-class development candidate from a proprietary drug discovery program conducted in-house by Novogen. Preclinical data from researchers at Yale University has shown broad-based evidence of activity in ovarian cancer[3], and results from a preclinical toxicology program were presented at the American Association for Cancer Research (AACR) Annual Meeting in New Orleans, LA in April 2016.[4] Novogen successfully opened an Investigational New Drug (IND) application with the United States Food and Drug Administration (FDA) in September 2016.

The Cantrixil study is publically registered via the US National Institutes of Health at https://www.clinicaltrials.gov/ct2/show/NCT02903771.

Ovarian cancer is the most common cause of cancer death from gynecologic tumors in the United States. Around the world, more than 200,000 women are estimated to develop ovarian cancer every year and about 100,000 die from the disease. Despite advances in the treatment of the disease, the prognosis remains poor, with a five-year survival rate of around 25-40% for patients in the more advanced stages. There remains a critical need for new therapeutic options to improve the outcome for patients suffering with ovarian cancer.

[ENDS]

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[1] Jaaback, K, Johnson, N, and Lawrie, TA, Intraperitoneal chemotherapy for the initial management of primary epithelial ovarian cancer. *Cochrane Database Syst Rev*, 2016(1): p. CD005340.

[2] Armstrong, DK, Bundy, B, Wenzel, L, et al., Intraperitoneal Cisplatin and Paclitaxel in Ovarian Cancer. *N Engl J Med*, 2006;354:34-43

[3] Alvero, A.B., et al., *TRX-E-002-1 induces c-jun-dependent apoptosis in ovarian cancer stem cells and prevents recurrence in vivo.* Molecular Cancer Therapeutics, 2016. **15**(6): p. 1-12

[4] Lilischkis, K., et al., *Preclinical toxicology of TRXE-002-1 (Abstract LB201)*, in *Annual Meeting of the American Association of Cancer Research*. 2016 AACR: New Orleans, LA

About the Cantrixil (TRX-E-002-1) development candidate

Cantrixil is a cyclodextrin-based formulation of the active ingredient, TRX-E-002-1, which has shown in vitro and in vivo anti-cancer activity in a range of tumour types. The Company anticipates that, if approved, the drug product would be used as an intra-peritoneal chemotherapy, either alone or in combination with other agents, and in one or more cancers of the abdominal or pelvic cavity (e.g. ovarian, uterine, colorectal or gastric carcinomas). A first-in-human clinical study in patients with ovarian cancer is currently underway.

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, commenced a first-in-human clinical study in patients with ovarian cancer in late 2016, while Anisina and Trilexium are in preclinical development.

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