

Press release

Oncology Venture increases its ownership in dovitinib

Hoersholm, Denmark, June 13, 2019 – Oncology Venture A/S (Nasdaq First North Stockholm: OV.ST) has acquired an additional 8% ownership in the dovitinib project from Sass & Larsen Aps. Following the transaction, Oncology Ventures ownership amounts to 63%. Further, Oncology Venture has negotiated an option to acquire Sass & Larsen's remaining ownership in dovitinib at a predefined price.

"We welcome this opportunity to increase our ownership in the dovitinib project. Also, we have negotiated a route and price for the acquisition of the full ownership. Following our analysis of available biopsies from Novartis' phase 3 study, communicated during this spring, we have proven that our AI-driven Drug Response Prediction – DRP® – is able to significantly strengthen the value of dovitinib," **said Peter Buhl Jensen, CEO, Oncology Venture.**

Oncology Venture has gained strong DRP® biomarker data for dovitinib, both as a stand-alone treatment and in combination with PD1 / PDL1 inhibitors – two types of rapidly emerging immuno-oncology drugs. Biostatistical analysis supports that dovitinib clinical data obtained by Novartis in renal cancer merits a direct application for approval based on non-inferiority to the marketed gold standard. This, together with the fact that DRP® can be used to specify who will benefit from dovitinib will be the basis for discussions with regulatory authorities in the US and Europe.

A first Dovitinib DRP® was established at the time dovitinib was in-licensed from Novartis. Since then, Oncology Venture has further developed the Dovitinib DRP® precision in renal, endometrial, breast and GIST cancers for prediction of the most likely responders.

Combination treatment with Lenvima (a TKI product like dovitinib) and Keytruda (a PD-1 inhibitor) has recently proved to be highly efficacious and high-value commercial deals based on products similar to dovitinib have been noted. No drug response predictor has previously been established for TKI products and to Oncology Venture's knowledge, DRP® is the first of its kind to predict the response of combinations of TKI and immuno-oncology treatments.

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About dovitinib

Oncology Venture's dovitinib DRP® (Drug Response Predictor) has in 2018 proved its ability to identify the best responders based on patient biopsies from clinical trials in renal, endometrial and GIST cancer. Early in 2019 analyses of biopsies from clinical 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 cancer forms using the same DRP in all cases. Oncology Venture aims to apply for a first FDA marketing approval of dovitinib and its companion DRP® based on the DRP and the positive existing data from a pivotal study done by Novartis in patients with renal cancer.

Oncology Venture has performed the data mining based on documentation from more than 2,500 patients to further document the ability of its dovitinib DRP® to track, match and treat those patients where dovitinib is a relevant therapy. This DRP® result point towards a 2-4 fold higher response rates and gives dovitinib a strong competitive advantage. Drugs very similar to dovitinib (multityrosine kinase inhibitors) e.g. Eisai's lenvatinib, have shown surprisingly strong data when used in combination with the new very successful immuno-oncology products (I-O) like Keytruda®. Lenvatinib has obtained breakthrough therapy designation in renal cancer and endometrial cancer when used with Keytruda®, leveraging a significant deal with Merck. The huge initial success in the immuno-oncology space has led to a global race to develop new I-O products, with many candidates underway. A combination with dovitinib guided by the DRP® is expected to provide a competitive advantage to I-O products.

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; ifofulven, 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 63% of dovitinib with an opportunity to acquire further 37%.

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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 13, 2019.