

# ASX RELEASE

### 16 December 2014

# ASX:NRT

# NASDAQ:NVGN

Novogen Ltd (Company)

ABN 37 063 259 754

### **Capital Structure**

Ordinary Shares on issue:

186 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

# NOVOGEN ANNOUNCES BREAKTHROUGH DISCOVERY IN THE TREATMENT OF MELANOMA

**16 December 2014, Sydney, Australia:** Novogen Limited (ASX:*NRT*; NASDAQ:*NVGN*): Australian/US biotechnology company, Novogen Limited, today announces that it has confirmed that its lead candidate product, TRXE-009, originally developed for the treatment of brain cancers, has been shown in pre-clinical studies also to be highly active against melanoma.

The Company believes this is an important breakthrough discovery for two reasons. The first is that it confirms that TRXE-009 is an important new potential treatment for melanoma, including for the treatment of secondary brain cancers due to melanoma, for which there currently are no effective therapies. The second is that it offers evidence for the first time of an hypothesized link between brain cancer and melanoma.

The link has long been considered a possibility because nerve cells and melanocytes (the melanin pigment-bearing cells in skin that lead to melanoma) have a common origin in the embryo known as the neural crest. This primitive tissue gives rise to the neural cells that go on to form the brain, spinal cord, and peripheral nerves, as well as cells that form the structures of the skull; melanocytes also come from this embryonic tissue. Up till now, no functional link has been found between brain cells and melanocytes, or between brain cancer and melanoma. TRXE-009 is the first compound to demonstrate the possibility of a common link, suggesting that is the first drug with the ability to identify cancers arising in cells that have the neural crest as their common origin.

TRXE-009 has been confirmed as a potential new treatment for both adult and paediatric neural cancers. TRXE-009 previously has been announced as a world-first in having exceptionally high killing activity against adult brain cancer (glioblastoma multiforme) stem cells, and against the paediatric brain cancers - medulloblastoma and DIPG (diffuse interstitial pontine glioma) - all tumors that are highly resistant to known chemotherapies. That same high potency is now confirmed against melanoma cells, with activity unaffected by the tumor's BRAF gene status.

Dr Graham Kelly, Novogen Group CEO, said, "This latest finding brings the value of TRXE-009 into true perspective for us. We initially developed the compound for brain cancer. We saw it as the first chemotherapy with the potential to make a meaningful difference to the survival prospects of patients, both adult and children, with primary brain cancer."

"From there we looked at its ability to kill other cancers of neural origin, and discovered that the same potency against brain cancer cells extended to neuroblastoma cells, a potential deadly cancer in children that arises in peripheral nerve tissue outside of the brain."

"With the realisation that we arguably had the first anti-cancer drug capable of recognising cancers arising in tissues with a common neural crest origin, it was an

obvious next step to look at melanoma, with the outcome that we are announcing today," Kelly explained.

Novogen will be delivering TRXE-009 as a proprietary construct known as Trilexium. Trilexium has been developed to maximise the bio-availability of the drug to cancer cells in the body. Animal xenograft studies of human cancer have confirmed the efficacy of Trilexium.

Kelly said, "This finding completely changes the outlook for this drug candidate. From a drug that was due to come into the clinic specifically for the treatment of adult and childhood neural cancers, we now are presented with a prospective treatment for malignant melanoma, including the treatment of secondary brain cancers due to melanoma for which there currently is no effective therapy."

"We naturally are keen to bring Trilexium into the clinic as soon as possible. But our entire focus at the moment in terms of a clinical program is the product candidate, Cantrixil. That is where our efforts are centred and where our current financial resources are committed, with the objective of achieving the key inflection point of transiting into a clinical-stage company as a firm strategy."

"Trilexium will enter the clinic only when we have been successful in raising funds specifically ear-marked for this project. Those discussions are current with interested stakeholders," Kelly said.

# **About Novogen Limited**

Novogen is a public, Australian 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, including the cancer stem cells. The molecular target is a trans-membrane electron-transfer pump mechanism oncogene that is common to all cancer cells. Cells die by respiratory distress and mitochondrial disintegration.

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

The Company pipeline comprises three SBP drug candidates (TRXE-002, TRXE-009, TRXE-0025) and one ATM drug candidate ('Anisina').

## About TRXE-009

TRXE-009 is an SBP compound generated by the Company's VAL-ID (Versatile Approach to Library-based Iterative Design) drug discovery process, with structure-activity relationship driving design based on activity against brain cancer stem cells and the known required chemical criteria to facilitate passage across the blood-brain barrier.

## **About Trilexium**

Trilexium is a construct of drug candidate, TRXE-009, in a proprietary oil-based formulation selected for its ability to maximize passage of drug across the cancer cell plasma membrane.

## About Melanoma



Malignant melanoma (Stage 4), where the cancer has spread away from the site of origin, remains a major unmet clinical need with limited effective treatment options. Main sites of metastasis are lungs, liver, brain, bones, and distant lymph nodes and skin. Immunotherapies (ipilumumab, vemurafenib, vaccines), chemotherapy (dacarbazine, vinblastine), radiotherapy and surgery are used to prolong life in Stage 4 disease, but these modalities provide little benefit where metastases has occurred to the brain.

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

For more information please contact:

# **Corporate Contact**

Dr. Graham Kelly Executive Chairman & CEO Novogen Group Graham.Kelly@novogen.com +61 (0) 2 9472 4100 Media Enquiries Cristyn Humphreys Operations Manager Novogen Group <u>Cristyn.Humphreys@novogen.com</u> +61 (0) 2 9472 4111