Hoersholm, Denmark, October 27th 2017
Press Release

Irofulven phase 2 application submitted to the Danish Ethics Comitte and Health Care Authorities

Hoersholm, Denmark -- October 27th 2017 – Oncology Venture Sweden AB:s (OV:ST) ("Oncology Venture" or "OV") announces the filing of the phase 2 protocol of Irofulven for castration- and docetaxel resistant Prostate Cancer has been submitted the Danish Ethics Comitte and Health Care Authorities. The study will include 13-27 patients selected for Irofulven benefit from DRP screened Swedish and Danish patients. The study will be run at two Danish sites – Swedish patients will be refered for Irofulven treatment at the University Hospital in Copenhagen.
Using genomic information from the individual cancer patient's tumor, Oncology Ventures patented DRP™ technology will identify patients most likely to benefit from Irofulven.
The primary endpoints are objective response rate and changes in PSA – a blood test for prostate cancer.
Irofulven is an anti cancer drug, isolated from the Jack O'lantern mushroom. The drug has been manufactured from scratch – and the process has been lengthy – but it is robust and finally more than 700 vails of Irofulven has been manufactured.
The authorities timelines are reply within 6 weeks. If no further questions will be asked Oncology Venture expects to initiate the study shortly after. Apriori Irofulven has shown good responses in 10% of prostate cancer patients. Oncology Venture aims to raise the response rate three fold as this will give a route to commercialization.

As previously announced, for Irofulven, we had to go back to restart manufacture and all methods had to be reinvented or new. Dr. Bruce Pratt, who is responsible for this project, successfully identified vials with fungus for fermenting - the initial steps of Irofulven has been more time consuming than originally expected. However, Irofulven has now after two years finally been successfully manufactured and filled into vials for clinical trials.

Irofulven has been studied in 38 clinical trials (19 published) including a phase 3 trial in Pancreatic Cancer, and has shown promising single agent activity in a range of indications. In Prostate Cancer, Irofulven demonstrated a 10% response rate in patients pre-treated with docetaxel.
Irofulven is according to OV's drug development experts a unique product within the DNA damage repair field which also includes the successful PARP inhibitors. The development of the product was stopped when there was no routes to identify responding patiets eventhough it had clear benefit and worked in Prostate Cancer, Ovarian Cancer and also demonstrated good activity in certain patients with Liver Cancer.

Oncology Venture has now restarted the program and has a granted patent on Irofulven DRP companion diagnostic.

Irofulven has shown good responses in 10% of prostate cancer patients. Oncology Venture aims to raise the response rate three fold. If reached Irofulven will according to Oncology Ventures cancer experts be an attractive treatment for patients with castration- and docetaxel resistant Prostate Cancer and give a route to commercialization.

Once initiated at the Irofulven will be the third active phase 2 study in Oncology Ventures pipeline accompanied by LiPlaCis for metastatic Breast cancer and APO010 for Multiple Myeloma.

About Prostate Cancer
Prostate Cancer is the second most common cancer among men worldwide, and the second leading cause of death from cancer in men. A majority of Prostate Cancers are adenocarcinomas, i.e. cancers that begin in cells producing and releasing mucus and other fluids. Progress is typically slow, and symptoms late. Prostate Cancer is most prevalent in older men, with a common age for diagnose around age 70. Treatment varies greatly, but in progressed Prostate Cancer usually comprises two or more of the alternatives surgery, radiation, chemotherapy and hormone treatment.
In progressed stages, the cancer eventually becomes resistant to hormone treatment (castration resistance) and chemotherapy (docetaxel resistance). It is among these patients that Irofulven will primarily be tested.

About Irofulven

Irofulven is a unique product within the DNA damage repair field which also includes the successful PARP inhibitors. The development of the product was stopped when there was no routes to identify responding patiets eventhough it had clear benefit and worked in 10% of prostate cancer, 12% of ovarian cancer and also demonstrated good activity in certain patients with liver cancer. Irofulven (6-hydroxymethylacylfulvene) 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.

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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 an exclusive license to use the Drug Response Predictor (DRP™) technology 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 with DRP™ 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 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 in Special Purpose Vehicles: 2X Oncology Inc. a US-based company focusing on precision medicine for women's cancers with a pipeline of three promising Phase 2 product candidates, and Danish OV-SPV 2 which will test and potentially develop the Novartis small molecule kinase inhibitor. Oncology Venture currently owns 92% of 2X Oncology Inc. and 40% of OV-SPV2 ApS.