NOVOGEN
THE FUTURE OF CANCER THERAPY

ASX:NRT
NASDAQ:NVGN

Novogen Ltd
(Company)

ABN 37 063 259 754

Capital Structure

Ordinary Shares on issue:

424 M

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
11 November 2015

PRECLINICAL STUDIES JUSTIFY MODE OF DELIVERY AND DOSING REGIMEN FOR ANISINA

- Intravenous Anisina drug product identified
- Efficacy in a preclinical model of neuroblastoma as monotherapy and in combination using IV delivery is retained
- Anisina safety assessment program has commenced

Fort Lauderdale FL, November 10, 2015: US-Australian drug discovery company, Novogen Limited (NRT: ASX; NVGN: NASDAQ), today announced details of preclinical studies which confirm the efficacy of the lead anti-tropomyosin (ATM) compound, Anisina, when delivered using a clinically relevant formulation, mode of administration and dosing regimen.

Presenting at the 'American Association for Cancer Research Advances in Pediatric Cancer Research: From Mechanisms and Models to Treatment and Survivorship' conference in Fort Lauderdale, Florida today, Justine Stehn PhD, Novogen Anti-Tropomyosin Program Director, said "These data validate the strategic decision to develop the Anisina drug candidate. We have shown that intravenously administered Anisina dosed less frequently in a preclinical study retained anti-cancer activity as a monotherapy, and enhanced the efficacy of a drug commonly used to treat pediatric neuroblastoma".

"Based on these data we have now identified the Anisina drug candidate to be progressed into preclinical safety studies, and, pending successful completion of those safety studies, into our clinical development programs in adult and pediatric indications," Dr Stehn said.

Lead Investigator Dr Timothy Cripe MD, PhD, from Nationwide Children's Hospital, Columbus Ohio, said "This is a key proof-of-concept study and confirmed the clinical potential for this class of drug in the treatment of neuroblastoma.

“This class of compounds now has the potential to improve the effectiveness of standard-of-care chemotherapeutics such as vincristine (VCR),” Dr Cripe said.

Background Detail

Anisina belongs to a unique ‘first in class’ family of compounds which target the cytoskeleton of a cancer cell. Previously the Company has highlighted that Anisina has activity *in vitro* against a diverse panel of both adult and pediatric tumor cells and is effective as a monotherapy in reducing tumor growth in preclinical models of cancer.

The real novelty and potential of this class of compound lies in their ability to enhance the effectiveness of standard-of-care microtubule inhibitors belonging to the taxane and vinca alkaloid families as observed preclinically. This enhanced activity has been observed *in vitro* in both adult (prostate) and pediatric (neuroblastoma) cancer types.

A recent study conducted by Dr Cripe demonstrated in a preclinical animal model of neuroblastoma that intraperitoneally delivered Anisina, when used in combination with vincristine, resulted in a significant regression of tumor growth in ~60% of animals treated. This translated to a significant improvement in median survival with one animal from this treatment group having no measurable tumor 100 days post treatment.

Whilst very informative, the initial proof-of-concept combinatorial study had limitations in that Anisina was delivered daily via intraperitoneal injection and this mode of delivery is not practical in a clinical setting. Today’s announcement concerns the important key step of validating the acceptable mode of delivery and dosing regimen of Anisina.

In this study, the, circulating blood levels of Anisina were measured after the delivery of the drug by either an intravenous (IV) or oral (PO) route. The level and length of time Anisina remained in the blood was significantly higher when delivered by IV compared with oral. The efficacy of Anisina delivered IV in combination with vincristine was evaluated in a preclinical model of neuroblastoma in collaboration with Dr Cripe’s group at Nationwide Children’s Hospital. In this study, animals with tumors were treated with: i) no drug (Control), ii) vincristine alone (05.mg/kg, 1x/week, IV), iii) Anisina alone (60mg/kg, 2x/week, IV) and iv) VCR (05.mg/kg, 1x/week, IV) + Anisina (60mg/kg, 2x/week, IV).

Again the combined treatment group showed a significant reduction in tumor growth (>90% at day 14) compared to no drug control and prolonged survival compared to either drug alone. Additionally Anisina alone, significantly retarded tumor proliferation (~50% at day 14) compared to control. This study confirms that it is possible to deliver Anisina using a clinically relevant formulation, reduced dosing schedule and mode of delivery without any impact efficacy. An additional key finding was that the Anisina doses as a monotherapy

and in combination was well tolerated *in vivo* as no significant change in percentage body weight was observed in these treatment groups compared to no drug controls.

In parallel Novogen is progressing very smoothly with the large-scale manufacture of the drug substance and drug product required for clinical trials. The Company is currently on track to commence a first-in-human safety study later in 2016.

About Anisina

Anisina is a small molecule which belongs to a family of compounds termed the anti-tropomyosins or ATMs. Anisina has been designed to inhibit a protein known as Tpm3.1. Tpm3.1 is a structural protein and is an indispensable component of the actin microfilaments which make up the cytoskeleton of the cancer cell. By binding to Tpm3.1, Anisina impacts the function of this structural protein causing the collapse of the cytoskeleton which results in the death of the cancer cell. Anisina has been shown to be effective against a broad range of cancer types. Novogen's current strategy is to develop Anisina as an adjunct therapy to improve the effectiveness of standard-of-care microtubule targeting agents, which are used for a large number of both adult and childhood cancers. We are currently focused on the clinical development of Anisina for the treatment of prostate cancer and neuroblastoma.

About Neuroblastoma

Neuroblastoma is the most common solid tumor in children outside the brain. It is most frequently observed in the young with more than 90% of diagnoses occurring in children under 5 years of age. Although childhood cancers such as neuroblastoma are relatively rare compared to adult cancers, the emotional burden and the potential years of life lost due to this cancer are substantial making it essential that new clinical strategies are developed to treat this disease. We believe this approach of targeting the actin to enhance the effect of existing standard-of-care chemotherapeutics represents a very promising and novel therapeutic strategy.

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

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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, Anisina, 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, Anisina, 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, Anisina, 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 Anisina, 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 factions 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.