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Press release
October 4, 2018

Oncology Venture receives authority clearance to expand an ongoing Phase 2 study of LiPlaCis® by inclusion of prostate cancer patients

Hoersholm, Denmark, October 4, 2018 – Oncology Venture A/S (Nasdaq First North Stockholm: OV.ST) announces that the Danish Medicines Agency (DKMA) has approved an application to broaden the scope of an ongoing Phase 2 study of LiPlaCis® – an intelligent, target controlled liposome formulation of one of the world's most widely used chemotherapies, cisplatin. The authority clearance will allow inclusion of prostate cancer patients into the clinical study, which has so far been focused on evaluating the safety and efficacy of LiPlaCis® in breast cancer patients.

During the screening and inclusion process, Oncology Venture’s Drug Response Predictor (DRP®) is used to identify those cancer patients who are most likely to benefit from treatment with LiPlaCis®.

Previously communicated interim efficacy data from the trial shows a response rate (partial remission) of 55% in a group of heavily pre-treated breast cancer patients that have been identified as most susceptible to LiPlaCis® treatment based on a DRP® analysis.* For comparison, the most recently approved drug for this patient group – eribulin – demonstrated a 12% response rate in its pivotal study. These strong data points to the possibility of obtaining an FDA Breakthrough Therapy Designation for LiPlaCis®.

The application approval from the Danish Medicines Agency now enables Oncology Venture to widen the development of LiPlaCis® to prostate cancer, a potentially fatal disease with a high unmet medical need. According to World Cancer Research Fund, 1.3 million men are expected to be diagnosed with prostate cancer in 2018.

More than 80 metastatic castration resistant prostate cancer patients have already consented to have their tumor tissue analyzed by use of DRP®. The first prostate cancer patient is estimated to be included in the trial in the fourth quarter of 2018. Following the amendment of the study protocol, the estimated total number of patients in the trial will be increased from 30 to 50. The overall objective of the Phase 2 study is to identify the breast and prostate patient populations relevant for submitting a Marketing Authorization application.

"We welcome the expedited approval from the Danish Medical Agency, and are thrilled by this opportunity to expand the clinical development of LiPlaCis® to yet another form of cancer with an urgent need for better treatment and, consequently, a high commercial potential” says Peter Buhl Jensen, M.D., CEO of Oncology Venture.

*A partial remission means a > 30% reduction in tumor size, measured in one dimension in a CT scan. 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 %).
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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, skin 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 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 6 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.

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 October 4, 2018.