

# ASX:NRT NASDAQ:NVGN

Novogen Ltd (Company)

ABN 37 063 259 754

#### **Capital Structure**

Ordinary Shares on issue:

423 M

#### **Board of Directors**

**Dr Graham Kelly** Chairman & Executive Director

# **Steve Coffey**Non-Executive Director

Non-Executive Director

John O'Connor Non-Executive Director

**Prof Peter Gunning**Non-Executive Director

lan Phillips Non-Executive Director

**Bryce Carmine**Non-Executive Director

#### **ASX RELEASE**

24 June 2015

#### **ANISINA ON TRACK TO ENTER CLINIC IN 2016**

- Anisina delivers potent anti-tumor effect in vivo
- Human melanoma tumors respond to Anisina treatment
- Potent anti-cancer effect with no observed toxicity

**Sydney, Australia, 24 June 2015**: US-Australian drug discovery company, Novogen Limited (NRT: ASX; NVGN: NASDAQ) (**Company**), announced today that its candidate cytotoxic chemotherapy drug, Anisina, has proved an effective anti-cancer agent in animals, the result of which it now has been fast-tracked by the Company to come into the clinic.

Anisina targets the cytoskeleton of cancer cells. This is the same target of the most widely used chemotherapy drugs in cancer, the taxanes and vinca alkaloids. These latter drugs are standard of care for some of the most common cancers in adults embracing both solid cancers (breast, ovary, prostate, lung, bladder, testicle) and non-solid cancers (acute leukaemias, Hodgkin's Disease), as well as in pediatric cancers (neuroblastoma, Wilm's tumor). Beyond these approved uses, they are widely used off-label across most forms of cancers following failure of standard of care drugs.

Despite their common use, the taxanes and vinca alkaloids come with the significant disadvantages of (i) being non-selective, resulting in significant side-effects, (ii) not working in many forms of cancer, and (iii) readily inducing resistance in cancer cells.

There remains a significant clinical need to improve on both the efficacy and safety of these commonly used drugs. Novogen believes that Anisina has the features to meet that need across a range of cancer types.

The taxanes and vinca alkaloids target a structural component of the cytoskeleton known as the microtubule. Destabilizing this structure prevents the cancer cell from dividing and promotes its death.

Anisina is a first-in-class drug candidate that targets the other main structural component of a cancer cell known as the microfilament.

There is a 20-year history of attempts to produce drugs against microfilaments. The commercial success of the taxanes and vinca alkaloids in the 1970s validated the cancer cell's cytoskeleton as a target for anti-cancer drugs, making the destruction of the microfilaments an obvious alternative drug target. These attempts failed because of

the inability to limit the destructive effect to cancer cells' microfilaments, with loss of muscle function being a pronounced toxic side-effect.

The breakthrough came 10 years ago with the discovery by Professor Peter Gunning and Dr Justine Stehn at the University of New South Wales (Sydney, Australia) of the role of a structural protein known as Tmp3.1 in the function of microfilaments. Cancer cells are far more reliant on Tmp3.1 for the integrity of their microfilaments than are normal cells. Anisina specifically targets Tmp3.1, destroying the microfilaments of cancer cells with proportionally much less effect on normal cells.

Compared to the taxanes and vinca alkaloids, Anisina offers three potential advantages, viz. (i) being more selective against cancer cells, (ii) being able to kill cancer cell types inherently insensitive to taxanes and vinca alkaloids, and (iii) not being subject to the same drug-resistance mechanisms that affect the taxanes and vinca alkaloids.

Ahead of bringing Anisina into the clinic, Novogen has focused on three indications – melanoma, prostate cancer, neuroblastoma – with animal studies underway in each indication in support of IND applications over the next 9 months.

We have previously announced that Anisina is active in vitro against human melanoma cells, a cancer that is relatively insensitive to the taxanes and vinca alkaloids. We also have announced that Anisina kills human melanoma cells irrespective of their mutational status.

Today's announcement concerns the important key step of establishing a significant anti-tumour effect in vivo. The study reported here is with melanoma; the neuroblastoma animal studies are being reported to a scientific conference on July 13; the prostate cancer studies will be reported shortly after that.

Mice bearing the human malignant melanoma cell line A-375 (BRAF-mutant) were treated with Anisina either intravenously (60 mg/kg/twice weekly) or orally (100 mg/kg/daily). Both dosing regimens delivered a significant anti-tumor effect with no observed toxicity.

Justine Stehn PhD, Novogen Anti-Tropomyosin Program Director, said, "This result clears the way for Anisina to enter the clinic. The potent effect observed here of the drug on a cancer as difficult to treat as malignant melanoma, combined with the lack of any obvious toxicity of the drug, justifies our earlier speculation that destroying a cancer cell's microfilaments would yield an equivalent therapeutic benefit to destroying the microtubules, but without the toxicity of the latter."

"Large-scale manufacture of the compound now is underway with a target of being in a first-in-man study in 2Q16," Stehn added.

#### **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 yielding drug candidates that

are first-in-class with potential application across a broad range of degenerative diseases. In the oncology field, the ultimate objective is to see both drug technologies used in combination as first-line therapy across most forms of cancer, with the objective of preventing tumor recurrence. This objective is based on a strategy of achieving comprehensive destruction of the full hierarchy of cells within a tumor with the super-benzopyran technology platform killing the tumor-initiating cells and the anti-tropomyosin technology, combined with vinca alkaloids, to deliver a potent chemical debulking effect on their daughter cells.

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.