Press release

Dovitinib regulatory strategy confirmed and new combination biomarker DRP PD1/PD-L1 + dovitinib developed. Oncology Venture engages in partnering activities with Destum Partners

Hoersholm, Denmark, April 3, 2019 – Oncology Venture A/S (Nasdaq First North Stockholm: OV.ST) today announces that the company has confirmed its regulatory strategy of submission of a new drug application to the FDA for marketing approval of dovitinib based on existing Novartis data in renal cancer. Furthermore, the new combination biomarker PD1- PD-L1/Dovitinib DRP® has completed development. This gives a strong competitive edge in the immuno-oncology field. Oncology Venture has appointed US based Destum Partners to support its out-licensing activities.

Dovitinib
Strong data are established for both a dovitinib DRP® biomarker and a combination biomarker PD1-PD-L1/Dovitinib DRP®. Biostatistical analysis supports that dovitinib clinical data in renal cancer merits a direct application for approval based on non-inferiority to the marketed gold standard.

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 and endometrial cancer for prediction of most likely responders to dovitinib. Recently, Lenvima + Keytruda which is a combination of a TKI product like dovitinib in combination with an immuno-oncology product (PD-L1/ PD1 inhibitors) has shown highly effective and high value deals based on products similar to dovitinib. No predictor has previously been established for the TKI products and to Oncology Venture's knowledge, the combination I-O&TKI DRP® is the first of its kind.

FDA expert biostatisticians have examined the possibility to build a preNDA briefing book based on data from a previously conducted study in renal cancer (an orphan drug indication possibility) and reported positively on that matter. A marketing approval will pave the way for supplemental NDAs.

LiPlaCis®
Oncology Venture has been working diligently on adding value to the LiPlaCis® project by accelerating the inclusion of breast cancer patients to its on-going study, opening inclusion for another big indication – namely prostate cancer patients – and paving the way for registration in the two most important markets: US and Europe.

The continued positive data from the ongoing phase 2 study of LiPlaCis® in breast cancer allows for a start of the US/EU pivotal study this year following the expected approval of the IND/IDE that was guided by the FDA comprehensive response to the briefing package.

There is a clear route to market for LiPlaCis and its companion diagnostic, LiPlaCis DRP® that gives strong support to the out-licensing efforts.

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About dovitinib
Oncology Venture has performed 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.
Dovitinib (a multi tyrosine kinase inhibitor TKI) has been tested on 60 cancer cell lines form National Cancer Institute (NCI) in order to calibrate the DRP®. In November, Oncology Venture received good quality data from the NCI and were able to build a strong dovitinib DRP®. Gene expression data from several of Novartis' dovitinib studies are available and the data mining process performed by OV's scientists on dovitinib and its companion diagnostic DRP® in renal cancer and in endometrial cancer resulted in identification of the responders. This DRP® result point towards a 2-4 fold higher response rates and gives dovitinib competitive advantage. This gives a strong support to further develop dovitinib as monotherapy and/or in combinations with different anticancer and immuno-oncology therapies.
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.

About LiPlaCis
Cisplatin is one of the most effective anticancer drugs ever developed. Many new chemotherapy drugs have arrived on the scene over the past few decades, but cisplatin still finds wide use. Even when it is not the sole or primary drug given to the cancer patient, it can be a valuable part of a combination chemotherapy regimen. Look at the regimens given to patients and you will often see cisplatin as one of the drugs. Even with the advent of the so-called targeted therapies in the past ten years, cisplatin use remains strong. Someone actually called cisplatin the penicillin of cancer (http://www.cisplatin.org/).
LiPlaCis is a third-generation liposomal formulation of cisplatin enabling direct delivery of this known agent to tumor sites. The liposomes are designed to be specifically degraded by secretory phospholipase sPLA2 – an enzyme which is known to be over-expressed in number of different tumor tissues which has been proved in a PD cohort where tumor tissue expressed 5-28 fold more cisplatin adduct compared to normal tissue.
Thus, LiPlaCis is intended to specifically target the cancer cells and potentially result in an improved therapeutic index due to an improved cytotoxic efficacy and possibly also an improved safety and tolerability profile compared to conventional cisplatin.
The LiPlaCis product combines the liposomal technology with a proven response predictor DRP® to cisplatin. LiPlaCis is initially being developed for metastatic breast cancer. We believe the product could have a place also in early breast cancer treatment as well, since adjuvant therapy still lacks efficacy with many patients dying of breast cancer in spite of early aggressive chemotherapy treatment.
LiPlaCis may also be useful in other cancers such as lung, head and neck, and prostate. We are working with Cadila Pharmaceuticals to expedite clinical trials with studies in India. Because the Indian regulatory authorities do not see a liposomal deep-frozen product as approvable in India, we are exploring alternate solutions such as freeze drying to potentially enable cancer patients in India access to LiPlaCis.

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 3, 2019.