NOVOGEN
THE FUTURE OF
CANCER THERAPY

ASX:NRT
NASDAQ:NVGN

Novogen Ltd
(Company)

ABN 37 063 259 754

**Capital Structure**

Ordinary Shares on issue:

281 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**
22 April 2015

# CANTRIXIL RECEIVES ORPHAN DRUG DESIGNATION FROM FDA

- **Cantrixil receives Orphan Drug Designation in U.S. for ovarian cancer**

**22 April 2015. Sydney AUSTRALIA:** US-Australian drug discovery company, Novogen, today announced that its subsidiary joint venture company with Yale University, CanTx, Inc, has today received notification from the U.S. Food and Drug Administration (FDA) that its chemotherapy candidate drug, Cantrixil, has been granted Orphan Drug Designation for ovarian cancer.

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

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

- Financial subsidization for clinical research
- Tax incentives
- Extended patent protection
- Enhanced marketing rights.

Cantrixil was granted Orphan Drug Designation under the U.S. Orphan drug Act following a review by the FDA of a package of pre-clinical data submitted by the Company.

Novogen and CanTx CEO, Graham Kelly, said, "Receiving this designation is one more step in our objective of bringing Cantrixil to market as a drug that we hope will provide meaningful clinical benefit to patients with ovarian cancer and deliver that long-sought breakthrough for patients with a cancer that has shown only slight improvement in 5-year survival rates over the last 30 years."

"CanTx came out of a belief by Yale University and some long-term ovarian cancer researchers in the Yale Medical School that Cantrixil represented a potential breakthrough in the treatment of ovarian cancer," Kelly added.

Key Cantrixil pre-clinical data was presented by Yale researchers two days ago at the American Association of Cancer Research annual conference. That data represented the final stringent challenge that CanTx and Yale clinicians had set Cantrixil in order to justify bringing it into patients. That data related to an animal model believed to be highly representative of late-stage chemo-resistant ovarian cancer. Cantrixil in that highly stringent model delivered a very potent (>95% tumor reduction) anti-tumor effect.

Cantrixil is on track to enter the clinic in Australia in late-2015/early-2016 in patients with the condition, malignant ascites, a terminal condition associated with cancers such as ovarian cancer and for which no effective long-term therapies exist. The Company sees this as a logical entry point into the clinic for the Cantrixil as being a clinical indication without any approved therapies in the U.S. and Australia, and as a prelude to the ultimate objective of using Cantrixil much earlier in the cancer process as a first-line therapy following diagnosis of ovarian cancer.

"The capital-raise Novogen announced yesterday was intended to give the Company the financial runway to bring drugs such as Cantrixil through to the point where we hope to see objective evidence of clinical efficacy. For

Cantrixil, as for all our other pipeline drugs, this is the next key inflection point for the Company in its quest to become a major global drug discovery company. The funds we hope to raise in the current Placement and Rights Issue offerings are intended to take the Company to that next key inflection point."

**About Ovarian Cancer**

Approximately 1 in 70 women will develop ovarian cancer in their lifetime. In the U.S. this equates each year to approximately 22,000 new cases diagnosed and 15,000 deaths from ovarian cancer; the figures for Europe are 66,000 and 41,000 respectively. There are different forms of ovarian cancer with epithelial ovarian cancer accounting for 90% of cases.

Approximately 15% of women present with disease localized to the ovaries and with successful surgery, the 5-year survival rate is >90%.

For women with more advanced disease at the time of diagnosis, the 5-year survival rate is <30%.

Approximately 85% of advanced cases respond to first-line therapy (typically paclitaxel and carboplatin), but about 80% of these will relapse within several years.

**About Cantrixil**

Cantrixil is a cyclodextrin envelope containing the active ingredient, TRXE-002. The construct has been designed as an intra-cavity chemotherapy to be injected directly into the peritoneal and pleural cavities without causing local irritation or toxicity. Its purpose is to achieve high drug levels in the environment in which the cancer is spreading through the migration of the cancer stem cell. The ultimate primary indication of Cantrixil to be sought is first-line therapy of early-stage cancers of the abdominal cavity (e.g. ovarian, uterine, colo-rectal and gastric carcinomas). Cantrixil will enter the clinic in later-stage cancers where the abdominal carcinomatosis has resulted in the terminal condition of malignant ascites.

Cantrixil is owned by CanTx, Inc.

**About CanTx, Inc**

CanTx is a joint venture company between Novogen and Yale University. Novogen owns 85% of the joint venture. Novogen has licensed the drug candidate, TRXE-002, to CanTx for use in Cantrixil. CanTx is based in New Haven, CT.

**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 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 slowly-dividing, less differentiated 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 currently comprises two SBP drug candidates (TRXE-002, TRXE-009) and one ATM drug candidate (Anisina).

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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, Cantrixil, 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 Cantrixil, 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, Cantrixil, 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 Cantrixil, 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.*