Press release

# FDA grants IDE approval to use Oncology Venture's LiPlaCis DRP for patient selection in a pivotal Phase 3 study

**Hoersholm, Denmark, August 15, 2019 – Oncology Venture A/S (Nasdaq First North Stockholm: OV.ST) today informs that the US Food & Drug administration (FDA) has approved an IDE (Investigational Device Exemption) application for use of the company's drug response predictor LiPlaCis DRP® in a planned pivotal Phase 3 study. In parallel, the FDA is evaluating Oncology Venture's IND (Investigational New Drug) application for the drug substance LiPlaCis®, which is primarily being developed as a potential new treatment of metastatic breast cancer in heavily pre-treated patients.**

Oncology Venture's drug candidate LiPlaCis® is a third-generation intelligent liposomal formulation of cisplatin, enabling direct delivery to the tumour site. LiPlaCis® is being developed in combination with a specific drug response predictor, LiPlaCis DRP®, which includes 205 genes and predicts the treatment response in individual patients based on a pre-treatment biopsy. Treatment of patients with LiPlaCis® selected by the DRP® continues to deliver encouraging results in an ongoing Phase 2 study.

The FDA is currently evaluating Oncology Venture's IND (Investigational New Drug) application for the drug substance LiPlaCis®. Oncology Venture has recently provided the authority with supplementary information on the characteristics of LiPlaCis® and has an ongoing dialogue with the authority on the details of the pivotal Phase 3 study design.

*"The FDA approval to use Oncology Venture's drug response prediction technology, DRP, in a pivotal Phase 3 study of LiPlaCis in the US is a major step forward in establishing our unique concept of precision medicine",* **says Peter Buhl Jensen, M.D., CEO of Oncology Venture.**

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**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 patients' 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.

**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 and prostate 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, a Phase 2 is ongoing 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 84% in Oncology Venture US Inc. and 63% of dovitinib with an an obligation to buy additional 12% and opportunity to acquire the final 25%.

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 undertakes 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 August 15, 2019.