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Press release

LiPlaCis Phase 2 Recruitment Ongoing in DRP Screened Breast Cancer Patients: Relevant Clinical Benefits in 3 out of 5 Treated Patients

Hoersholm, Denmark, September 19th, 2017 – Oncology Venture Sweden AB (OV:ST) announces early data from the ongoing LiPlaCis® Phase 1/2 study show response and clinical benefits in hard to treat patients with metastatic Breast Cancer. A total of 12-15 patients are to enter the Phase 2 part of the study, which as previously announced is expected to be achieved during this September. So far, a total of eight patients have been included in the phase 2 part, and as of now five of these have received LiPlaCis® treatment during a time period sufficient to evaluate efficacy – please see below!
Full clinical information will be published once mature data is available.
Patients have been included in the trial based on a positive LiPlaCis® Drug Response Predictor (DRP™) analysis of each individual patients' tumor biopsy.

Early data from five evaluable included metastatic Breast Cancer patients predicted to be likely responders to LiPlaCis® shows:

- One patient has a confirmed Partial Remission (PR, i.e. >30% reduction of her tumor) of 32 weeks. In addition to surgery and adjuvant treatment, the patient has received five prior medical treatments for her disease, with the best response being Stable Disease (i.e. no change in overall measurement of the tumor burden) The patient is suffering from a hard to treat tumor.
- Another patient has Stable Disease for >24 weeks. When SD > 24 weeks, patients are accounted for as responders. The patient is still receiving LiPlaCis® treatment. Prior to the LiPlaCis® treatment, the patient has received seven medical treatments of her disease, with the best response being Stable Disease (i.e. no change in the overall measurement of the tumor burden) Consequently, this is also a patient with a hard to treat tumor. Alongside a durable Stable Disease, this patient has clinical benefit of LiPlaCis® as metastases to the lung have resulted in production of fluid in the lungs (pleural effusion) which the patient needed to have removed.
  This is normally a repetitive procedure but since the LiPlaCis® treatment started, no thoracentesis has been needed. In addition, the patient has resumed a part-time work.
- A third patient, currently with Stable Disease for 17 weeks, has metastases in the liver. At the time of inclusion in the study, her liver function values were severely elevated as a consequence of her cancer disease. This patient belongs to a fragile and hard to treat group of mBC patients. During treatment with LiPlaCis®, the liver enzyme values have all been normalized, demonstrating a clinical response.
- One patient has a short Stable Disease (SD), and one patient had Progressive Disease (PD). It may be of interest that both these patients have previously received 12 prior treatments, including carboplatin - a cisplatin-like product - and may be resistant to treatment with LiPlaCis®.
- Five patients are currently receiving treatment in the study (are ongoing), whereof three have not yet been in the study for a sufficient time period to evaluate efficacy of LiPlaCis.

Furthermore, data show that LiPlaCis® is well tolerated with mainly mild and only few moderate side effects (five grade 3 and no grade 4).

*"I'm excited about these early clinical results of LiPlaCis in hard to treat metastatic breast cancer and look forward to finalizing the study"**, said MD, PhD Erik Hugger, Senior Consultant and Investigator at Vejle Hospital.***

"I'm excited about these promising early results of the Phase 2 part of the LiPlaCis® study, where patients are screened as high likely responders before entering the trial", **says Peter Buhl Jensen, MD, PhD and CEO of**

Oncology Venture. *"Several of the metastatic Breast Cancer patients are considered hard to treat, with seven to twelve lines of treatment before receiving LiPlaCis®. We are dedicated to developing new effective treatment options for these patients, guided by our Drug Response Predictor, DRP™. For LiPlaCis the goal is to obtain more than 10% response rate. My expectations are high for the DRP technology, as I believe it will bring new hope and better treatments for cancer patients"***, comments Peter Buhl Jensen "***I look forward to finalize the inclusion in the study later this month, and to report the final results as they mature."***, Buhl Jensen further comments.**

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 has entered a collaboration agreement with Cadila, according to which they will invest in research and development activities for 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 Cancer, and a pivotal randomized clinical Phase 3 trial in metastatic Breast Cancer.
As previously communicated, a total of 18 million SEK has been granted to OV's LiPlaCis® project by Oncology Venture's partner Smerud Medical Research and the EUROSTARS program. Oncology Venture and Smerud now begin preparations for a randomized Phase 2 in Breast Cancer, 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.
The drug is administered intravenously in three (3) week cycles on day 1 and day 8. Upon the investigator's judgement, the patient may continue treatment for more than three (3) cycles when benefitting from it.
LiPlaCis® has shown activity in Skin Cancer, Esophageal Cancer, Head and Neck Cancer, and Breast Cancer.
Response (confirmed PR = Partial Response) has been published for the first DRP-screened patient with a hard to treat metastatic Breast Cancer.
The drug has received status as a phase 2 study by the Danish authorities and three out of four planned Danish Medical Centers are now active in recruiting 12-15 metastatic Breast Cancer patients who are screened and expected to be highly likely responders to LiPlaCis®. The Phase 2 study in metastatic Breast Cancer expect to finalize its recruitment during Q3 2017.
LiPlaCis® has been registered together with its DRP™ companion diagnostic for EU marking.
Next step in the regulatory strategy is building a data package for a Pre-Submission meeting with the FDA.
This will be 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 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.
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 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.

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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 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: 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 as Special Purpose Vehicles: 2X Oncology Inc. is a US based company focusing on precision medicine for women's cancers, currently with a pipeline of three promising phase 2 product candidates.
OV-SPV 2 is a Danish company that 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 September 19th, 2017.