Press release issued by Oncology Venture Sweden AB
Hoersholm, Denmark, June 28, 2018
Press release

Oncology Venture now holds US Orphan Drug designation on dovitinib for Adenoid Cystic Carcinoma

Hoersholm, Denmark, June 28, 2018 – Oncology Venture AB (OV:ST) and Medical Prognosis Institute A/S (MPI:ST) announces that the Office of Orphan Products Development at the FDA has transferred the Dovitinib Orphan drug designation for the treatment of adenoid cystic carcinoma to Oncology Venture from Novartis.

Dovitinib is an oral available phase 3 multi Tyrosine Kinase Inhibitor (previously TKI258), for which OV holds the exclusive global rights for development and commercialization. OV is developing the dovitinib Drug Response predictor DRP® based on existing data from patient's biopsies and clinical outcome. The dovitinib DRP® will be used to both retrospectively and prospectively to identify patients that responded to treatment vs non-responders from the existing clinical trials.

Adenoid cystic carcinoma (AdCC) is a rare form of adenocarcinoma, a type of cancer that begins in glandular tissues. It most commonly arises in the major and minor salivary glands of the head and neck. Each year, about 1,200 people are diagnosed with AdCC in the United States and about 60% are women. The 5-year survival rate for people with AdCC is approximately 89%. The 15-year survival rate for people with AdCC is approximately 40%.
Whether the indication of AdCC is relevant for development by OV is expected to be revealed during the analysis of data from AdCC patients.

The FDA's Office of Orphan Drug Products grants orphan status to support development of medicines for safe and effective treatment, diagnosis or prevention of rare diseases or disorders that affect fewer than 200,000 people in the United States. Orphan drug designation provides certain benefits, including a seven-year period of market exclusivity if the drug is approved, tax credits for qualified clinical trials and an exemption from FDA application fees.

"This orphan drug designation in adenoid cystic carcinoma may become a valuable asset for the development of dovitinib," **said Peter Buhl Jensen CEO of Oncology Venture***. "Our initial aim is to analyze the large amount of data from Novartis to further refine the Dovitinib DRP® biomarker to hone its predictive ability to identify high likelihood responders for dovitinib. Adenoid cystic carcinoma could well be our first approved orphan indication",* **Peter Buhl Jensen further commented.**

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About the Drug Response Predictor - DRP® Companion Diagnostic
Oncology Venture uses the Medical Prognosis Institute (MPI) 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.

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 MPI for Personalized Medicine. The DRP® is used by Oncology Venture for drug development.
DRP® is a registered trademark of Medical Prognosis Institute A/S.

About dovitinib
Dovitinib is an oral available phase 3 multi Tyrosine Kinase Inhibitor (previously TKI258), for which OV holds the exclusive global rights for development and commercialization. OV is developing a Drug Response predictor DRP® for dovitinib on the basis of existing data from patient's biopsies and their related clinical outcome. The transfer of documents and material is ongoing. Oncology Venture estimates that the work of analyzing the huge amount of data that determine the dovitinib DRP will take 6-8 month. The dovitinib DRP® will then be used to prospectively select patients most likely to respond to the compound in clinical trials.
In a Phase 3 trial in metastatic renal cell carcinoma, dovitinib achieved therapeutic equivalence with the current standard of care, sorafenib. Earlier stage studies explored its potential utility in multiple therapeutic indications including liver cancer, breast cancer and various solid tumors. OV intends to advance the compound in clinical trials together with a validated, drug-specific DRP® biomarker as a companion diagnostic.

About Oncology Venture AB
Oncology Venture Sweden AB is engaged in the research and development of anti-cancer drugs via its wholly owned Danish subsidiary Oncology Venture ApS. Oncology Venture has a license to use Drug Response Prediction – DRP® – in order 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. The Company uses a model that 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 product portfolio: LiPlaCis® for Breast Cancer in collaboration with Cadila Pharmaceuticals, Irofulven developed from a fungus for Prostate Cancer, and APO010: an immuno-oncology product for Multiple Myeloma.
Oncology Venture has spun out two companies as Special Purpose Vehicles: Oncology Venture US Inc. (previously 2X Oncology Inc.) is a US based company focusing on precision medicine, currently with a pipeline of two promising phase 2 product candidates.
OV-SPV 2 is a Danish company that will test and potentially develop an oral phase 2 Tyrosine Kinase inhibitor.

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, that 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.