Press release issued by Oncology Venture Sweden AB
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Press release

Oncology Venture announces positive interim results from a Phase 1/2 study with LiPlaCis and its DRP in heavily pretreated metastatic breast cancer patients

Hoersholm, Denmark, January 31, 2018 – Oncology Venture Sweden AB (AktieTorget: OV) announces the second interim report from the Phase 2 part of an ongoing LiPlaCis® Phase 1/2 study in hard to treat metastatic breast cancer patients. Clinical benefit to LiPlaCis – a targeted liposomal formulation of cisplatin – is shown in 7 out of 10 evaluable patients, whereas conventional cisplatin treatment of metastatic breast cancer has reported a response rate of only 10 percent in previously conducted trials. The selection of patients for the Phase 1/2 study is aided by the DRP® companion diagnostic tool, allowing inclusion of those patients most likely to respond to treatment. In the third of patients identified by DRP® to be most susceptible to treatment, 5 out of 5 experienced clinical benefit. Further, 3 out of 5 heavily pretreated patients had a better response than with all prior medical therapies. The interim data shows that LiPlaCis® is well tolerated, with mainly mild and only few moderate side effects.

When looking at the top third of the patients most likely to respond to LiPlaCis® treatment based on the DRP® analysis, five out of five experienced clinical benefit from study treatment. Further to this, three out of five of these heavily pretreated patients had a better or longer response than with previous medical treatments for advanced disease, including combination- and hormone therapies. LiPlaCis® has so far been well tolerated in the trial, with only four grade 3 events and two grade 4 events being recorded as related to study drug.

The Phase 2 part of the study is set up to recruit a total of 20 evaluable patients with high likelihood of response (a DRP® cutoff of two third, i.e. the two thirds of a patient population most likely to respond). The study is progressing according to plan, and the last patient is expected to be included before end of Q1 2018.

"*To choose the right anticancer treatment and to opt out a treatment that will not benefit the patient is what all Oncologists want to offer patients. Therefore there is a huge need for a technology like Oncology Ventures DRP which looks promising in identifying the right patient for the right anticancer drug,"* **Said DMSc, PhD Bent Ejlertsen, Copenhagen University Hospital, Rigshospitalet and Chairman of Scientific Committee for Medical Therapy at the Danish Breast Cancer Cooperative Group "***I look forward to the final data and to participate in the subsequent randomized trial",* ***Dr Ejlertsen further commented.***

Detailed enrolment status
To date, a total of 17 patients have been included in the Phase 2 part of the study. Ten of these have been followed sufficiently long for evaluation of efficacy. In total, seven patients have experienced clinical benefit, whereof two had a Partial Remission (PR) and five had Stable Disease (SD). Three had Progressive Disease (PD) and three patients are not evaluable for response (two due to early death – by the Data Committee not deemed to be related to the study drug – and one due to inclusion failure).

Data from Top third DRP® level and excluding patients previously treated with platin drugs
- 5 of 5 heavily pretreated patients, with a mean of seven previous treatments, had clinical benefit (SD+PR) at a mean duration of 25 weeks compared to a mean duration of 14 weeks of their latest prior treatment ("Doctors choice").
- 3 of 5 patients experienced better response or longer effect duration (2 PR's and 1 SD) than all prior medical treatments against their advanced disease.

"*These interim Phase 2 results are as good as we could have hoped for. In a hard to treat metastatic breast cancer population like this, with a mean of seven prior treatments, it is remarkable that in the top third most susceptible patients as identified by the DRP® companion diagnostic kit, all had clinical benefit of LiPlaCis®. It not only demonstrates the benefit of LiPlaCis®, but also that DRP® can find the responding patients for a prospective clinical study*," **said Peter Buhl Jensen, MD, PhD and CEO of Oncology Venture.**

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LiPlaCis® Phase 2 study in 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. Recommended dose per patient is 75 mg on day 1 and 75mg on day 8. 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 two DRP-screened patient with a hard to treat metastatic Breast Cancer.

The drug candidate has received clearance for phase 2 studies by the Danish authorities and three out of four planned Danish Medical Centers are now active in recruiting up to 20 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 Q1 2018.

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. The 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. 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.

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 January 31, 2018.