Press release

Oncology Venture provides news on its clinical development projects dovitinib, 2X-121 and LiPlaCis

Hørsholm, Denmark and Cambridge, MA, US, April 30, 2019 – Oncology Venture A/S today provides news on DRP® based analyses of biopsies from clinical trials with dovitinib. In addition to renal, endometrial and GIST tumors Oncology Venture has now also shown in two new indications liver cancer and breast cancer that the DRP can predict the responding patients. Moreover, the first patient has been dosed with 2X-121 at the Dana Farber Cancer Institute. Boston, US for the treatment of advanced ovarian cancer. Also, Oncology Venture has submitted an IND (Investigational New Drug Application) for LiPlaCis® and its DRP® to the FDA, with the intention to start a pivotal study in metastatic breast cancer.

Dovitinib
Oncology Venture's dovitinib DRP® (Drug Response Predictor) has previously proved its ability to identify the best responders based on patient biopsies from clinical trials in renal, endometrial and GIST cancer. New analyses of biopsies from clinical trial cohorts of liver and breast cancer patients resulted in equally good predictability. Oncology Venture has thereby been able to confirm its DRP® for dovitinib in five out of five of Novartis' clinical trials and this without having to invest in own studies.

Oncology Venture aims to apply for a first FDA marketing approval of dovitinib and its companion DRP® based on existing data from a pivotal study done by Novartis in patients with renal cancer.

2X-121/PARPi
The first U.S. patient has now been dosed at Dana-Farber Cancer Institute Boston with 2X-121, a PARP inhibitor in development for advanced ovarian cancer. 2X-121 has previously shown promising results in ovarian cancer patients in a phase 1 study performed by EISAI. The DRP® selection aimed to find the best responding patients is expected to lift the response rate to outperform currently marketed drugs for the same indication. 2X-121 is also in development for the treatment of metastatic breast cancer.

LiPlaCis®
An IND (Investigational New Drug Application) for LiPlaCis® in metastatic breast cancer has been submitted to the FDA for the purpose of performing a pivotal study of LiPlaCis® and its DRP® in patients with metastatic breast cancer. An IDE (Investigational Device Exemption) will follow in this quarter.

In metastatic breast cancer patients with the highest DRP® score (top 20%), LiPlaCis® treatment resulted in a response rate of 40%. In comparison, the latest product approved by the FDA in this patient group, Halaven®, showed a response rate of 12%. LiPlaCis® is also being evaluated in an ongoing Phase 2 study in patients with prostate cancer.

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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 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.

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 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 April 30, 2019.