ASX:NRT

NASDAQ:NVGN

Novogen Ltd
(Company)

ABN 37 063 259 754

Capital Structure

Ordinary Shares on issue:

260 M

Board of Directors

Dr Graham Kelly
Chairman &
Executive Director

Steve Coffey
Non Executive Director

John O'Connor
Non Executive Director

Prof Peter Gunning
Non Executive Director

ASX RELEASE
9 April 2015

AUSTRALIAN STUDIES CONFIRM ANISINA AS POTENTIAL IMPORTANT NEW WEAPON AGAINST MELANOMA

- **Anisina kills melanoma cells regardless of their mutation status**
- **Melanoma cells with normal and mutated BRAF gene killed by Anisina**
- **Anisina to come into the clinic as a new weapon against melanoma**

Sydney, Australia, 9 April 2015: US-Australian drug discovery company, Novogen (NRT:ASX; NVGN: NASDAQ), today announced that studies conducted at The University of Queensland Diamantina Institute (UQDI) revealed that experimental drug, Anisina, killed melanoma cells irrespective of their mutational status.

The significance of this finding lies in the fact that melanoma is associated with a variety of mutations, with those to the BRAF gene being the most prominent. A mutation to the BRAF gene occurs in about half of all melanoma patients and two drugs that target that mutation (vemurafenib and dabrafenib) have come to market in recent times. No targeted therapy exists for the 50% of melanoma patients whose tumors do not have the BRAF mutation. But even where a response is obtained with a BRAF-inhibitor, resistance typically develops within a year of treatment. Therefore the development of a drug that kills melanoma cells irrespective of their BRAF or any other mutational status has become an urgent clinical imperative.

Novogen believes that Anisina represents a significant potential opportunity to meet this need.

UQDI screened Anisina against a panel of melanoma cells obtained from patients and which represented the spectrum of mutations (BRAF, NRAS and c-KIT) commonly found in the community. Anisina was uniformly cytotoxic to the panel of cells, regardless of their mutational status. Importantly, Anisina showed a high level of specificity to cancer cells, with toxicity against normal melanocytes requiring a four-fold drug level.

Anisina is an anti-tropomyosin compound that targets the cytoskeleton of the cancer cells. It is being brought into the clinic for the treatment of cancers as a companion drug for the anti-mitotic family of drugs…the taxanes and vinca alkaloids. The rationale is that the use of Anisina (targeting the microfilaments) in combination with anti-mitotic drugs (targeting the microtubules), provide comprehensive destruction of the two key parts of the cancer cell's skeleton resulting in a 20-fold increase in the anti-cancer effect of either drug family alone.

Anisina is being brought into the clinic in early-2016 for the treatment of solid cancers, with late-stage melanoma and prostate cancer in adults and neuroblastoma in children being three key target indications. The current results give strength to the aim of conducting a clinical study in patients with late-stage melanoma using a combined treatment of Anisina and vincristine.

Nikolas Haass MD PhD and Brian Gabrielli PhD conducted the research studies.

Dr Haass said, “These findings from the preliminary screen with Anisina are exciting. Finding a compound that is equally effective against a wide panel of melanoma cell types irrespective of the genetic background has been a long-held goal. The University of Queensland Diamantina Institute is pleased to be part of the effort to bring this new drug candidate into the clinic.”

Justine Stehn PhD, Novogen Anti-Tropomyosin Program Director, said, “Melanoma is a notoriously difficult cancer to treat. The standard first-line cytotoxic drugs such as the taxanes and vinca alkaloids have little anti-cancer effect.”

“But we see a 20-fold increase in the cancer killing effect of these drugs when combined with Anisina. We have demonstrated this combination effect with vincristine in prostate cancer cells, neuroblastoma cells, and now melanoma cells. The idea that we now have a means of making melanoma cells respond to potent anti-cancer drugs such as vincristine is an exciting development for patients with melanoma.”

Graham Kelly PhD, Novogen Group CEO, said, “These results support our belief that Anisina has the potential to become one of the most widely used anti-cancer drugs across the full spectrum of cancer. In conjunction with our clinical advisors, we have a clinical strategy laid out which we intend to prosecute all the way through to achieving regulatory approval.”

About Melanoma

The incidence of melanoma has doubled since 1973 and continues to increase, with countries such as Australia and New Zealand taking the lead with one of the highest rates of morbidity and mortality of melanoma. Around 12,500 new cases are diagnosed each year in Australia with malignant melanoma and it is responsible for over 1,500 deaths. In the US, approximately 74,000 thousand cases of invasive melanoma are expected to be diagnosed, with 10,000 deaths. In the UK, malignant melanoma is the 5th most common cancer.

There are limited therapeutic options for the treatment of metastatic melanoma as standard of care chemotherapy is ineffective against this highly resistant disease.

Melanomas are now “molecularly classified” based on the activating mutations in the MAP kinase pathway. The most frequent mutations are activating oncogenic mutations in the BRAF gene. These mutations are present in 40-60% of malignant melanoma. There is a smaller subset of less common activating mutations which include: *NRAS*, which is found in approximately 15-20% of melanomas; *c-KIT* mutations, make up a smaller percentage of the mutation found in melanoma among the white population (6-7%) but are the most common mutation found in the Asian population; and *CDK4* mutations which have been identified in in approximately 4% of melanomas.

Despite remarkable clinical responses to targeted therapies and to immunotherapies, relapse of the disease is common in the vast majority of patients. In addition, selectivity of these targeted inhibitors leaves greater than 50% of patients with inadequate treatment options. Therefore it is a clinical imperative that new therapeutic strategies be developed.

About Anisina

Anisina is a small molecule that belongs to a class of compounds known as anti-tropomyosins which target and destroy the microfilaments of cancer cells. Anisina binds to and inhibits the function of a core component of the microfilaments, tropomyosin Tpm3.1 (previously known as Tm5NM1). The role of Tpm 3.1 is to protect and stabilise the microfilaments of a cell. Inhibition of this protein by Anisina leads to the disassembly and collapse of the microfilaments resulting in cell death. Despite the target protein, Tpm3.1 being found in both

normal and cancer cells, Anisina is significantly more effective against cancer cells as these cells rely more heavily on a functional Tpm3.1 for survival.

About Anti-Mitotic Drugs

Anti-mitotic drugs are drugs that block cell division (mitosis) by targeting the microtubule component of a cell's cytoskeleton. Anti-microtubule drugs are the taxanes (paclitaxel, docetaxel, abraxane) and vinca alkaloids (vincristine, vinblastine and vinorelbine). These drugs remain among the most widely prescribed anti-cancer drugs after 35 years of use. Anti-mitotic drugs are standard of care for breast, prostate, lung, ovarian, colo-rectal, gastric and head and neck cancer, and many forms of leukaemia.

About The University of Queensland Diamantina Institute

UQDI is a modern research facility where clinical and basic science converge in the translational research of cancer, immunology and genomic medicine.

UQDI is host to more than 300 researchers, students and support staff. It lays claim to global, world-changing discoveries such as the world's first cervical cancer vaccine.

Based at the Translational Research Institute (TRI) beside the Princess Alexandra Hospital, UQDI has strong clinical interactions and world-class facilities that enable researchers to be at the forefront of their fields. UQDI's position within the TRI allows for a collaborative research environment, enabling researchers to focus their efforts on turning their scientific discoveries into better treatments for diseases.

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 main drug technology platforms: super-benzopyrans (SBPs) and anti-tropomyosins (ATMs). SBP compounds have been designed to kill the full heterogeneity of cells within a tumor, but with particular activity against the cancer stem (tumor-initiating) cell.

The ATM compounds target the micro-filament component of the cancer cell's cytoskeleton and have been designed to combine with anti-microtubule drugs (taxanes, vinca alkaloids) to produce comprehensive and fatal destruction of the cancer cell cytoskeleton.

The Company pipeline comprises two SBP drug candidates (TRXE-002, TRXE-009) and one ATM drug candidate (Anisina).

Further information is available on our websites www.novogen.com

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Forward-Looking Statements:

To the extent that statements contained in this press release are not descriptions of historical facts regarding Anisina, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "anticipate," "estimate," "intend," and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. Examples of forward-looking statements contained in this release include, among others, statements regarding the safety, efficacy and therapeutic potential of Anisina, the availability of data from clinical studies and our expectations regarding our research and development programs, expanding our pipeline and advancing our two drug technology platforms. Forward-looking statements in this release involve substantial risks and uncertainties that could cause our clinical development programs, future results, working capital performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the conduct of future clinical studies, enrolment in clinical studies, availability of data from ongoing clinical studies and other matters that could affect the commercial potential of our drug candidates. Novogen undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of Novogen in general, the reader is referred to filings made the U.S. Securities and Exchange Commission.