

## Novogen's ovarian cancer drug set for trials in H1 2016

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US-Australian drug discovery company, Novogen Limited has provided an update on progress regarding the development of Cantrixil (TRXE-002-1), its lead superbenzopyran (SBP) molecule, which is intended for the treatment of ovarian cancer.

Cantrixil remains on track to commence clinical trials in the second half of 2016, as the company has previously indicated. The company says that the proposed design of the phase I study has been amended in light of emerging data to focus more specifically on patients with ovarian cancer in order to better understand its effects in the target population, and it is no longer anticipated to be restricted to patients with malignant ascites. It is envisaged that the study will be conducted at centers in Australia and the United States, and discussions are ongoing with potential clinical investigators in both countries.

Novogen also indicates that Quintiles, the global clinical research organization (CRO), has been engaged to support execution of the study. Novogen plans to submit an Investigational New Drug (IND) application to the United States Food and Drug Administration (FDA) in August 2016, and expects to achieve First Patient In (FPI) to the study in the fourth quarter of 2016.

In preparation for transition of Cantrixil into the clinic, Novogen has concluded funding to the CanTx joint venture with Yale University, and the CanTx entity will be wound-up in an appropriate manner. All intellectual property licensed from Novogen to CanTx will be returned to Novogen, in accordance with the terms of the agreement between the two companies.

CanTx was formed in November 2013 as a joint venture between Novogen, Yale University, and certain of its faculty, with Novogen owning 85% of the company. The primary purpose of the joint venture was to facilitate the application of Yale's experimental models and preclinical test systems to Novogen's molecules. Novogen licensed components of its intellectual property to CanTx for investigation in the laboratories of Professor Gil Mor, and this work has provided useful data to guide further development of Cantrixil, Novogen's lead superbenzopyran molecule, in the field of ovarian cancer.

A scientific review by Novogen's Board in August 2015 resolved to advance Cantrixil into clinical development in this indication, and the company's R&D team has since been focused on designing and implementing an appropriate first-in-human study.