Press release

First Patient dosed in Phase 2 Study of the PARP Inhibitor 2X-121 for Breast Cancer

Hoersholm, Denmark, June 26, 2018 – Medical Prognosis Institute A/S (MPI:ST), Oncology Venture AB (OV:ST) and Oncology Venture US Inc. (former 2X Oncology Inc.) announces dosing of the first patient in a Phase 2, clinical study to investigate the anti-tumor effect and tolerability of 2X-121 in patients with metastatic breast cancer selected by a novel drug response predictor (DRP®) mRNA driven multiple biomarker, the 2X-121 DRP®.

2X-121 is a PARP inhibitor. This clinical trial will enroll metastatic Breast Cancer patients, who have relapsed on two or more different prior therapies. The 2X-121 DRP is a novel biomarker based on 414 genes predictive of response to 2X-121. In a study presented at ASCO, the 2X-121 DRP correctly identified responders and non-responders to treatment irrespective of BRCA mutation status.

In this trial patients will receive oral treatment with 600 mg 2X-121, in a 21-day cycle. The primary endpoint of this study is clinical benefit rate defined as complete response, partial response, or stable disease at greater than 24 weeks post-treatment. Secondary endpoints include progression free survival, duration of response (from first response to progression) and overall survival.

“The Phase 2 study will enable us to rapidly evaluate the efficacy of our PARP inhibitor in metastatic breast cancer patients, using the 2X-121 DRP® using over 400 genes to select likely responders,” said Peter Buhl Jensen CEO of MPI and OV. “We are very encouraged by the DRP data based on the available biopsies from 13 patients from the foregoing phase 1 study. In this small population the DRP could convincingly pick responding patients. Use of PARP inhibitors is a revolution in the right patients and we believe that our DRP can find these patients.” Peter Buhl Jensen further commented.

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This information is information that Medical Prognosis Institute A/S is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, on June 26, 2018.

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About MPI’s multiple biomarker called Drug Response Predictor – DRP®
MPI’s DRP® is a tool for developing tumor-derived genetic signatures to predict which cancer patients are high likely to respond to a given anti-cancer product. The DRP® has been tested in 37 trials, where 29 trials showed that drug-specific DRP® Biomarkers could predict which patients responded well to the treatment. The DRP® platform has amongst others been externally validated and published in collaboration with leading statisticians at the MD Anderson Cancer Center. The DRP® method can be used to design the Clinical Development Plan, i.e. to select which indications are relevant for a given anti-cancer drug. In addition to this, the individual genetic patterns of patients can be analyzed as part of a screening procedure for a clinical trial to ensure inclusion of patients with a high likelihood of response to the drug. DRP® builds on comparison between sensitive and resistant human cancer cell lines, including genomic information from cell lines combined with clinical tumor biology and clinical correlates in a systems biology network. The DRP® is a Big Data tool based on messenger RNA. The DRP® platform can be used in all cancer types and has been patented for more than 60 anti-cancer drugs in the US.
About MPI
Medical Prognosis is a publicly traded international company specialized in improving cancer patients' lives by developing Personalized Medicine using its unique DRP® technology. MPI's exceptional opportunity to personalize cancer treatment - begins with Breast Cancer moving on to Multiple Myeloma and Prostate Cancer as the first steps. MPI's DRP® tool has shown its ability to separate patients who benefit and who do not benefit from a specific cancer treatment. This has been shown in as many as 29 out of 37 trials, and covers more than 80 anti-cancer treatments in a wide range of cancer indications. MPI has built a significant large database with over 1,100 screened breast cancer patients and is building up a database in Multiple Myeloma to be followed by Prostate cancer in collaboration with oncologists and hematologists throughout Denmark.

2X-121 Phase 2 study in metastatic Breast Cancer (mBC)
2X-121 is an investigational, orally-available small molecule targeted inhibitor of Poly ADP ribose polymerase (PARP), a key enzyme involved in DNA damage repair in cancer cells. The drug candidate has a novel dual-inhibitory action against both PARP 1/2 and Tankyrase 1/2. The molecule is also active in P-glycoprotein expressing cells, suggesting it may overcome PARP inhibitor resistance. Patients will receive oral treatment with 600 mg 2X-121, as a single agent, in a 21-day cycle. The primary endpoint of this study is clinical benefit rate defined as complete response, partial response, or stable disease at greater than 24 weeks post-treatment using the RECIST criteria. Secondary endpoints include progression free survival, duration of response (from first response to progression), and overall survival.
Separate, targeted Phase 2 studies of 2X-121 are planned using the validated DRP® biomarker in recurrent ovarian cancer, castration resistant prostate cancer, and pancreatic cancer to identify patients likely to respond to and benefit from treatment with the drug.

About the Drug Response Predictor - DRP® Companion Diagnostic
Oncology Venture uses the Medical Prognosis Institute (MPI) multigene 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 Oncology Venture Sweden 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: 2X Oncology Inc. is a US based company focusing on precision medicine, currently with a pipeline of three 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.

About Oncology Venture US Inc. (previously named 2X Oncology Inc.)
Oncology Venture US Inc. (OV US) is a clinical stage precision medicine company developing targeted therapeutics addressing significant unmet needs in hard-to-treat cancers. Our pipeline leverages a proprietary Drug Response Predictor (DRP®) technology generating drug specific companion diagnostics to identify patients who are most likely to respond and benefit from treatment. DRP® also identifies likely non-responder patients, providing a precision medicine approach for the treatment of patients who can benefit from our therapies.
The OV US pipeline of product candidates, including a PARPi, are focused on the treatment of breast, ovarian, prostate and pancreatic cancers and primary and secondary brain tumors. These programs have demonstrated clinical efficacy and safety and are positioned to enter focused Phase 2 studies with study data and potential accelerated approval filings expected in 2H 2018.
A Cambridge, MA based spin-out from Oncology Venture ApS, OV US works in close collaboration with Oncology Venture and leverages a Danish registry of over 1,200 cancer patients which only counts for the breast cancer patients for select clinical studies. 2X Oncology Inc. has recently changed name to Oncology Venture US Inc. to take into account that the DRP® technology is aimed to benefit all genders. Learn more at 2xoncology.com.