

Press release issued by Oncology Venture Sweden AB
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Press release

Green light to Oncology Venture for DRP focused clinical APO010 study in Multiple Myeloma

Hoersholm, Denmark, March 21th, 2017 – Oncology Venture Sweden AB (OV:ST) today announced that the Danish Medicines Agencies (DHMA) have approved the focused APO010 Multiple Myeloma study. APO010 is a first-in-class FAS-ligand anticancer product in the immuno-oncology field.

The DRP Screening for sensitive patients at four centers of Multiple Myeloma patients is already ongoing for the study with Oncology Ventures Immuno-Oncology drug APO010. In total 150 evaluable patients, will be screened using OV's DRP™ (Drug Response Predictor) with the aim to identify 15 Multiple Myeloma patients with the highest likelihood to benefit from treatment with APO010. The APO010 product has already been manufactured for two clinical trials. The study will be initiated during May 2017 and recruit patients during the 12 following month.

"I'm excited that APO010 is now approved for use in our DRP focused studies. APO010 is a new immuno-oncology product that kills tumor cells as our immune system, 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 against Multiple Myeloma and the aim is to demonstrate single agent efficacy. In due course the APO010 is expected to be used in combination with other active immune-oncology products. We aim to treat 15 Multiple Myeloma patients that have been screened for high likelihood of effect to APO010 as per our Drug Response Predictor - DRP™ - technology," This DRP™ enables us to develop drugs in a highly focused way," 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™, 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.

For further information, please contact

Peter Buhl Jensen, CEO
Telephone: +45 21 60 89 22
E-mail: pbj@oncologyventure.com

Ulla Hald Buhl
Telephone: +45 21 70 10 49
E-mail: uhb@oncologyventure.com

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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.