

## Successful prediction of Cancer response to LiPlaCis® in Breast cancer and other tumors by OV's DRP™ – strong support for randomized Phase 2

Hoersholm, Denmark June 27<sup>th</sup> 2017 – Oncology Venture Sweden AB (OV:ST) announces that data from the ongoing LiPlaCis Phase 1/2 study shows that tumor response to LiPlaCis can be predicted by Oncology Ventures Drug Response Predictor (DRP™) independent of tumor type and including Breast Cancer. Data included in the analysis of 11 patients derives from available tissue from patients – some who responded to the LiPlaCis treatment and some who did not. These early data suggest that patients predicted sensitive to LiPlaCis (top third) have a 67% probability of response, and a median of 18 weeks to progression. Of the 11 patients with mixed tumor types (where 8 come from the dose escalation cohort and 3 from the ongoing Phase 2 part) 2 patients had a Partial Remission (PR) and 4 patients had Stable Disease (SD). Patients currently in LiPlaCis treatment in the ongoing Phase 2 are not included in the analysis. LiPlaCis® is evaluated in an ongoing, multicenter Phase 2 study in metastatic Breast Cancer expected to finalize recruitment in Q3 2017.

*"If these early results hold in the completed Phase 2 in Breast Cancer, LiPlaCis would be of substantial benefit to those patients predicted sensitive,"* **Said Peter Buhl Jensen, Adjunct professor, MD, PhD and CEO of Oncology Venture.** *"The aim is to develop new effective treatment options for patients with hard to treat cancers guided by our Drug Response Predictor - DRP. Our results support that the LiPlaCis DRP is broadly applicable in Breast Cancer and across several cancer types,"* **Commented Peter Buhl Jensen** *"Cisplatin is one of the most active anticancer agents ever developed and LiPlaCis is developed as a new improved cisplatin which we can use with precision for the individual patient. We are of course aware that these are early results which need further validation but they do give us good hope for the ongoing and continued studies of LiPlaCis,"* **Peter Buhl Jensen further commented.**

### Data

Oncology Venture has now completed analysis of those patients - where tumor tissue was available - from the dose escalation phase of the LiPlaCis Phase 1/2 trial. A total of 11 patients have been analyzed whereof 3 patients from the Phase 2 part have been included. Patients in ongoing LiPlaCis treatment are not included in the analysis. Of the 11 patients with mixed tumor types (where 8 come from the dose escalation cohort) 2 patients had a Partial Remission (PR) and 4 patients had Stable Disease (SD). The correlation between prediction and response to treatment was 0.5 with a one-sided p-value of 0.06. Due to the small number of patients and mixed tumor types, this is a successful validation of the DRP's ability to predict response. These early data suggest that patients predicted sensitive to LiPlaCis (top third) have a 67% probability of response, and a median of 18 weeks to progression.

### Strong support of randomized Phase 2 in Breast Cancer

The above data supports the ongoing LiPlaCis development in collaboration with Cadila Pharmaceuticals LTD ("Cadila") and Smerud Medical Research. Oncology Venture entered a collaboration agreement with Cadila. Cadila invest in kind i.e. in research and development activities of 310 cancer patients and DRP screening of more than 1400 patients. Cadila will perform four (4) Phase 2 trials in Prostate, Head & Neck, Skin and Esophageal cancers and a pivotal randomized clinical Phase 3 trial in metastatic Breast Cancer.

A total of 18 million SEK has, as previously communicated, been granted to OV's LiPlaCis project by Oncology Ventures partner Smerud Medical Research and the EUROSTARS program and Oncology Venture and Smerud

now starts the preparation of a randomized Phase 2 in Breast Cancer which is expected to include other European countries.

#### **LiPlaCis® Phase 2 for metastatic Breast Cancer (mBC)**

LiPlaCis is an intelligent targeted liposomal formulation of cisplatin. LiPlaCis has finalized the dose escalation part of the trial and has demonstrated promising activity in patients already in the dose escalation part.

LiPlaCis™ is administered intravenously in 3 week cycles on day 1 and day 8. Upon the investigator's judgement, the patient may continue treatment for more than 3 cycles when benefitting from the study. Response (confirmed PR = Partial Response) has been published for the first DRP-screened patient with a hard to treat metastatic Breast Cancer.

LiPlaCis has received status as a phase 2 study by the Danish authorities and i.e. 3 out of 4 in total Danish centers are now active in recruiting 12-15 metastatic Breast Cancer patients screened and expected to be highly likely responders to LiPlaCis. Phase 2 study in metastatic Breast Cancer expected to finalize recruitment in Q3 2017.

LiPlaCis® has been registered together with its DRP™ companion diagnostic for an EU-marking. Next step in the regulatory strategy is building a data package for a 'Pre-Submission meeting' with the FDA. This is done in collaboration with US-experts.

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

Oncology Venture uses the Medical Prognosis Institute (MPI) multi gene DRP™ to select those patients that by the genetic 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™ is based on messenger RNA from the patients 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 in Oncology Venture for drug development.

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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' 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 two companies in Special Purpose Vehicles: 2X Oncology Inc. a US based company focusing on Precision medicine for women's cancers with a pipeline of three promising phase 2 product candidates and Danish OV-SPV 2 will test and potentially develop an oral phase 2 Tyrosine Kinase inhibitor.*

*This information is information 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 27<sup>th</sup>, 2017*