Oncology Venture Sweden AB
Hoersholm, Denmark, May 31st 2016
Press release

OV LiPlaCis™ - First Screened Breast Cancer Patient Dosed in First Prospective Study

Hoersholm, Denmark; May 31st, 2016 – Oncology Venture Sweden AB (OV:ST) announces that the first patient has been dosed in the proof of concept extension phase of the dose escalation phase 1 study with LiPlaCis. LiPlaCis has already in the dose escalation part shown promising clinical activity in unselected, hard to treat patients. LiPlaCis is the lead product in Oncology Ventures pipeline, and this is the first prospective trial using the Drug Response Predictor, DRP™.
Twelve to fifteen (12-15) screened patients with metastatic Breast Cancer (mBC) are now to be enrolled in the LiPlaCis extension phase of the study to demonstrate safety and efficacy.
Using DRP-analysis of biopsies - patients are screened beforehand for high likelihood of effect of the LiPlaCis™ drug. The DRP™ should thereby 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 1000 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%.

"I am very excited that our lead product LiPlaCis is now including Breast Cancer patients in this first prospective study. This is a major step ahead for Oncology Venture. The LiPlaCis extension study 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 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 a Phase 1 Unit at a University Hospital 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.

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.*