Oncology Venture’s immuno-oncology drug APO010 for Multiple Myeloma receives EUROSTARS grant of a total value of 12.7 mNOK from Norway

Hoersholm, Denmark; June 17th, 2016 – Oncology Venture Sweden AB (OV:ST) announces that up to 6 million NOK (app. 632,000 EUR) has been granted by the Norwegian Research Council through the EUROSTARS program for the development of Oncology Venture’s immuno-oncology product APO010. The grant will i.a. cover the costs of a clinical proof of concept trial to investigate the effect of APO010 in patients with multiple myeloma (MM), a disease in the bone marrow. Patients entering the trial will be screened for high likelihood of effect of the drug by the use of Oncology Venture’s Drug Response Predictor (DRP™) – a unique tool based on Big Data from a multi gene signature identified in the MM patients’ biopsies.

The grant for APO010 was received by Smerud Medical Research International AS (SMERUD), Oncology Venture’s co-development partner, which in addition to co-funding the trial will also use its contract research division to manage the clinical trial. The 6 million NOK granted by the Norwegian Research Council, releases private investment from SMERUD with co-development R&D work valued 6,7 million NOK (app. 721,000 EUR) so that the total value of the grant and SMERUD’s contribution is 12,7 million NOK. Screening of MM patients has already begun and if the APO010 product on shelf is approved it is expected that the clinical proof of concept trial will start including patients in Q3 2016. This clinical trial will be conducted in University Hospitals in Denmark and other countries in Northern Europe.

“This non-dilutive EUROSTARS grant is very valuable for our immuno-oncology project APO010 for development in Multiple Myeloma patients. 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 of Multiple Myeloma. The grant supports the clinical proof of concept trial where patient’s biopsies will be screened ahead of treatment with APO010 to increase the likelihood of effect of the drug and success of the trial”, says Peter Buhl Jensen, Adjunct Professor, MD, PhD and CEO of Oncology Venture. We look very much forward to the collaboration with the highly qualified and experienced team in SMERUD and the Danish haematologist experts with the goal of improving treatment for cancer patients”, Dr. Buhl Jensen further commented.

SMERUD’s founder and CEO, Knut Smerud, commented that “We are very pleased to see that our EUROSTARS proposal was ranked well by an independent board of peer reviewers, and we wish to emphasise that the support from the Norwegian Research Council’s Eurostars office has been tremendous throughout the entire process. SMERUD is a long-standing supporter of EUROSTARS as an unrivalled and excellent grant system for smaller, R&D-intensive companies in Europe. As evident herein, receiving some support from the public, releases even bigger private funds to support the project, and as such we look forward to continuing our generation of employments within the European biotech sector. For SMERUD, this particular grant is of huge symbolic value as well, as it is the first time in which we take such a leading role in a consortium and cement our role as a drug development company, expanding our business from almost 25 years of history as a conventional CRO. Working with the skilled and seasoned oncology experts within OV has been mutually fruitful from the very beginning, and we look forward to advancing APO010 through to clinical proof-of-concept within multiple myeloma”.

Approximately 150 patients will be screened using OV’s DRP™ (Drug Response Predictor). The DRP™ uses genomic information from the individual cancer patient’s tumor. The screening will identify 15 patients with the highest likelihood to benefit from treatment with APO010. These 15 Multiple Myeloma patients will then be included in a focused proof of concept multi-center study. If the product already in stock is approved, the study is expected to start Q3 2016. APO010 is a first-in-class FAS-ligand anticancer product in the immuno-oncology field.
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 PD1-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 clinical proof of concept phase 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, and 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 SMERUD

Smerud Medical Research International AS (SMERUD) is a European drug development company and contract research organization (CRO) with headquarters in Oslo, Norway. The core competence is strategic drug development including regulatory affairs planning related to clinical development, and specifically to proof-of-concept trials (phase Ila). Functional services are primarily focused on clinical project management and monitoring of phase II-III studies, regulatory affairs, data management, statistics, medical writing and general drug development consulting. In recent years, SMERUD has achieved an unrivalled position in Europe as the CRO for obtaining public grants for clinical trials. The consistent and huge investment into internal R&D projects has enabled SMERUD to act both as a successful grant writer and as a risk-sharing co-development partner for many of their clients. The project-orientated co-investment service has been particularly welcomed by smaller, cash-strapped biotech companies – seeing this option as an excellent source of non-dilutive funding. SMERUD has – together with its associated venture firm Scandinavian Biotech Venture AS – become one of the largest private biotech investors in the Nordic countries. SMERUD also has a full-service in-house clinical Contract Research Organisation division operating throughout Europe with head office in Norway and subsidiary offices in Denmark, Finland, Sweden, United Kingdom, Germany, Austria, Poland and Russia. The CRO division has been involved in more than 1000 clinical trials in a wide variety of indications, countries and study phases.

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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 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: LiFlAcru™, for Breast Cancer, Irofulven, developed from a fungus, for Prostate Cancer, and APO010, an immuno-oncology product for Multiple Myeloma.