

ASX:NRT  
NASDAQ:NVGN

Novogen Ltd  
(Company)

ABN 37 063 259 754

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#### Capital Structure

Ordinary Shares on  
issue:

424 M

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#### Board of Directors

**Mr Ian Phillips MNZM**  
Interim Chairman

**Mr Iain Ross**  
Director  
Acting CEO

**Mr Steve Coffey**  
Non-Executive Director

**Mr John O'Connor**  
Non-Executive Director

**Prof Peter Gunning**  
Non-Executive Director

**Mr Bryce Carmine**  
Non-Executive Director

**ASX RELEASE**  
24 November 2015

### **NOVOGEN ENGAGES CONTRACT RESEARCH ORGANISATION TO CONDUCT CANTRIXIL PHASE 1 CLINICAL TRIAL**

- **Novogen engages Novotech as CRO for upcoming Phase 1 clinical study**
- **Cantrixil Phase 1 clinical trial to be conducted in patients with refractory/recurrent peritoneal malignancies with malignant ascites, including ovarian cancer**

**Sydney, November 24, 2015** - US-Australian drug discovery company, Novogen Limited (ASX:NRT: NASDAQ: NVGN), announced today that it has engaged Novotech as the Contract Research Organisation (CRO) to conduct its Phase 1 clinical study for the drug candidate, Cantrixil, which will commence in 2016.

This first-in-human study will investigate the safety and feasibility of Cantrixil administered via the intraperitoneal route for patients with refractory /recurrent peritoneal malignancies with malignant ascites.

According to Novogen's Clinical and Regulatory Affairs Manager, Kimberley Lilischkis, PhD, the Cantrixil Phase 1 study will be weighted towards ovarian cancer patients with the selection of a gynecological oncology site.

"However, patients with other cancer types will also be eligible to enrol in this first study since early preclinical data suggests the drug candidate may benefit patients with a range of cancer types," Dr Lilischkis said.

"Patients with malignant ascites have been chosen because ethically this patient group stands to receive the most benefit and face the least risk from the insertion of a peritoneal port or catheter, which can be used for drug administration but also for the on-going drainage of malignant ascites."

Dr Lilischkis said Novogen was continuing to progress Cantrixil through the necessary preclinical regulatory requirements and safety evaluations and was on track to complete the 'in-life' phase of the toxicity studies by the end of 2015. The Company expected to receive the final report in early 2016 once a comprehensive pathology review was completed.

Acting CEO, Iain Ross said the appointment of Novotech was a key milestone in progressing Novogen's first oncology drug candidate, Cantrixil, to the clinic. "Novogen is confident that Novotech will add significant value to the clinical trial program bringing their standard of excellence to the development of this promising drug candidate," Mr Ross said.

Novotech is a prominent Australian-based CRO with extensive background in oncology drug development and a broad range of clinical trial outsourcing services. Novotech has well-established working relationships with the Australian sites and KOLs working with Novogen on this study. This CRO has world-class electronic data and trial management systems that will support the data management, monitoring and safety reporting activities for this study. Novotech is the only Australian-based CRO that has a Quality Assurance system with ISO9001:2008 accreditation and has a superb track record in managing early phase oncology studies.

"We're delighted to be working with Novogen on this important study. The development of Cantrixil has the potential to add an important new tool in the fight against cancer, and we are looking forward to leveraging our previous experience in all phases of oncology drug development to the management of this program," CEO of Novotech, Alek Safarian, said.

### **About the Cantrixil drug candidate**

The candidate Cantrixil drug product is cyclodextrin-based containing the active ingredient, TRXE-002-1. The Company anticipates that if approved the drug product would be used as an intra-cavity chemotherapy to be injected directly into the peritoneal cavity. The aim of intraperitoneal administration is to achieve high localized drug levels within the peritoneal cavity and attenuate the spread of resident tumor initiator cells. The target indication sought for Cantrixil is early-stage cancers of the abdominal cavity (eg. ovarian, uterine, colorectal and gastric carcinomas) with Cantrixil being used as an adjuvant first-line therapy. On completion of the requisite safety studies, Cantrixil will enter the clinic in late-stage patients with abdominal cancers including ovarian cancer. The active pharmaceutical ingredient, TRXE-002, has pan anti-cancer activity resulting in caspase-dependent apoptosis via c-Jun activation and pERK downregulation. The actual drug target remains unidentified.

### **About Novogen Limited**

Novogen is a public, Australian-US drug development company whose shares trade on both The Australian Securities Exchange (NRT) and NASDAQ (NVGN). The Novogen Group includes US-based, CanTx Inc., a joint venture company with Yale University. Novogen has two drug technology platforms [the superbenzopyrans (SBPs) and anti-tropomyosins (ATMs)] yielding drug candidates that are first-in-class with potential application across a range of degenerative diseases. Given the encouraging data from *in vitro* and *in vivo* preclinical proof-of-concept studies in the field of oncology, the Company's immediate focus is to undertake the respective toxicology programs. The target indication for Cantrixil is ovarian cancer, and

Diffuse Intrinsic Pontine Glioma (DIPG) for Trilexium. While the initial target pediatric indication for Anisina has been identified as neuroblastoma, Novogen is yet to identify the adult indication and is intending to open an all-comers Phase 1 trial initially based on its preclinical studies. For more information, please visit [www.novogen.com](http://www.novogen.com)

### **Media Enquiries:**

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### **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, 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, 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, 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, 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.*