



Press release

Oncology Venture receives response from the FDA to the IND-application and proposed pivotal study for LiPlaCis

Hoersholm, Denmark and Cambridge, MA, US, June 3, 2019. – Oncology Venture A/S (“OV” or “the Company”) today announced that the FDA has given its initial response to the Company’s IND application and proposed pivotal Phase 3 study of LiPlaCis® in the US. The FDA has requested some additional testing of the LiPlaCis related to the product characterization. Oncology Venture expects to have these additional tests completed in good time before initiation of the study. Oncology Venture will in parallel modify the study design to accommodate FDA’s recommendation for the pivotal study. The earlier communicated timeline for the development of the LiPlaCis is unchanged.

The LiPlaCis pivotal Phase 3 study in the US will, in similarity to the ongoing Danish Phase 2 trial evaluate LiPlaCis and its companion diagnostic LiPlaCis-DRP® for the treatment of metastatic breast cancer. The protocol will be upgraded from a single arm study to a randomized study and the number of patients is expected to be around 200 as previously communicated. The new design is also expected to comply with the requirements that the European Medicines Agency, EMA, has on registrational studies.

LiPlaCis® is an intelligent, target controlled liposome formulation of one of the world’s most widely used chemotherapies, cisplatin. The specific LiPlaCis® formulation allows delivery of LiPlaCis® directly at tumor site. Oncology Ventures drug specific diagnostic tool DRP® selects the patients whom are expected to benefit from the treatment. LiPlaCis® is showing promising results in an ongoing Phase 2 study in patients with metastatic breast cancer.

“As expected, there will always be questions to a registrational study. Upon the useful feedback from the FDA we will design a randomized study, and we are confident that we can deliver the requested product characterization information allowing us to keep the timelines. The ongoing Phase 2 study in Denmark is showing strong results. The OV team has taken advantage of the DRP technology as a differentiating factor and moved this project forward from a phase 1 study to a registrational study in only two years,” says Peter Buhl Jensen, M.D., CEO of Oncology Venture.

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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 and ovarian 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 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 June 3, 2019.