

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**  
19 October 2015

## **CANTRIXIL PLUS A STANDARD-OF-CARE PLATINUM SHOWN TO PROLONG SURVIVAL IN AN ANIMAL MODEL OF RECURRENT OVARIAN CANCER**

**Orlando FL (October 18, 2015)** - US-Australian drug discovery company, Novogen Ltd, (ASX:NRT; NASDAQ:NVGN), and Yale University today disclosed key pre-clinical data generated in an animal model of recurrent ovarian cancer suggesting that the experimental anti-cancer drug, Cantrixil, may have utility as an adjuvant therapy when dosed in combination with platinum-based drugs.

The data was presented by Dr Ayesha Alvero of Yale Medical School to the American Association for Cancer Research (AACR) Advances in Ovarian Cancer Research: Exploiting Vulnerabilities special conference in Orlando Florida as a poster (A61) on October 18, 2015 (Poster session A at 5:30 pm).

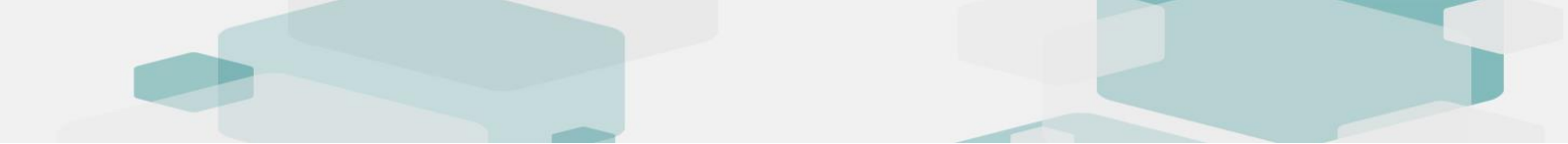
Professor Gil Mor, Director Division of Reproductive Services at Yale University, said "Previous studies from our laboratory have shown that conventional chemotherapy is not effective against Ovarian Cancer Stem Cells [OCSC] and cannot prevent recurrence. Our finding that Cantrixil, by targeting OCSC, can prevent recurrence *in vivo* as maintenance therapy or in combination with chemotherapy provides an opportunity for developing new therapeutic strategies that may improve survival in ovarian cancer patients".

David Brown PhD, Novogen's Chief Scientific Officer, said "With the reporting of these data, we have now completed our designated pharmacology studies demonstrating Cantrixil proof-of-concept. We remain on track to complete the requisite safety studies for our Cantrixil IND application."

"Following a final review of the Safety Data Package and approval of the Phase 1 clinical protocol by the Cantrixil Study Committee, we will submit the necessary documentation to our Australian trial site, Human Research Ethics Committees, with a view to opening a Phase 1 trial in Australia in 2016. We also intend to open a Phase 1 trial site in the USA once Cantrixil has been granted IND status by the US FDA," Dr Brown said.

### Study Detail

Disease recurrence is thought to occur due to the presence of residual disease following standard-of-care treatment (i.e. optimal debulking and chemotherapy). Residual disease post-chemotherapy is composed of a unique population of chemo-resistant cancer stem cells with a high capacity for tumor repair. Currently, there are no approved (or proven) treatment options that target these cells and as such, there remains an urgent unmet clinical need for patients with recurrent ovarian cancer.



Researchers at the Yale Medical School have established clinically relevant *in vitro* and *in vivo* animal models of chemo-resistant ovarian cancer. This is a stringent model that Yale believes provides rapid go/no-go decision points for lead drug-candidates.

The Yale team previously reported on the preclinical efficacy of Cantrixil to induce cell death in chemo-resistant ovarian cancer stem cells (OCSC) at nanomolar concentrations (IC<sub>50</sub> of 130 – 250 nM). Here, Yale researchers have expanded those studies in their animal models and report on the efficacy of Cantrixil in an *in vivo* model of primary ovarian cancer and in an *in vivo* model of recurrent disease.

Intraperitoneal administration of Cantrixil at a dose of 100 mg/kg as a first-line therapy in combination with standard of care (cisplatin or paclitaxel), improved survival compared with the respective monotherapy controls ( $p < 0.001$ ). Furthermore, Cantrixil, given as maintenance therapy following paclitaxel treatment, was able to retard the onset of recurrent disease, ( $p = 0.002$ ).

## About Ovarian Cancer

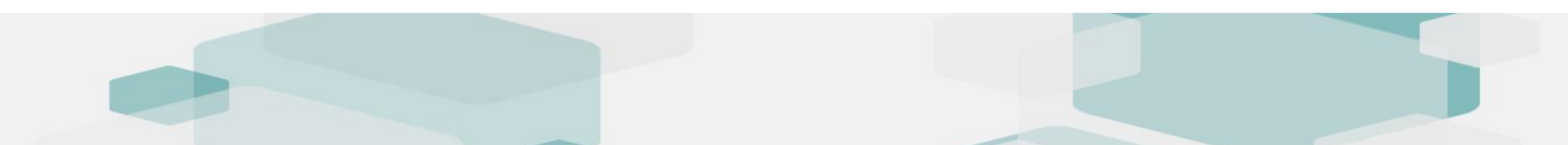
Approximately 1 in 70 women will develop ovarian cancer in their lifetime. In the US this equates each year to approximately 22,000 new cases diagnosed and 15,000 deaths from ovarian cancer. The figures for Europe are 66,000 and 41,000 respectively. There are different forms of ovarian cancer with epithelial ovarian cancer accounting for 90% of cases. Approximately 15% of women present with disease localized to the ovaries and with successful surgery, the 5-year survival rate is >90%. For women with more advanced disease at the time of diagnosis, the 5-year survival rate is <30%. Approximately 85% of advanced cases respond to first-line therapy (typically paclitaxel and carboplatin), but 80% of these will relapse within several years.

## About the Cantrixil drug candidate

The candidate Cantrixil drug product is cyclodextrin-based containing the active ingredient, TRXE-002-1. We anticipate that if approved, the drug product will be used as 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 late-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, our immediate focus is to undertake their respective toxicology programs. Our 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, we are yet to identify the adult indication and are intending to open an all-comers Phase 1 trial initially based on our 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.*