Updated LiPlaCis data positions LiPlaCis and its DRP for an FDA Breakthrough Therapy designation application for breast cancer

Hoersholm, Denmark, September 17, 2018 – Oncology Venture A/S (Nasdaq First North Stockholm: OV.ST) (“OV” or “the Company”) announce the fourth update from the ongoing LiPlaCis® Phase 2 study. In the ongoing study, the data points to the possibility of obtaining a Breakthrough Therapy designation by the FDA. In the LiPlaCis DRP top tier group (1/3) of highest likelihood responders (nine of 18 patients) five (55%) obtained a partial remission*. A response rate of 55% in heavily pre-treated breast cancer patients indicates that LiPlaCis and its DRP® could bring substantial improvement over existing therapies. For comparison the product Halaven™*, which is approved for this patient group, demonstrated a 12% response rate in its pivotal study.

In the ongoing LiPlaCis study Oncology Venture’s Drug Response Predictor (DRP®) has been used to track, match and treat those heavily pre-treated breast cancer patients with metastatic disease, who were most likely to benefit from treatment with LiPlaCis. To date, a total of 22 patients meet the study’s inclusion criteria in the Phase 2 part of the study. Eighteen (18) of these have been followed sufficiently long for evaluation of efficacy. Based on input from the Danish Medicines Agency (DKMA) the Company has expanded the target cohort to approximately 30 patients.

The overall objective of this ongoing phase 2 study part is to identify the patient population relevant for submitting a Marketing Authorization application.

The patients have been categorized into groups according to their DRP score, which predicts the likelihood of an effective treatment. The 1/3 of patients with lowest DRP scores were not offered treatment with LiPlaCis as they are believed not to benefit from the drug. During the analysis of the data a statistically significant group emerged. This top-tier group consists of 1/3 of the patients with the highest DRP scores. Fifty-five (55) percent of these patients experienced a partial remission when treated with LiPlaCis, meaning a clinically relevant tumor shrinkage.

“These early data look promising for metastatic breast cancer patients as new effective treatment options are highly sought for. The Drug Response Prediction – DRP - tool is also good news for those who are not sensitive to LiPlaCis as they can avoid being treated with an ineffective drug,” Dr Hugger commented. “If data keeps substantiate the DRP accuracy the DRP is a precision medicine tool of clinical relevance to guide doctors in their choice of anticancer treatment” Said MD, Erik Hugger, Senior Consultant and Investigator at Vejle Hospital.

“In essence, these data contain the full story of Oncology Venture. We identify an effective drug and we match with our DRP®, which helps us turn the product into a precision medicine drug, thereby achieving response rates well above previously approved, comparable drugs. If these data hold true for the remainder of the trial an FDA Breakthrough Therapy designation is within sight, meaning a much shorter time-to-market period,’ says Peter Buhl Jensen, M.D., CEO of Oncology Venture.
In total, 8 of 9 patients, all heavily pretreated with a median of 5 previous treatments, experienced a clinical benefit from their LiPlaCis treatment, meaning either partial remission, stable disease or long-term stable disease. Another remarkable finding was that 6 out of 9 patients experienced better response or longer effect duration than ever before, when compared to earlier treatments in their individual treatment history.

Further details of the LiPlaCis study

All in all, 22 have ended treatment or are still on treatment, whereof 6 had a Partial Remission (PR), 2 had long-term stable disease (>24 weeks) and 4 had Stable Disease (SD). Six (6) had Progressive Disease (PD) and 4 patients are not evaluable for response, one because of early renal toxicity and 3 due to early death – 2 deaths deemed unrelated to study drug by the Data Committee. One death was deemed possibly related to toxicity of LiPlaCis. This was a tiny patient and a safety change in the administration of LiPlaCis has been agreed with the authorities so that patients are now treated according to their size. The toxicity is a known rare side effect of cisplatin and other chemotherapies and is expected to be prevented by the individually adapted dosing. Four (4) patients are not yet evaluable for response.

*A partial remission means a > 30% reduction in tumor size, measured in one dimension in a CTscan. A 30% reduction measured in only one dimension equals an estimated a 66 % reduction of total tumor size, since the tumor will, in plain language, not only have been reduced in length (one dimension) but also in height and depth. Thus, on average the tumor is reduced to 34 % of its initial size, or less (0.7 x 0.7 x 0.7 *100 %= 34 %).

**“Halaven® is the most recently approved product for treating metastatic breast cancer patients, who have previously received at least two chemotherapeutic regimens for the treatment of metastatic disease.

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About LiPlaCis:
Cisplatin is one of the most effective anticancer drugs ever developed. Many new chemotherapy drugs have arrived on the scene over the past few decades, but cisplatin still finds wide use. Even when it is not the sole or primary drug given to the cancer patient, it can be a valuable part of a combination chemotherapy regimen. Look at the regimens given to patients and you will often see cisplatin as one of the drugs. Even with the advent of the so-called targeted therapies in the past ten years, cisplatin use remains strong. Someone actually called cisplatin the penicillin of cancer (http://www.cisplatin.org/).

LiPlaCis is a third-generation liposomal formulation of cisplatin enabling direct delivery of this known agent to tumor sites. The liposomes are designed to be specifically degraded by secretory phospholipase sPLA2 – an enzyme which is known to be over-expressed in number of different tumor tissues which has been proved in a PD cohort where tumor tissue expressed 5-28 fold more cisplatin adduct compared to normal tissue. Thus, LiPlaCis is intended to specifically target the cancer cells and potentially result in an improved therapeutic index due to an improved cytotoxic efficacy and possibly also an improved safety and tolerability profile compared to conventional cisplatin. The LiPlaCis product combines the liposomal technology with a proven response predictor DRP® to cisplatin. LiPlaCis is initially being developed for metastatic breast cancer. We believe the product could have a place also in early breast cancer treatment as well, since adjuvant therapy still lacks efficacy with many patients dying of breast cancer in spite of early aggressive chemotherapy treatment.

LiPlaCis may also be useful in other cancers such as lung, head and neck, and prostate. We are working with Cadila Pharmaceuticals to expedite clinical trials with studies in India. Because the Indian regulatory authorities do not see a liposomal deep-frozen product as approvable in India, we are exploring alternate solutions such as freeze drying to potentially enable cancer patients in India access to LiPlaCis.

About the Drug Response Predictor - DRP® Companion Diagnostic
Oncology Venture uses its 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.

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 and is currently demonstrating promising results in an ongoing phase 2 study prospectively using LiPlaCis and its DRP® to track, match and treat patients with metastatic breast cancer.

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 Oncology Venture for Personalized Medicine. The DRP® is used by Oncology Venture for drug development.

DRP® is a registered trademark of Oncology Venture A/S.

About Oncology Venture A/S
Oncology Venture A/S is engaged in the research and development of anti-cancer drugs via its wholly-owned subsidiary, Oncology Venture Product Development ApS. Oncology Venture uses Drug Response Prediction – DRP® – 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 and is currently demonstrating promising results in an ongoing phase 2 study prospectively using LiPlaCis and its DRP® to track, match and treat patients with metastatic breast cancer. The DRP® 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 OV product portfolio includes: LiPlaCis®, a liposomal formulation of cisplatin in an ongoing Phase 2 trial for breast cancer; 2X-121 a PARP inhibitor in an ongoing Phase 2 for breast cancer; dovitinib, which will enter Phase 2 trials for indications dependent on further Dovitinib-DRP retrospective/prospective analysis of studies completed by Novartis. 2X-111, a liposomal formulation of doxorubicin under manufacturing for Phase 2 in breast cancer; irofulven, for which a Phase 2 is planned for prostate cancer; and APO010, an immuno-oncology product in Phase 1/2 for multiple myeloma.

Oncology Venture has spun out two companies as Special Purpose Vehicles: Oncology Venture U.S. Inc. (previously 2X Oncology Inc.), a US-based precision medicine company focusing on developing 2X-121 and 2X-111, and OV-SPV 2, a Danish company that will test and develop dovitinib. Oncology Venture A/S has an ownership of 92% in Oncology Venture US and 55% of dovitinib with an opportunity to acquire further 30%.

Learn more at oncologyventure.com

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Forward-looking statements
This announcement includes forward-looking statements that involve risks, uncertainties and other factors, many of which are outside of OV’s control and which could cause actual results to differ materially from the results discussed in the forward-looking statements. Forward-looking statements include statements concerning OV’s plans, objectives, goals, future events, performance and/or other information that is not historical information. All such forward-looking statements are expressly qualified by these cautionary statements and any other cautionary statements which may accompany the forward-looking statements. OV undertake no obligation to publicly update or revise forward-looking statements to reflect subsequent events or circumstances after the date made, except as required by law.

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This information is information that Oncology Venture A/S is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication on September 17, 2018.