NOVOGEN
THE FUTURE OF CANCER THERAPY

ASX:NRT
NASDAQ:NVGN

Novogen Ltd (Company)

ABN 37 063 259 754

**Capital Structure**

Ordinary Shares on issue:

423 M

**Board of Directors**

**Ian Phillips**
Non-Executive Director

**Steve Coffey**
Non-Executive Director

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

**Prof Peter Gunning**
Non-Executive Director

**Bryce Carmine**
Non-Executive Director

**Dr Graham Kelly**
Chief Executive Officer

**ASX RELEASE**
16 July 2015

# ANISINA RECEIVES ORPHAN DRUG DESIGNATION FROM FDA FOR NEUROBLASTOMA

**16 July 2015, Sydney AUSTRALIA:** US-Australian drug discovery company, Novogen Limited, today announced that it has received notification from the U.S. Food and Drug Administration (FDA) that its chemotherapy candidate drug, Anisina, has been granted Orphan Drug Designation for neuroblastoma.

Orphan Drug Designation encourages the development of experimental drugs for clinical indications that do not have a high incidence and has been instigated in a number of territories including the U.S, Europe and Australia.

Orphan Drug Designation can provide the following benefits to a drug developer:

- Eligibility for US government grants to defray clinical trial costs
- Tax incentives for clinical research conducted in the United States
- Waiver of US prescription drug filing fees
- Enhanced marketing rights upon Market authorization.

Anisina was granted Orphan Drug Designation for neuroblastoma under the U.S. Orphan Drug Act following a review by the FDA of a package of pre-clinical data submitted by Novogen.

The data is from preclinical studies which were done as part of the Children's Oncology Drug Alliance (CODA) involving Australian charity, The Kids' Cancer Project (Sydney), The University of New South Wales (Sydney), The Nationwide Children's Hospital (Columbus, Ohio), and Novogen. The key findings from these studies showed that Anisina significantly improved the effectiveness of the standard of care microtubule targeting compound, vincristine, in an animal model of neuroblastoma. The data from these studies were recently announced and presented at Eighth Annual Cancer Molecular Therapeutics Research Association (CMTRA) meeting in Boston, USA.

Novogen Interim Chairperson, Ian Phillips said "Obtaining the FDA approved Orphan drug designation for Anisina is an important strategic achievement for us. It demonstrates the company's commitment to bringing a drug to market which we hope will improve the outcome for children with neuroblastoma. These incentives provided by the FDA have the potential to offset those significant costs associated with the clinical development of Anisina."

The ATM program director, Dr Justine Stehn said, "Given it is our intention to take this drug through to the clinic to treat childhood cancer, the designation affords additional guidance from the FDA in

the design of our clinical trial program enhancing the efficiency and innovativeness of Anisina's development."

Researchers have demonstrated efficacy in an animal model of neuroblastoma both as a monotherapy and in combination with vincristine as stated in the company's announcement earlier this month and Novogen is now conducting pre-clinical studies to further validate the combinatorial effect of Anisina with a range of microtubule-targeting compounds in animal models of adult cancer. Once the company has completed its pre-clinical toxicology program for Anisina, the drug is expected to enter the clinic for adults in mid-2016 with clinical trials in childhood cancer in Australia and the United States to follow in early 2017.

**About Orphan Drug Status**

Orphan Drug Designation is granted to a drug or biological product when it is to treat a rare disease or condition and there is a scientific rationale that supports its use in that disease or condition. "Rare" is defined by the number of people that have the disease (prevalence) and is under 200,000 in the USA. The sponsor or company developing the new drug, requests Orphan Drug Designation from the FDA or local regulatory authority, as appropriate.

The Orphan Drug Act (ODA) in the USA provides the sponsor of the drug with various incentives to continue developing the drug, including tax credits for qualified clinical testing, a waiver of the marketing application and a period of market exclusivity. Importantly, the FDA also offer extra guidance and consultative opportunities during the development period as explained on their web-site. Other regulatory regions, such as Europe and Australia, have similar orphan drug designation and incentive schemes that Novogen intends to access in due course.
http://www.fda.gov/forindustry/developingproductsforrarediseasesconditions/howtoapplyfororphanproductdesignation/default.htm

**About Neuroblastoma**

Neuroblastoma is a cancer that is most frequently observed in the young with more than 90% of diagnoses occurring in children under 5 years of age. It is considered to be the most common solid tumour in children outside the brain. Although childhood cancers such as neuroblastoma are relatively rare compared to adult cancers, the potential years of life lost are substantial making it imperative that new clinical strategies are developed to treat this disease.

**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 a core component of the skeleton, or cytoskeleton of a 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. At Novogen we are focused on the clinical development of

Anisina for the treatment of both adult (melanoma and prostate) and pediatric (neuroblastoma) cancers.

**About Novogen**

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 super-benzopyrans (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 pre-clinical Proof-of-Concept studies in the field of Oncology, our immediate focus is to bring our lead Oncology drug candidates Cantrixil, Anisina and Trilexium into the clinic in 2016 pending successful completion of their respective toxicology programs. Ovarian cancer, colorectal cancer, malignant ascites, prostate cancer, neural cancers (glioblastoma, neuroblastoma in children) and melanoma are the potential clinical indications being pursued, with the ultimate objective of employing both technologies as a unified approach to therapy. For more information, please visit www.novogen.com

**About The Kids' Cancer Project**

The Kids' Cancer Project is an Australian charity dedicated to funding medical research to find a cure for childhood cancer. Thanks to community support the charity has invested more than $24 million into research and is currently supporting 13 research projects. The independent charity is the largest not-for-profit funder of childhood cancer in Australia. The Kids' Cancer Project was inspired by one man who promised to find the cure for childhood cancer and make a difference. The Kids' Cancer Project supports research that will increase a child's chance of survival and that will eradicate or minimise the toxicity of current treatments children endure. The Kids' Cancer project supports collaborative research that has the greatest chance of clinical success and is excited about the potential that Anisina presents as a potential improvement in chemotherapy treatment. Visit www.thekidscancerproject.org.au for further information or to donate.

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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.*