

## OV LiPlaCis™ - First DRP-positive Breast Cancer Patient obtained reduction of tumor

**Hoersholm, Denmark; August 23<sup>rd</sup>, 2016 – Oncology Venture Sweden AB (OV:ST) announces that the first patient with metastatic breast cancer included in the extension – proof of concept part of the LiPlaCis trial has obtained a confirmed Partial Remission (ie >30% reduction of her tumor). The patient has – in addition to surgery and adjuvant treatment received five prior medical treatments of her disease with the best response of Stable Disease (i.e. no change in the overall measurement of the tumor burden) and is a patient with a hard to treat tumor.**

**The patient is the first out of 12-15 patients whose tumor tissue has been screened for genomic expression by the Drug Response Predictor – DRP™ and found to be in the top 10% of patients who have the highest likelihood of response to LiPlaCis treatment.**

**The DRP is designed to enable a high response rate and give Breast Cancer patients a new effective personalized treatment opportunity.**

**The extension PoC phase will take approximately 12 months, with interim data expected during this period.**

More than 1100 patients have had their tumors DRP-screened beforehand. The included patients in the LiPlaCis proof of concept study will be in the top 10% of high likely responders according to the DRP, by which patients' individual biopsies are analyzed for sensitivity (effect) to LiPlaCis. Using a conservative cut off of top 10% is to demonstrate the ability of the DRP to select sensitive patients. Later, the cut off is expected to be less conservative, as the relevant patient population is expected to be at a cut off around 30-40%.

*"Knowing that this in one patient out of up to 15 and therefore not data that can promise that LiPlaCis will be approved, I am however happy every time OV's drug and Professor Knudsen's Drug Response Predictor technology makes a difference for a patient. LiPlaCis - OV's lead product - is the first prospective study which is set up to demonstrate that our DRP can select those patients who will benefit from the treatment", said Adjunct Professor Peter Buhl Jensen, MD, PhD and CEO of Oncology Venture. "The hope is that we can keep delivering good results in the study and develop a new, effective personalized treatment option for Breast Cancer patients with metastatic disease. We believe the future lies in personalized treatment, and that Oncology Venture is at the forefront with its DRP technology", Dr. Buhl Jensen further commented.*

### **About LiPlaCis**

Cisplatin is one of the most widely used drugs in the treatment of cancer due to its documented efficacy in a number of tumour types. Cisplatin is used in the treatment of large indications such as Lung Cancer (EU+US ≈ 480,000 new cases annually), Head and Neck Cancer (500,000 cases annually worldwide) Bladder Cancer (EU+US ≈ 170,000 annually) and Ovarian Cancer (EU+US ≈ 71,000 annually). The lipid formulation LiPlaCis is the answer to a well-established need for improving cisplatin therapy and the formulation of the drug, so that a more selective up-take of cisplatin takes place at the site of the tumor.

### **More About LiPlaCis™ and the Clinical Testing**

The Phase 1 study to evaluate the safety and tolerability of LiPlaCis in patients with advanced tumours has been conducted at two Oncology sites at University Hospitals in Copenhagen and has included 20 patients in the dose escalation part of a phase 1 study in solid tumors. The LiPlaCis program has now moved into the extension proof of concept phase, which is part of the phase 1 application where patients with a specific disease – here metastatic Breast Cancer - are included to investigate early Proof of Concept, i.e. effect of the drug. 75mg LiPlaCis™/patient is administered intravenously in weekly cycles on day 1 and day 8. Upon the investigator's judgement, the patient may continue treatment for more than three cycles when benefiting from the study drug.

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## **About the Drug Response Predictor - DRP™ - Screening Tool**

Oncology Venture uses the MPI DRP™ to select those patients that by the gene signature in their cancer is found to have a high likelihood of response to the drug. The goal is to develop the drug for the right patients and by screening patients before treatment the response rate can be significantly increased.

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. The DRP™ based on microRNA is used on certain products where the DRP™ based on messenger RNA is more broadly useable and more validated.

## **For further information, please contact**

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## **About Oncology Venture Sweden 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™ – 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 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, **Irofulven**, developed from a fungus, for Prostate Cancer, and **APO010**, an immuno-oncology product for Multiple Myeloma.