



Press release

Oncology Venture's Novel PARP Inhibitor Stenoparib (formerly 2X-121) Shows Anti-Viral Activity Against Coronavirus in Pre-Clinical Studies

-Company to advance Stenoparib into human clinical trials as a potential therapy for COVID-19

-Company provides updates on prioritized Stenoparib program in Ovarian cancer

Hørsholm, Denmark (26 August 2020) – Oncology Venture A/S today announced that its PARP inhibitor Stenoparib (formerly known as 2X-121) has shown in vitro anti-viral activity against Coronavirus in pre-clinical studies conducted at the Pathogen and Microbiome Institute at Northern Arizona University (NAU), a leading U.S. infectious disease test center. Based on these findings, Oncology Venture plans to advance the compound into human clinical trials as a potential therapy for COVID-19. Stenoparib (2X-121) is a novel small molecule (oral), targeted inhibitor of Poly ADP-Ribose Polymerase (PARP), a key DNA damage repair enzyme active in cancer cells, currently being evaluated for cancer.

The series of pre-clinical studies indicated that Stenoparib showed inhibitory activity against Coronavirus in LLC-MK2 cells as a single agent. In addition, Stenoparib in combination with remdesivir was active in inhibiting SARS-Cov-2, the virus that causes COVID-19, in VERO E6 cells. The concentration of Stenoparib required for virus inhibition was lower in the combination study than in the single agent study. The two drugs target the virus through unique but different mechanisms of action. Remdesivir blocks the RNA replication enzyme, while Stenoparib, as an inhibitor of PARP1/PARP2 (Poly ADP-Ribose Polymerases) and tankyrase 1 and 2 inhibits virus assembly and inhibits the negative effects of virus infection on the human body such as cytokine storm and necrosis.

“We are very excited that the pre-clinical tests of Stenoparib showed anti-viral activity against SARS-Cov-2 indicating its promise as a potential treatment for COVID-19,” said Steve R. Carchedi, CEO of Oncology Venture. “We intend to work with FDA and NIH, as well as other funding sources, to advance Stenoparib as soon as possible into

clinical trials for the treatment of COVID-19. Exploring our novel drug as a promising new treatment for COVID-19 underscores our company commitment to develop new therapies for the improvement of patient care, and we are pleased to do whatever we can to provide a meaningful impact on solutions to this global pandemic.”

Stenoparib Program Updates

Oncology Venture announced today that it has adopted the drug name Stenoparib for 2X-121 moving forward. Stenoparib is currently being evaluated for the treatment of advanced ovarian cancer in a DRP®-guided Phase 2 clinical trial at the Dana-Farber Cancer Institute (Boston, MA U.S.A.) using a DRP® companion diagnostic to guide patient enrollment and improve therapeutic outcome. The drug has been tested in over 60 patients to date and is demonstrated to be safe and well tolerated. Through use of DRP® patient selection, OV aims to provide a superior clinical benefit, to ovarian cancer patients receiving Stenoparib, as compared to other approved PARP inhibitors.

In order to focus resources and efforts on the clinical advancement in ovarian cancer and Covid-19, the Phase 2 study (Denmark) of Stenoparib in heavily pretreated breast cancer (mBC) patients, that was initiated in 2018, will be terminated. The current data from that mBC trial suggest that a diagnostic biopsy cannot be used for predicting likelihood of drug response in heavily pretreated mBC patients, and instead new biopsies are needed. By terminating the mBC study, OV will focus on advancing Stenoparib in indications with a higher likelihood of success, including ovarian and pancreatic cancer.

Following temporary new patient enrollment delays results from the ongoing Coronavirus pandemic, the Company expects enrollment to restart in its Phase 2 ovarian cancer trial for Stenoparib at the Dana-Farber Cancer Institute (Boston, MA U.S.A.) by late Q4 2020. Thus far, 10 of a target 30 patients are enrolled in the study.

Additionally, the clinical validation of the DRP® companion diagnostic for Stenoparib has been published in the British Journal of Cancer: Plummer, R., Dua, D., Cresti, N. *et al.* “First-in-human study of the PARP/tankyrase inhibitor E7449 in patients with advanced solid tumours and evaluation of a novel drug-response predictor.” *Br J Cancer* (2020). <https://doi.org/10.1038/s41416-020-0916-5>

Dr. Steen Knudsen, Ph.D., CSO of Oncology Venture, added, “We are also pleased to announce updates on our priority Stenoparib cancer program, including our focus of resources and efforts on our lead indication, ovarian cancer, and continuing to advance this program despite the challenges and delays due to the Coronavirus pandemic.”

About Oncology Venture A/S

Oncology Venture A/S (Nasdaq First North Growth Market Stockholm: OV.ST) develops drugs for personalized treatment of cancer guided by its proprietary drug response predictor technology, DRP®. The company has a mature portfolio of six drug candidates, including compounds in the pre-registration stage. The product portfolio includes: Stenoparib (2X-121), a PARP inhibitor in Phase 2 for Ovarian cancer; Dovitinib, a pan-TKI in pre-NDA phase for Renal Cell Carcinoma; IXEMPRA® (Ixabepilone), a microtubulin inhibitor approved in the U.S. for the treatment of breast cancer; LiPlaCis®, a liposomal formulation of cisplatin in Phase 2 trials for breast and prostate cancer; 2X-111, a liposomal formulation of doxorubicin under manufacturing for Phase 2 in breast cancer; and Irofulven, a DNA damaging agent in Phase 2 for prostate cancer.

About the Pathogen and Microbiome Institute

The Pathogen and Microbiome Institute (PMI) is a research unit at NAU that spans department and colleges to gather infectious disease and microbiome scientists into a single multi-disciplinary environment. The joint efforts span computational, genomic, microbiology, immunology, and public health disciplines to generate synergy that can't be achieved within academic silos. The world-class science makes for an ideal training environment for students to achieve their personal professional goals. PMI is closely associated with TGen North, with whom the institute shares infrastructure to maximize Arizona's investment in science.

About the Drug Response Predictor – DRP® Companion Diagnostic

Oncology Venture uses its drug specific DRP® to select those patients who, by the genetic signature of their cancer, are found to have a high likelihood of responding to the specific drug. 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 prior clinical trial outcomes. 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 nearly 40 clinical studies that were examined, including an ongoing, prospective Phase 2 trial. The DRP® platform can be used in all cancer types and is patented for more than 70 anti-cancer drugs in the U.S.

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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 undertakes 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 26 August 2020.**