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Press release

Positive data from Oncology Venture's Lead Product LiPlaCis

Hoersholm, Denmark; April 26th, 2016 – Oncology Venture Sweden AB (OV:ST) announces positive feed-back on data presented at the AACR (American Association for Cancer Research) Annual Meeting 2016 in New Orleans. An ongoing phase 1 dose-escalating PoC study to evaluate the safety and tolerability of LiPlaCis in patients with advanced refractory tumors was presented as a poster. Preliminary efficacy data from the dose escalation part of the ongoing LiPlaCis phase 1 study where clinical activity and disease control was observed in 5 patients out of a total of 16 evaluable on doses on and above 60mg: 2 Partial Remissions and 3 Stable Diseases in previously heavy treated patients with solid tumors. The overall conclusion was that the MTD has not yet been settled, but ongoing PoC cohorts indicate that LiPlaCis is favorably released in tumor by sPLA2 and potentially improving the therapeutic index of cisplatin. In the 60 mg PoC cohort of 3 pts, the tumor- to normal tissue ratio of platinum-DNA adducts was from 5.7 to 8.3. This indicates that the delivery technology behind LiPlaCis works which will be sought further documented in a larger number of patients.

"The phase 1 study of LiPlaCis aims to increase efficacy of the conventional cisplatin hopefully with a better toxicity profile. The data presented at AACR indicates favorably released of LiPlaCis in tumor by sPLA2 which can potentially improve the therapeutic index of cisplatin and give a new treatment option to cancer patients. LiPlaCis will be investigated closer in an extension phase of the ongoing study in metastatic breast cancer patients to further validate these data and to investigate the potential of the Drug Response Predictor – DRP™ – to increase the effect of LiPlaCis in an enriched patient population", **says Professor Ulrik Lassen, MD, PhD, Principal Investigator and Head of the Phase 1 Unit at the University Hospital, Rigshospitalet in Copenhagen.**

"I'm very happy about the positive feed back from the principle investigator who presented the data on the AACR conference. Data from 3 patients at dose level 60mg shows that the platin levels (the active part of LiPlaCis) at tumor site are significantly higher than in normal tissue indicating that the liposomal delivery technology is effective and that LiPlaCis in fact works as targeted therapy as hoped. The aim with target LiPlaCis therapy is to deliver more effective treatment to cancer patients," **Said Adjunct professor Peter Buhl Jensen, M.D., PhD and CEO of Oncology Venture.** *"I believe it is very promising that LiPlaCis has already demonstrated effect in 2 patients (PR) and durable disease control (SD) in further 3 cancer patients with solid tumors out of 16 evaluable patients"***, Peter Buhl Jensen further added.**

In the following extension proof of concept phase of this ongoing LiPlaCis study we will further to the cutting edge liposomal delivery technology add the Drug Response Prediction (DRP™) screening of breast cancer patients with metastatic disease to increase the likelihood of responding patients. The LiPlaCis targeted therapy is expected to be more efficient than the conventional cisplatin treatment.

LiPlaCis in Phase 1

Objective

The primary objectives were safety and establishment of MTD. Secondary objectives were determination of PK, clinical activity, and PD. This included two PoC cohorts to study platinum-DNA adducts in tumor compared to normal tissue following administration of LiPlaCis.

Methods

Standard 3-3 design was used to include patients with advanced solid tumors and PS 0-1. LiPlaCis was administered weekly on day 1, day 8, and possibly day 15 every 3 wks. CTCAE v4.03 and RECIST were used to assess safety and activity. Pre-treatment tumor biopsies and Day 2 tumor and normal tissue biopsies were used to assess $sPLA_2$-IIA protein levels and platinum-DNA adducts (by ^{32}P-postlabeling assay) in two cohorts of 60 and 90 mg LiPlaCis.

Results

A total of 16 patients were included at dose levels of 60, 90 and 120 mg. At 120 mg two DLTs were observed and an intermediate dose level of 90 mg Day 1 and 8 and 45 mg Day 15 was explored. After 1 DLT, this dose level was halted and the PoC cohorts were

initiated sequentially. The observed DLTs included renal toxicity and infusion reactions. Most frequent AEs of all grades were fatigue, hypomagnesemia and vomiting. The most common (>10%) grade 3-4 AEs were hypomagnesemia, hypokalemia and anemia. Clinical activity was observed in patients with: H&N (Head and Neck Cancer), 60 mg: Partial Remission, SCC (Skin Cancer), 120 mg: Partial Remission, BC (Breast Cancer), 60 mg: Stable Disease, CC (Colorectal Carcinoma), 90 mg: Stable Disease - 18 weeks, and GCA (Gastric Cancer), 90 mg: Stable Disease - 21 weeks. In the 60 mg PoC cohort of three patients, the tumor- to normal tissue ratio of platinum-DNA adducts was from 5.7 to 8.3.

Conclusion
MTD has not yet been settled, but ongoing PoC cohorts indicate that LiPlaCis is favorably released in tumor by sPLA2, and is potentially improving the therapeutic index of cisplatin.

About LiPlaCis™
Thanks to its documented efficacy in a number of tumour types, cisplatin is one of the most widely used drugs in the treatment of cancer. Cisplatin is used in the treatment of large indications as lung cancer (EU+US ≈ 480,000 new cases annually), head and neck cancer (over 500,000 cases annually worldwide) bladder cancer (EU+US ≈ 170,000 annually) and ovarian cancer (EU+US ≈ 71,000 annually). The lipid formulation from LiPlasome, from where Oncology Venture recently in-licensed LiPlaCis, is the answer to a well-established need for improving cisplatin therapy and improving the formulation of the drug, so that a more selective up-take of cisplatin takes place at the tumour sites. LiPlasome Pharma ApS has identified and incorporated a mechanism into their liposomes - called LiPlasomes. It is designed to trigger the release of an encapsulated drug specifically in the tumour tissue. An enzyme especially present on tumors called secretory phospholipase A2 (sPLA2), is utilised to break down the LiPlaCis once it has accumulated in the cancer tissue. The lipid composition of the LiPlasomes is tailored to be specifically sensitive to degradation by the sPLA2 enzyme and thereby for release of the encapsulated drug. The technology behind LiPlaCis™ was originally developed by scientists from Danish Technical University –DTU.

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.

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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 an intelligent liposomal formulation of cisplatin for Breast Cancer, Irofulven developed from a fungus for prostate cancer and APO010 – an immuno- oncology product for Multiple Myeloma.