

Press release issued by Oncology Venture Sweden AB Hoersholm, Denmark, May 31<sup>th</sup> 2017 **Press release** 

# OV's second drug candidate in the clinic – First Multiple Myeloma patient in study with APO010, an Immuno-Oncology drug

Hoersholm, Denmark, May 31<sup>th</sup>, 2017 – Oncology Venture Sweden AB (OV:ST) today announced that the first patient has entered the APO010 Phase 1/2 study for Multiple Myeloma (MM). APO010 is a first-in-class FAS-ligand anticancer product in immuno-oncology ("IO"). The DRP™ (Drug Response Predictor) Screening for sensitive patients with MM at four centers has been ongoing and >50 patients have already consented to have their tumor tissue DRP analyzed. In total 150 evaluable patients, will be screened using OV's DRP™ with the aim to identify those Multiple Myeloma patients with the highest likelihood to benefit from treatment with APO010.

"I'm excited that APO010 will now be in clinical use in Multiple Myeloma. APO010 is a new Immuno-Oncology product that kills tumor cells exactly as our immune system's T-Cells, and is a first-in-class product which we believe can become a new treatment option in Immuno-Oncology," says Adjunct Professor Peter Buhl Jensen, M.D., CEO of Oncology Venture. "Our first study is for the treatment of Multiple Myeloma and the aim is to demonstrate single agent efficacy. Immuno-Oncology is a very fast growing field, however the initial success has plateaued as several cancer types apparently are "cold" and avoid the immune attack. APO010 attack is like an immune attack and has the potential to turn "cold tumors into hot tumors". The current challenge in Immuno-Oncology is cold tumors without T Cells – this is where APO010 can be an opportunity," Peter Buhl Jensen, further comments.

#### **About APO010**

APO010 is a multimeric form of FAS-ligand for immuno-cancer therapy with a unique mechanism of action. APO010 acts through the FAS-receptor leading to apoptosis of the malignant cells. APO010 is expected to act in synergy with other cancer immunology agents such as ipilimumab and PD-1/PD-L1 inhibitors. The drug candidate is complemented by a companion diagnostic technology (APO010 DRP™) for enrichment of the patient population. APO010 was tested in 25 patients with solid tumors in a phase 1 study. The drug was well tolerated. Pre-clinical studies have revealed that APO010 is highly efficient in Multiple Myeloma. Next step is a focused study on 15 patients with Multiple Myeloma that have been pre-screened for sensitivity using the APO010 DRP™ technology.

## **About Multiple Myeloma**

Multiple Myeloma (bone marrow cancer) is a systemic malignancy in the blood, affecting plasma cells. The introduction of high-dose therapy with autologous stem cell support, and introduction of new therapies like the proteasome inhibitor bortezomib and IMIDs (thalidomide and lenalidomide) has improved the outcome. In spite of this, eventually all patients will experience progressive disease and continue into second and later lines of treatment. OV will approach this important clinical issue by introducing a novel systemic chemotherapeutic treatment together with a predictive biomarker test. Based on DRP<sup>IM</sup>, APO010 will be developed for use in treatment of Multiple Myeloma.

## About the Drug Response Predictor (DRP™) screening tool

This method builds on the 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.

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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 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 will test and potentially develop an oral phase 2 Tyrosine Kinase inhibitor