Screening Study of prostate cancer patients for OV’s Irofulven approved by Ethics Committees in Sweden and Denmark

Hoersholm, Denmark, June 21st, 2016 – Oncology Venture Sweden AB (OV:ST) today announced that the Ethics Committee in Lund (Regionala Etikprövningsnämnden), Sweden and the Danish Ethics Committee have approved the screening study for the Phase 2 study of Irofulven in castration-resistant prostate cancer which now allows Swedish an Danish prostate cancer patients to be included in the screening part of the study that includes two University Hospital sites in Denmark and Lund University Hospital in Sweden.

Three hundred evaluable castration-resistant prostate cancer patients with metastatic disease are expected to be screened and 15 patients with the highest likelihood of benefit from Irofulven will be offered to participate in an international, multicenter Phase 2 trial to evaluate the effect of Irofulven. The Phase 2 trial is expected to be initiated in Q3 2016.

“It is excellent that Oncology Venture can now move the irofulven project into the next important phase “ says Adjunct Professor Peter Buhl Jensen, M.D., CEO of Oncology Venture. “ We know that Irofulven works. In a study without our technology irofulven has demonstrated 10% success in unselected prostate cancer patients that have previously received chemotherapy. We expect that our technology can identify those who will have the benefit from this exciting drug and look forward to work with outstanding clinical experts in this field,” Peter Buhl Jensen, further comments.

Oncology Venture is developing the promising phase 2 drug candidate Irofulven, together with a companion diagnostic technology (Irofulven DRP™) to identify patients highly likely to respond to Irofulven therapy. The Irofulven DRP™ companion diagnostic is derived from the Drug Response Predictor (DRP™) Platform of Medical Prognosis Institute (MPI) wherefrom the Irofulven DRP™ has been in-licensed. Previous substantial clinical investigations in 38 clinical trials (19 published) of Irofulven by US biotech company MGI Pharma and pharmaceutical company Eisai led to objective responses in subsets of patients, including for a range of hard to treat cancers; such as prostate, ovarian, liver and pancreatic cancer. However, a lack of understanding of response biomarkers led to small overall response rates and failure to achieve suitable efficacy endpoints.

Utilizing the DRP Platform, Oncology Venture has now identified the genetic signatures associated with likely response to Irofulven, and has secured rights to the drug for focused development in patient populations with a very high likelihood of response. Oncology Venture will soon commence a focused phase II trial of Irofulven in likely patient responders with castration-resistant prostate cancer as the next step towards the commercialization of Irofulven as a precision therapy for a range of hard to treat cancers.

Irofulven is in-licensed from Lantern Pharma. Oncology Venture and Lantern received a grant of 800.000 USD from Massachusetts Life Sciences Center to develop Irofulven in prostate cancer.

A clinical phase 2 trial including a screening process is now to be initiated in selected patients with castration – and docetaxel resistant prostate cancer by using the Irofulven DRP™. The aim is to improve the response rate to a clinical relevant and approvable level. Following the production of Irofulven which has already been initiated first screened patient treated with Irofulven is expected in Q3 2016.

About Irofulven
Irofulven is a semi-synthetic derivative of illudin S, a natural toxin isolated from the Jack O’lantern mushroom (Omphalotus illudens). A pro-drug, Irofulven requires catalysis by prostaglandin reductase 1 to become active. Created at the University of California, San Diego (UCSD), Irofulven was exclusively licensed to US biotech company MGI Pharma, which was acquired by Eisai in 2007. After being returned to UCSD in 2009, Lantern Pharma licensed Irofulven in 2015, and subsequently sub-licensed Irofulven to Oncology Venture.

Irofulven is more active in vitro against tumour cells of epithelial origin and is more resistant than other alkylating agents to deactivation by p53 loss and MDR1. Irofulven exhibits impressive anti-cancer results in xenograft models in vivo, shows synergy
with topoisomerase I inhibitors, and has demonstrated activity against cell lines that are resistant to other therapies. Irofulven has significant scope for combination with other therapies, including standard chemotherapeutic regimes.

**About the Drug Response Predictor - DRP™ screening tool**

Oncology Venture uses the MPI multi gene DRP™ to select those patients that by the gene signature in their cancer is found to have a high likelihood of response to the drug. The goal is to develop the drug for the right patients and by screening patients before treatment the response rate can be significantly increased.

This 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. The DRP™ is based on messenger RNA.

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**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 clinical outcomes from drug treatment in cancer patients in 29 of the 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 screened first and only those who are most likely to respond to the treatment will be treated. Via a more well-defined patient group, the risk and costs are reduced while the development process becomes more efficient.

The current product portfolio: LiPlaCis for Breast Cancer, Irofulven developed from a fungus for prostate cancer and APO010 – an immuno-oncology product for Multiple Myeloma.