US FDA approves Oncology Venture’s IDE and IND for a clinical trial in ovarian cancer patients with its PARP inhibitor and biomarker 2X-121 DRP®

Hoersholm, Denmark, August 27, 2018 – Medical Prognosis Institute A/S and Oncology Venture AB (OV:ST) ("OV" or the "Company") and Oncology Venture US Inc today announced that the US Food and Drug Administration (FDA) has accepted its Investigational Device Exemption (IDE) and its Investigational New Drug Application (IND) to begin a Phase 2 clinical trial in advanced ovarian cancer with 2X-121 -a PARP inhibitor- using it’s Drug Response Predictor – DRP – to select patients with high likelihood of responding to the treatment. The 2X-121 DRP has a gene signature consisting of more than 400 genes. This multi-gene technology captures the complexity of cancer to provide more precise guidance in identifying patients with high likelihood of responding to treatment as well as identifying patients that are likely resistant to the treatment.

The study is an international multicenter trial to be conducted in the US and Germany. Initially the study is expected to include up to 30 patients who will receive 2X-121 600 mg orally daily until progression. The primary endpoint is antitumor efficacy (Complete Remission (CR) or Partial Remission (PR)). Secondary endpoints are other efficacy parameters as well as safety evaluation. This study follows a study of 2X-121 in metastatic breast cancer initiated in Denmark in Q2 2018. That study also uses the 2X-121 DRP to select patients with high likelihood of responding.

Oncology Venture in-licensed the active PARP inhibitor from Eisai in Q2 2017. Clinical data were presented at the world’s largest cancer congress ASCO 2018. The presentation included validation of Oncology Ventures novel 2X-121 DRP®s ability to identify the patients who will benefit from the 2X-121 therapy as well as identifying patients that were resistant to the treatment.

“I’m proud to obtain this first Oncology Venture prepared FDA IND and IDE approval to run trials with our PARP inhibitor in the US and look forward to initialize study in ovarian cancer to prove the patient benefit of our PARP inhibitor and it’s DRP for precision treatment”, says Chief Medical Officer of Oncology Venture Marie Foegh, M.D. “Our Drug Response Prediction – DRP technology to track, match and treat patients with our PARP inhibitor enables us to be precise in selecting patients who will benefit from PARP inhibitor treatment. We expect the results of the clinical trials will confirm the DRP technology advantage and will position us very favorably in the market,” said Peter Buhl Jensen M.D., CEO of Oncology Venture.

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About MPI
Medical Prognosis Institute A/S 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.

On the May 30, 2018, MPI and Oncology Ventures respective general assemblies decided to merge. Last day of trading in the Oncology Venture share is August 31, 2018.

Forward-looking statements
This announcement includes forward-looking statements that involve risks, uncertainties and other factors, many of which are outside of MPI’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 MPI’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. MPI 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.