

## Oncology Venture and Eisai Forge Exclusive Global License Agreement for Clinical Stage Oncology Drug PARP Inhibitor E7449 / 2X-121

*2X Oncology to conduct Phase 2 Study of 2X-121 in metastatic breast cancer patients*

**Hoersholm, Denmark, and Cambridge, MA, July 7, 2017 – Oncology Venture AB (“Oncology Venture”) and 2X Oncology Inc. (“2X Oncology”), today announced that Oncology Venture has entered into an exclusive global license agreement with Eisai Inc. for Eisai’s Phase 2 PARP inhibitor E7449 – now called 2X-121. 2X-121 will be developed by 2X Oncology, a precision medicine company developing targeted therapeutics to address significant unmet needs in women’s cancer.**

2X-121 is a small molecule targeted inhibitor of Poly ADP ribose polymerase (PARP), a key enzyme involved in DNA damage repair in cancer cells. The PARP inhibitor demonstrated clinical activity in a prior Phase 1 study in a number of cancers, including ovarian and breast. The drug also has potential to treat brain metastases and primary brain tumors based on its ability to pass through the blood-brain barrier.

*“We are excited to in-license this promising PARP-inhibitor from Eisai. The cutting-edge science and compelling clinical data behind 2X-121 in combination with our unique Drug Response Predictor (DRP™) biomarker technology provide an exceptional risk-reduced opportunity to develop effective treatments for hard to treat cancers,” said Peter Buhl Jensen, M.D., CEO of Oncology Venture.*

Oncology Venture successfully validated its DRP™ biomarker for 2X-121 using clinical biopsy materials and blinded patient response data provided by Eisai under a prior agreement between the companies.

The drug will be developed in the pipeline of 2X Oncology, a Cambridge, MA-based spin-out of Oncology Venture focused on developing precision medicines for unmet needs in women’s cancers.

*“We plan to initiate a focused Phase 2 trial of 2X-121 for the treatment of metastatic breast cancer later this year, using a DRP™ biomarker to identify patients who are most likely to respond to and benefit from treatment with this promising therapeutic,” said George O. Elston, CEO of 2X Oncology. “Positive data from this study will position this program for a pivotal Phase 2 study initiation in 2018,” Mr. Elston added.*

Under the terms of the agreement, Oncology Venture will be responsible for the development and commercialization of 2X-121 in oncology. Oncology Venture will, through 2X Oncology, Inc., execute a mutually agreed upon clinical development plan, which includes an initial Phase 2 clinical study in patients with metastatic breast cancer using the DRP™ biomarker. Further terms of the agreement were not disclosed.

### **About 2X-121**

2X-121 has a novel dual-inhibitory action against both PARP 1/2 and Tankyrase 1/2. The molecule is also active in P-glycoprotein expressing cells, suggesting it may overcome PARP inhibitor resistance.

A Phase 2 study (>20 patients) is planned using a DRP™ biomarker in metastatic breast cancer patients to identify patients likely to respond to and benefit from treatment with 2X-121. Positive data from this study will position the program for a pivotal Phase 2 study initiation in 2018.

In a prior Phase 1 study conducted without a DRP™, two patients had a durable partial response (281 and 208 days, respectively). 2X-121 was well tolerated with no myelotoxicity observed. The planned Phase 2 study using a DRP™ is expected to significantly improve response rates seen in this initial study.

#### **About the Drug Response Predictor (DRP™) Companion Diagnostic**

Developed by and in-licensed from Medical Prognosis Institute A/S (MPI.ST), the DRP™ screening platform utilizes messenger RNA (mRNA) gene expression signatures from patient biopsies to identify patients with a high likelihood of responding to specific cancer-fighting therapies. This DRP™ method builds on the comparison of sensitive vs. resistant human cancer cell lines, including genomic information from cell lines, combined with clinical tumor biology and clinical correlates in a systems biology network. Specific DRP™s are developed for each pipeline product, which will enable Oncology Venture and its spin-out 2X Oncology to identify and predict which patients are most likely to respond and thereby benefit from a given pipeline product. This would enable likely responders to receive appropriate treatment while expediting the decision path for predicted non-responders, saving them critical time and money in their cancer fight.

#### **About Oncology Venture AB**

Oncology Venture AB is engaged in the research and development of anti-cancer drugs through its wholly-owned Danish subsidiary Oncology Venture ApS. Oncology Venture has an exclusive license to use the Drug Response Predictor (DRP™) platform in order to significantly increase the probability of success in clinical trials. The Company uses a model that alters the odds in comparison with traditional pharmaceutical development. Instead of treating all patients with a particular type of cancer, patients' tumors genes are screened first and only those who are most likely to respond to the treatment will be treated. Focusing on this defined patient group reduces risk and costs are reduced while increasing efficiencies in the development process. The current Oncology Venture product portfolio includes LiPlaCis for breast cancer in collaboration with Cadila Pharmaceuticals; Irofulven for prostate cancer; and APO010, an immuno-oncology product in development for the treatment of multiple myeloma.

In addition to 2X Oncology, of which Oncology Venture currently owns 92%, Oncology Venture has spun out Danish OV-SPV 2, which will test and potentially develop an in-licensed, oral phase 2 Tyrosine Kinase inhibitor.

#### **About 2X Oncology**

2X Oncology Inc. is developing targeted therapeutics that leverage the proprietary Drug Response Predictor (DRP™) biomarker technology to address significant unmet needs in women's cancer. The DRP™ generates a precision mRNA-based companion diagnostic for each compound, enabling the identification of patients that are most likely to respond and benefit from treatment.

The 2X pipeline includes product candidates focused on breast and ovarian cancers and primary and secondary brain tumors. Our product candidates have been selectively in-licensed using strict criteria, including established clinical efficacy and safety and a known mechanism of action. We expect to advance these programs through focused Phase 2 studies using a targeted DRP™ CDx with key data available in 2018. Learn more at [2xoncology.com](http://2xoncology.com).

#### **About Eisai Inc.**

At Eisai Inc., human health care (hhc) is our goal. Eisai gives its first thoughts to patients and their families, and

helping to increase the benefits health care provides. As the U.S. pharmaceutical subsidiary of Tokyo-based Eisai Co., Ltd., Eisai Inc. has a passionate commitment to patient care that is the driving force behind Eisai's efforts to discover and develop innovative therapies to help address unmet medical needs.

Eisai is a fully integrated pharmaceutical business that operates in two global business groups: oncology and neurology (dementia-related diseases and neurodegenerative diseases). Each group functions as an end-to-end global business with discovery, development, and marketing capabilities. Eisai's U.S. headquarters, commercial and clinical development organizations are located in New Jersey; discovery labs are in Massachusetts and Pennsylvania; and the global demand chain organization resides in Maryland and North Carolina. To learn more about Eisai Inc., please visit us at [www.eisai.com/US](http://www.eisai.com/US).

#### **Eisai Co., Ltd.**

Eisai Co., Ltd. is a leading global research and development-based pharmaceutical company headquartered in Japan. Eisai defines its corporate mission as "giving first thought to patients and their families and to increasing the benefits health care provides," which Eisai calls its *human health care (hhc)* philosophy. With over 10,000 employees working across its global network of R&D facilities, manufacturing sites and marketing subsidiaries, Eisai strives to realize its hhc philosophy by delivering innovative products in various therapeutic areas with high unmet medical needs, including oncology and neurology. For more information about Eisai Co., Ltd., please visit [www.eisai.com](http://www.eisai.com).

*DRP™ is a trademark of Medical Prognosis Institute A/S.*

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