

## OV predicts drug efficacy in breast cancer patients. New study on cornerstone drug epirubicin published in “Breast Cancer Research and Treatment”

**Hoersholm, Denmark, August 14, 2018 – Oncology Venture Sweden AB (“Oncology Venture”) today announced the publication of the scientific article *“Predicting efficacy of epirubicin by a multigene assay in advanced breast cancer within a Danish Breast Cancer Cooperative Group (DBCG) cohort: a retrospective-prospective blinded study”* in the peer reviewed scientific journal: Breast Cancer Research and Treatment.**

**The Drug Response Predictor (DRP) is OV’s technology for personalized and precision medicine. The DRP was significantly associated to its primary endpoint Time to Progression (TTP) in a cohort of 140 consecutive metastatic breast cancer patients treated with single drug epirubicin. TTP is a measure of the time from start of treatment to progression of the disease. 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%. Please see the publication in the scientific journal: Breast Cancer Research and Treatment [here](#).**

Epirubicin is an anthracycline and like its sister molecule doxorubicin a cornerstone in the treatment of primary and advanced breast cancer. In primary breast cancer epirubicin or doxorubicin are part of the adjuvant therapy given after surgery to prevent later recurrence. In advanced breast cancer usually about 50% will benefit with a reduction in their tumor size. Until now there has been no method to find out who will benefit and who will not. The current study looked at 140 consecutive patients receiving epirubicin to evaluate Oncology Ventures anthracycline Drug Response Predictor (DRP®). The DRP was significantly associated to Time to Progression (TTP). TTP is a measure of the time from start of treatment to progression of the disease.

The estimated median time to progression (TTP) for a patient with a DRP value of 25% was 7 months versus 13 months for a patient with a DRP value of 75%. Hazard Ratio was 0.55 for a 50% points difference in DRP score meaning that the patient has a statistically significant and clinically relevant longer benefit (TTP) of the drug at a DRP score of 75 compared to a DRP score of 25.

Data from this study substantiates a pool of previous retrospective/prospective DRP data from OV and the presented clinical validation provides a strong tool to be applied in clinical studies of OV’s liposomal doxorubicin – where patients tumor tissue can be measured by the DRP method for likelihood of response ahead of entering a 2X-111 study.

Oncology Venture’s 2X-111 is a GSH-liposomal- doxorubicin product for breast and brain cancer. After finalization of manufacturing 2X-111 will be developed in two focused Phase 2 trials in metastatic breast cancer and in Glioblastoma.

*“Oncology Ventures proprietary Drug Response Prediction - DRP - technology again provides strong and convincing data on its ability to match patients with effective drugs. I feel confident by these epirubicin results that we will be able to develop 2X-111 as a very effective drug for breast cancer patients. Knowing who will be likely to benefit is of outmost importance and so in knowing who will not – these patients needs a treatment with a different drug”, said Peter Buhl Jensen, M.D., CEO of Oncology Venture. “Epirubicin and doxorubicin are used in many different cancers and the DRP is of value for treatment of several tumor types as lymphoma, multiple myeloma, sarcomas, endometrial cancer and ovarian cancers”, Peter Buhl Jensen further commented.*

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#### **About 2X-111 – a liposomal doxorubicin**

2X-111 is an anthracycline which is able to pass the blood brain barrier and has the potential to treat cancers also in the brain. This is a very unusual opportunity. 2X-111 is enriched by a technology for enhanced delivery of doxorubicin to the brain and to enable better treatment of metastatic cancer types and primary brain tumors. In preclinical studies it has been shown that conjugation of glutathione to liposomes can provide a five-fold increased delivery of doxorubicin to the brain compared to untargeted liposomes. 2X-111 has been studied in a phase 1/2a clinical trial in 10 clinical sites in the United States, the Netherlands, Belgium, and France confirming its tolerable safety profile in 85 patients and showing encouraging signs of anti-tumor activity in metastatic Breast Cancer and Glioblastoma (primary brain tumor). Initial data using the DRP was presented as a poster at the annual ASCO conference 2017. A robust manufacturing procedure is in place, and we look forward to developing this product once contract negotiations on product manufacturing are in place. After finalization of manufacturing 2X-111 will be developed using the DRP technology in two focused Phase 2 trials in metastatic breast cancer and in glioblastoma.

#### **About the Drug Response Predictor - DRP® Companion Diagnostic**

Oncology Venture uses the Medical Prognosis Institute (MPI) multi gene DRP® to select those patients who by the genetic signature of their cancer are found to have a high likelihood of responding to the drug. The goal is developing the drug for the right patients, and by screening patients before treatment the response rate can be significantly increased. The 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. DRP® is based on messenger RNA from the patient's biopsies. The DRP® platform, i.e. the DRP® and the PRP™ tools, can be used in all cancer types and is patented for more than 70 anti-cancer drugs in the US. The PRP® is used by MPI for Personalized Medicine. The DRP® is used by Oncology Venture for drug development. DRP® is a registered trademark of Medical Prognosis Institute A/S.

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

Oncology Venture Sweden AB 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® –to significantly increase the probability of success in clinical trials. DRP® has proven its ability to provide a statistically significant prediction of the clinical outcome from drug treatment in cancer patients in 29 out of 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 first screened, and only the patients most likely to respond to the treatment will be treated. Via a more well-defined patient group, risks and costs are reduced while the development process becomes more efficient.

The current product portfolio includes: LiPlaCis® for breast cancer in collaboration with Cadila Pharmaceuticals; irifolven for prostate cancer; and APO010, an immuno-oncology product for multiple myeloma.

Oncology Venture has spun out two companies as Special Purpose Vehicles: Oncology Venture U.S. Inc. (previously 2X Oncology Inc.), a US-based precision medicine company focusing developing two promising phase 2 product candidates, and OV-SPV 2, a Danish company that will test and potentially develop a Phase 2 oral Tyrosine Kinase inhibitor.

On the May 30, 2018, MPI and Oncology Ventures respective general assemblies decided to [merge](#). Trading in the Oncology Venture share continues the next couple of months and all OV shares will - when the merger is finalized - give 1,8524 MPI shares.

#### **Forward-looking statements**

This announcement includes forward-looking statements that involve risks, uncertainties and other factors, many of which are outside of OV's control and which could cause actual results to differ materially from the results discussed in the forward-looking statements. Forward-looking statements include statements concerning OV's plans, objectives, goals, future events, performance and/or other information that is not historical information. All such forward-looking statements are expressly qualified by these cautionary statements and any other cautionary statements which may accompany the forward-looking statements. OV undertake no obligation to publicly update or revise forward-looking statements to reflect subsequent events or circumstances after the date made, except as required by law.