

ASX:NRT
NASDAQ:NVGN

Novogen Ltd
(Company)

ABN 37 063 259 754

Capital Structure

Ordinary Shares on
issue:

429 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

Prof Peter Gunning
Non-Executive Director

ASX RELEASE

11 AUGUST 2016

NOVOGEN SUBMITS INVESTIGATIONAL NEW DRUG (IND) APPLICATION TO THE US FDA FOR CANTRIXIL™ IN OVARIAN CANCER

- **Cantrixil (TRX-E-002-1) is Novogen's lead development candidate, and is being developed as a therapy for patients with ovarian cancer**
- **Investigational New Drug (IND) application is the key regulatory filing to initiate clinical trials in the United States**
- **First-in-human (FIH) phase I study remains on track for initiation in the fourth calendar quarter of 2016, in line with previous guidance**

Sydney, 11 August 2016 – Australian oncology-focused biotechnology company Novogen Ltd (ASX: NRT; NASDAQ: NVGN) today announced that it has submitted an Investigational New Drug (IND) application to the United States Food and Drug Administration (FDA) for Cantrixil (TRX-E-002-1) in ovarian cancer.

The IND is a detailed regulatory filing which is required to initiate clinical studies in the United States. It has been compiled over the past twelve months, following a decision to move Cantrixil into clinical development at the Company's strategic pipeline review in August 2015.

The IND submission includes a comprehensive package of data, encompassing preclinical pharmacology and toxicity, manufacturing, quality control and clinical development plans. Novogen will be able to move forward to the next step of setting up the clinical trials program thirty days after submission, unless FDA reviewers have questions or concerns which cannot be resolved during that time.

Dr Kimberley Lilischkis, Director of Clinical & Regulatory Affairs at Novogen, commented, "the Cantrixil IND is a critical step on the path to the clinic. We will work closely with the FDA to resolve any queries they may have. Following that, we expect to initiate the study swiftly in the last quarter of 2016, with participation from centres in the US and Australia."

Cantrixil is a first-in-class development candidate which is being studied as a therapy for ovarian cancer, administered directly into the abdominal cavity via the intra-peritoneal route. Preclinical data has shown broad-based evidence of anti-tumour activity in animal models of ovarian cancer,¹ and a toxicology program conducted under GLP (Good Laboratory Practice (GLP) has demonstrated a toxicity profile that appears appropriate for use in humans at therapeutic doses.²

¹ AB Alvero, A Heaton, E Lima, *et al.* (2016). *Molecular Cancer Therapeutics*, 15(6):1279-90 (June 2016)

² K Lilischkis, A Heaton, A Alvero, *et al.* (2016). Abstract LB201, Annual Meeting of the American Association of Cancer Research (New Orleans, LA)

Dr James Garner, CEO of Novogen, added, “this is an important milestone in Novogen’s transition to a clinical stage drug development company. I am delighted that the team has succeeded in delivering on schedule, in accordance with our prior guidance of an August 2016 submission. The Cantrixil trial has received strong interest from clinicians in Australia and the United States. The team is working with Quintiles, our contract research organisation, to select and initiate the most appropriate trial sites and prepare for the phase I study.”

[ENDS]

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 is planned to commence in the fourth quarter of 2016.

About Novogen Limited

Novogen Limited (ASX: NRT; NASDAQ: NVGN) is an oncology-focused biotechnology company based in Sydney, Australia. Novogen has two proprietary drug discovery platforms (superbenzopyrans and anti-tropomyosins) with the potential to yield first-in-class agents across a range of oncology indications. The three lead molecules Cantrixil, Anisina, and Trilexium are in preclinical development, with the most advanced molecule, Cantrixil, slated to enter clinical trials in late 2016. For more information, please visit: www.novogen.com

Forward Looking Statement

This press release contains "forward-looking statements" within the meaning of section 27A of the Securities Act of 1933 and section 21E of the Securities Exchange Act of 1934. The Company has tried to identify such forward-looking statements by use of such words as "expects," "appear," "intends," "hopes," "anticipates," "believes," "could," "should," "would," "may," "target," "evidences" and "estimates," and other similar expressions, but these words are not the exclusive means of identifying such statements. Such statements include, but are not limited to any statements relating to the Company's drug development program, including, but not limited to the initiation, progress and outcomes of clinical trials of the Company's drug development program, including, but not limited to Cantrixil, Anisina, Trilexium, and any other statements that are not historical facts. Such statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to the difficulties or delays in financing, development, testing, regulatory approval, production and marketing of the Company's drug components, including, but not limited to, Cantrixil, Anisina, Trilexium, the ability of the Company to procure additional future sources of financing, unexpected adverse side effects or inadequate therapeutic efficacy of the Company's drug compounds, including, but not limited to, Cantrixil, Anisina, Trilexium, that could slow or prevent products coming to market, the uncertainty of patent protection for the Company's intellectual property or trade secrets, including, but not limited to, the intellectual property relating to Cantrixil, Anisina, Trilexium, and other risks detailed from time to time in the filings the Company makes with Securities and Exchange Commission including its annual reports on Form 20-F and its reports on Form 6-K. Such statements are based on management's current expectations, but actual results may differ materially due to various factors including those risks and uncertainties mentioned or referred to in this press release. Accordingly, you should not rely on those forward-looking statements as a prediction of actual future results.