Oncology Venture A/S
Venlighedsvej 1
2970 Hoersholm,
Denmark
CVR: 28106351
www.oncologyventure.com

Company News

Oncology Venture receives positive feed-back from the FDA on approval pathway for LiPlaCis and DRP in the US

Hørsholm, Denmark and Cambridge, MA, US, December 18, 2018 – Oncology Venture A/S ("OV" or the Company) today announced that the US Food and Drug Administration, FDA has responded positively on questions posed by the company in a Pre-IND/IDE package for the approval pathway for LiPlaCis® and its companion diagnostic DRP® - Drug Response Predictor – in metastatic breast cancer.

The FDA agreed that the 505(b)(2) pathway is an acceptable registration route for LiPlaCis and that no further toxicology studies are needed. Based on current good data the number of patients to be treated is in line with previous guidance in the upcoming pivotal phase 3 trial of LiPlaCis and its DRP® for the treatment of patients with advanced breast cancer.
The FDA accepts objective response rate (ORR) as the primary endpoint but asked for further characterization of sub-groups in the breast cancer population aimed for treatment with LiPlaCis.

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. The specific LiPlaCis DRP® selects the patients whom are expected to benefit from the treatment. LiPlaCis has shown very promising results in an ongoing phase 2 trial, a study that will continue as planned. Recruitment timelines of the pivotal phase 3 study will be updated following the FDA approval of the Investigational New Drug Application (IND) and the Investigational Device Exemption (IDE) expectedly in H1 2019.

"Oncology Venture in-licensed LiPlaCis as a phase 1 project in 2016. The 505(b)(2) strategy allows us to refer to data for a listed drug and will save us important time and resources. Our team has done a remarkable job by moving this project from an early stage to a late stage project in only two years. The discussions with the FDA gave no barrier for proceeding with our pivotal development plans for a fast route to commercialization and we can now increase our partnering activities with pharma," **comments Peter Buhl Jensen, M.D., CEO of Oncology Venture.**

Data from the ongoing Phase 2 LiPlaCis® study in patients with metastatic breast cancer shows a 50% objective response rate (five out of ten patients) in the upper one third of DRP® selected patients and a 24% objective response rate (6 out of 25 patients) in the upper two thirds of DRP® selected patients. These data should be compared with historical response rates to the established cancer drugs in metastatic breast cancer with a 10-12% objective response rate of eribulin, vinorelbine and gemcitabine and 10% of conventional cisplatin.

If the ongoing phase 2 study will continue to show strong efficacy data, Oncology Venture aims for a Break through designation. This application is planned for filing shortly after the IND and its IDE application for LiPlaCis.

Oncology Venture's regulatory strategy is to first obtain approval in the US. The aim is then to run randomized pivotal studies in Europe and Asia.

For further information, please contact:

For investor inquiries
Ulla Hald Buhl, IR & Communication
E-mail: uhb@oncologyventure.com
Telephone +45 21 70 10 49

For media inquiries
Thomas Pedersen, Carrotize PR & Communications
E-mail: tsp@carrotize.com
Telephone +45 60 62 93 90

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 a post phase 3 product, which will enter Phase 2 trials for indications dependent on further Dovitinib-DRP analysis of studies completed by Novartis. 2X-111, a liposomal formulation of doxorubicin under manufacturing for Phase 2 in breast cancer; irofulven is in Phase 2 in 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.

Certified Adviser: Sedermera Fondkommission, Norra Vallgatan 64, 211 22, Malmö, Sweden.

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 December 18, 2018.