

OV's spinout - 2X Oncology Obtains US IND for 2X-111 a Liposomal Doxorubicin for Breast and Brain Cancer

Hoersholm, Denmark, June 8th, 2017 – Oncology Venture Sweden AB ("OV") today announced that its spinout 2X Oncology, Inc. ("2X") (Cambridge, MA), a precision medicine company developing targeted therapeutics to address significant unmet needs in women's cancer, has obtained the Investigational New Drug (IND – i.e. allowance to run clinical trials in the US) application for 2X-111 (doxorubicin hydrochloride and glutathione) from 2-BBB Medicines B.V. wherefrom the drug has been in-licensed: 2X-111 is being developed as a new treatment option for women with brain metastases from breast cancer and for patients with recurrent glioblastoma multiforme (GBM). 2X-111 will be developed in two focused Phase 2 trials in metastatic Breast Cancer and in Glioblastoma an orphan-designated condition in 2X Oncology Inc. Data from these studies are expected in 2018 which, if positive, can position this program for possible accelerated approval filings. 2X is currently owned 92% by Oncology Venture.

"It is of great value for the 2X-111 project to have the IND in place in the US for the running of clinical trials", said Adjunct Professor Peter Buhl Jensen, M.D., CEO of Oncology Venture. "The Breast cancer trial will in accordance with our plans initially be run in already screened breast cancer patients at Danish sites; The study in Glioblastoma (Cancer in the Brain) is planned to be initiated at Danish sites followed by US site(s) for which we have now obtained an IND", Peter Buhl Jensen further commented.

"Having this IND in place is an important step as we focus on initiating Phase 2 clinical trials of 2X-111 in GBM and brain metastases from breast cancer later this year. "These studies will employ our proprietary DRP™ companion diagnostic to identify patients based on their unique tumor mRNA expression and treat those most likely to respond to and benefit from therapy," said George O. Elston, CEO of 2X Oncology, "Patient selection based on the unique genetic properties of a tumor is an important new direction in the treatment of cancer, and we are pleased to have this capability for our programs and patient," Mr. Elston added.

Formerly known as 2B3-101, 2X-111 improves on commercially available PEGylated liposomal doxorubicin products with an additional glutathione coating that safely enhances drug delivery across the blood-brain barrier. Doxorubicin is an anthracycline that inhibits the growth of many cancerous cell lines, including glioblastoma and breast cancer cell lines. It is among the most widely used anti-cancer agents.

An [abstract](#) on the predictive ability of the DRP in treating advanced breast cancer with a similar anthracycline, epirubicin, was presented in a poster-session at the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting. The abstract describes a retrospective-prospective blinded study which evaluated the ability of the DRP to predict the efficacy of epirubicin in a cohort of 135 metastatic breast cancer patients. The DRP was significantly associated with progression free survival in this study. The estimated median time to progression for a patient with a DRP value of 25% was 7 months, versus 13 months for a patient with a DRP value of 75%.

Mr. Elston will discuss 2X-111 and other 2X pipeline drugs at the Jefferies 2017 Global Healthcare Conference on June 9, 2017, at 10:00am EDT. The presentation will be available as a and the link will be distributed in an Investor Information press release and posted on the companies' websites once available.

For further information on Oncology Venture please contact

Ulla Hald Buhl, COO and
Chief IR & Communications
Mobile: +45 2170 1049
E-mail: uhb@oncologyventure.com

or

Peter Buhl Jensen, CEO
Mobile: +45 21 60 89 22
E-mail: pbj@oncologyventure.com

This information is that Oncology Venture Sweden AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, on June 8th 2017.

About Breast Cancer Brain Metastases

Breast cancer is the second most common cause of brain metastases, with metastases occurring in 10–16 % of patients. Patients who develop brain metastases tend to have poor prognosis with short overall survival. Furthermore, brain metastases are a major cause of morbidity, associated with progressive neurologic deficits that result in a reduced quality of life.

About Glioblastoma Multiforme

Glioblastoma multiforme (GBM) is the most common class of malignant primary brain tumors and one of the most aggressive forms of cancer. This highly invasive and proliferative cancer resists standard chemotherapy and radiotherapy. Current therapeutic strategies for the treatment of GBM fail to demonstrate adequate efficacy and/or are generally palliative. Median overall survival is 12 to 14 months.

About the DRP™ Companion Diagnostic

Developed by and in-licensed from Medical Prognosis Institute, 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 us 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. DRP™ is a trademark of Medical Prognosis Institute A/S.

About Oncology Venture Sweden AB (OV)

OV is engaged in the research and development of anti-cancer drugs via its wholly owned Danish subsidiary Oncology Venture ApS. Oncology Venture has a license to use Drug Response Prediction – DRP™ – in order to significantly increase the probability of success in clinical trials. DRP™ has proven its ability to provide a statistically significant prediction of clinical outcomes from drug treatment in cancer patients in 29 of the 37 clinical studies that were examined. 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. Via a more well-defined patient group, the risk and costs are reduced while the development process becomes more efficient.

The current product portfolio: LiPlaCis for Breast Cancer in collaboration with Cadila Pharmaceuticals, Irofulven developed from a fungus for prostate cancer and APO010 – an immuno-oncology product for Multiple Myeloma.

Oncology Venture has spun out 2X Oncology Inc. a company focused on developing precision medicine for women's cancer with three anticancer products in pipeline and OV-SPV2 which will test and potentially develop an oral Tyrosine Kinase inhibitor from a Big Pharma the treatment of cancers.

About 2X Oncology

2X Oncology Inc. is a clinical stage precision medicine company developing targeted therapeutics that leverage proprietary Drug Response Predictor (DRP™) 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 with potential utility in the treatment of breast, ovarian, and endometrial cancers and primary and secondary brain tumors. These programs have shown clinical efficacy and safety and are positioned to enter focused Phase 2 studies with data expected in 2018.

A Cambridge, MA based spin-out from [Oncology Venture ApS](#), 2X works in close collaboration with Oncology Venture and leverages its Danish registry of over 1,100 cancer patients for initial clinical studies. Learn more at 2xoncology.com.