

Additional two centers started screening of Multiple Myeloma patients in OV's APO010 Study

Hoersholm, Denmark, August 19th, 2016 – Oncology Venture Sweden AB (OV:ST) today announced that additional two centers have been opened to support the inclusion rate of Multiple Myeloma patients in the screening study for phase 2 with Oncology Ventures Immuno Oncology drug APO010 as planned. Three out of four Danish hematology sites now participates. Approximately 150 patients will be screened using OV's DRP™ (Drug Response Predictor). The screening study aims to identify 15 Multiple Myeloma patients with the highest likelihood to benefit from treatment with APO010. The 15 patients will be included in a focused phase 2 multi-center study. If the product already in stock is approved the application for phase 2 is expected to be sent in Q3 2016. APO010 is a first-in-class FAS-ligand anticancer product in the immuno-oncology field.

"The opening and inclusion of patients for the screening of MM patients for the APO010 protocol forms the basis of inclusion of patients who are expected to have a high likelihood of responding to APO010. This DRP™ enables us to develop drugs in a highly focused way where the potential benefit for the patients goes hand in hand with saving time and resources," says Adjunct Professor Peter Buhl Jensen, M.D., CEO of Oncology Venture. "This new immuno-oncology product mimics our immune system, and is a first-in-class product which we believe can become a new treatment option against Multiple Myeloma," Peter Buhl Jensen, further comments.

APO010 is a FAS-ligand drug that only works when the FAS-receptor is present. To increase response odds, OV uses DRP™ to find patients whose tumor gene signature matches APO010, and therefore high likelihood responders. OV will screen the patients and include only those with the highest likelihood of response in a phase 2, proof-of-concept clinical trial.

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. Therefore, a phase 2 trial will be conducted in patients with Multiple Myeloma that have been pre-screened for sensitivity using the APO010 DRP™ technology.

There is a great need for effective treatment against Multiple Myeloma, where it is believed that a drug like APO010 can position itself right after Daratumumab which was recently approved for the indication. The market value was over 7 billion USD during 2014. Researchers estimate the value of the cancer immunotherapy market to 35 billion USD by 2023 (Citi GPS).

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.

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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.