

# ASX:NRT NASDAQ:NVGN

Novogen Ltd (Company)

ABN 37 063 259 754

# **Capital Structure**

Ordinary Shares on issue:

250 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**

4 March 2015

# US STUDIES CONFIRM ABILITY OF TRXE-009 TO KILL BRAIN CANCER STEM CELLS

- Potent killing of highly resistant adult and pediatric brain cancer cells
- Opportunity to effect prevention of recurrence of brain cancer

**4 March 2015, Sydney, Australia:** Novogen Limited (ASX:*NRT*; NASDAQ:*NVGN*): Australian/US biotechnology company, Novogen Limited, today announces that it has confirmed that one of its lead candidate products, TRXE-009, is showing the potential to become an important new therapy in the fight against adult and pediatric brain cancer.

The latest study looked at the ability of TRXE-009 to kill a library of patient-derived cell cultures from subjects with glioblastoma multiform (GBM). The cells were cultured under conditions that promote cancer stem cell growth. These stem-like cancer cells are believed to be responsible for chemotherapy resistance and tumor recurrence.

Killing these highly-resistant GBM cancer stem cells is considered to be a fundamental requirement to successfully treating this highly destructive disease.

All patient derived cancer cells represented in the library responded to TRXE-009 at clinically relevant doses, suggesting a strong therapeutic potential.

The studies were conducted by Drs John Boockvar and Marc Symons at the Feinstein Institute for Medical Research (Feinstein) and with which Novogen is forging a strong collaboration to oversee advancing TRXE-009 into the clinic for adult and pediatric brain cancers.

These findings join with other recently announced pre-clinical studies showing that TRXE-009 is highly cytotoxic of chemo-resistant pediatric brain cancers such as Diffuse Intrinsic Pontine Glioma (DIPG) as well as other pediatric neural and neural crest-derived tumors (i.e. medulloblastoma and neuroblastoma, respectively). Together, these studies suggest that TRXE-009 is a unique drug candidate in preferentially targeting tumors with a common embryonic origin in neural/neural crest cells.

The next step in this drug's development is to confirm it's ability to cross the bloodbrain barrier, a key filtering mechanism that effectively blocks the majority of chemotherapic drugs from reaching brain tissue.

TRXE-009 was designed to cross the blood-brain barrier and has been formulated as a proprietary drug product known as Trilexium. It is anticipated that Trilexium will have

application in the treatment of cancers both with and without brain involvement. Trilexium is due to enter a Phase 1 study in early-2016.

In conjunction with Feinstein, alternative means of delivering TRXE-009 to the brain are under investigation including direct injection into the brain cancer by the process known as convection-enhanced delivery, and the use of lipid brain-targeting particles injected intravenously.

Dr Graham Kelly, Novogen Group CEO, said, "TRXE-009 has been a drug development success story, thanks to a team led by Andrew Heaton PhD and Eleanor Ager, PhD. The TRXE-009 story started with the discovery of a compound that was highly cytotoxic against GBM brain cells that came from patients who had failed to respond to Temozolomide, the only standard of care chemotherapy for GBM; it then showed itself to be an equally effective killer of GBM cancer stem cells; it also is highly active in vitro against a range of pediatric brain cancer cells that are notoriously resistant o chemotherapy; it has been designed to cross the blood-brain barrier; it shows little toxicity against normal human brain cells (astrocytes) in vitro; in its parenteral delivery form, the Trilexium drug-product is highly active in animal models of xenografted human tumors, including GBM, and is reasonably well tolerated. So far it has ticked every box asked of it."

"The urgent need to find a successful treatment for devastating cancers such as primary and secondary brain cancers in adults and children is what is driving our collaboration with Feinstein to bring TRXE-009 into the clinic," Kelly added.

# **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 the name give to a proprietary parenteral formulation of TRXE-009 selected for its ability to maximize systemic drug delivery and effectiveness in pre-clinical rodent models of human cancer.

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

# About the Feinstein Institute of Medical Research

Feinstein is the research entity of the North Shore-LIJ Health System, New York, one of the largest healthcare providers in the US and the largest integrated health system in the State of New York.

John Boockvar MD holds the following appointments:

- Director, Brain Tumor and Pituitary/Neuroendocrine Center
- Department of Neurosurgery
- The New York Head and Neck Institute
- Lenox Hill Hospital/Manhattan Eye, Ear and Throat Hospital
- Investigator, Laboratory for Brain Tumor Biology and Therapy
- Center for Neuroscience and Oncology
- · Director, Brain Tumor Biotech Center
- · Feinstein Institute for Medical Research
- Professor of Neurosurgery and Otolaryngology/Head and Neck Surgery
- Department of Neurosurgery
- Hofstra-North Shore LIJ School of Medicine

Marc Symons PhD holds the following appointments:

- Investigator, The Feinstein Institute for Medical Research
- Co-Director, Brain Tumor Biotech Center, The Feinstein Institute for Medical Research
- · Director, Light Microscopy Facility, The Feinstein Institute for Medical
- Professor, Department of Molecular Medicine and Department of Neurosurgery, Hofstra North Shore-LIJ School of Medicine

For more information please contact:

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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, TRXE-009, 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 TRXE-009, 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, TRXE-009, 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 [DRUG], 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

