Press release issued by Oncology Venture Sweden AB
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Press release

DRP™ for Oncology Ventures lead product LiPlaCis® registered for CE-marking in EU

Hoersholm, Denmark, January 9th, 2017 – Oncology Venture Sweden AB (OV.ST) today announced that CE-marking for the in vitro diagnostic medical device (IVD); the Drug Response Predictor – DRP™ – has been technically validated and registered for the lead drug candidate LiPlaCis®. A CE-marking shows that conformity assessment has been carried out and a technical file has been established by Medical Prognosis Institute A/S from whom OV has in-licensed the DRP™. The LiPlaCis DRP™ is key in the selection of high likely responding patients and pivotal in OV's clinical breast cancer trial in Denmark and also key for OV's partner Cadila Pharmaceuticals Ltd. (Cadila) who is in the process of starting four phase 2 trials and one phase 3 trial with LiPlaCis® and LiPlaCis DRP™.

The CE-IVD validation and registration allows marketing the product in all of the EU. LiPlaCis DRP™ uses a diagnostic sample of the patient's tumor to determine response to treatment with LiPlaCis®. In that way, it can be avoided giving a patient a treatment that will be of no benefit.

CE-marking shows that compliance with EU Directives has been achieved and demonstrates that specific standards of performance, quality, safety, and efficacy for the LiPlaCis DRP™ has been met. CE-marking indicates a product complies with the applicable EU regulations and enables the commercialization in 32 European countries.

"*The CE-mark registration in EU of LiPlaCis is an important milestone for Oncology Venture. LiPlaCis and its DRP-companion diagnostic is OV's lead product and is the first in a series of precision medicine we aim to develop. The CE mark is recognized in several ex-EU countries and may support registration also in our partner Cadila's territory",* ***says Peter Buhl Jensen, M.D., CEO of Oncology Venture.*** *"The Drug Response Predictor is key in the development of LiPlaCis as a precision anticancer product where only patients with high likelihood of response should be treated with LiPlaCis,"* ***Buhl Jensen further commented.***

About LiPlaCis®

Cisplatin is one of the most widely used drugs in the treatment of cancer due to its documented efficacy in a number of tumor types. Cisplatin is used in the treatment of large indications as lung cancer (Europe+US ≈ 673,000 new cases annually), head and neck cancer (500,000 cases annually worldwide) bladder cancer (EU+US ≈ 170,000 annually) and ovarian cancer (EU+US ≈ 71,000 annually). The lipid formulation from LiPlasome is an answer to a well-established need for improving cisplatin therapy and improving the formulation of the drug, so that a more selective up-take of cisplatin administered takes place at the tumor sites. The liposomes are designed to trigger the release of an encapsulated drug specifically in the tumor tissue. An enzyme especially present on tumors called secretory phospholipase A2 (sPLA2), is utilised to break down the LiPlaCis® once it has accumulated in the cancer tissue. The lipid composition of the LiPlasomes is tailored to be specifically sensitive to degradation by the sPLA2 enzyme and thereby for release of the encapsulated drug.

About the Drug Response Predictor - DRP™ screening tool

Oncology Venture uses the MPI multi gene DRP™ to select those patients that by the genetic signature in their cancer is found to have a high likelihood of response to the drug. The goal is to develop the drug for the right patients and by screening patients before treatment the response rate can be significantly increased.
This DRP™ method builds on the comparison of sensitive vs. resistant human cancer cell lines including genomic information from cell lines combined with clinical tumor biology and clinical correlates in a systems biology network. The DRP™ is based on messenger RNA from the patients biopsies.
The DRP™ platform i.e. the DRP™ and the PRP™ tools can be used in all cancer types, and is patented for more than 70 anti-cancer drugs in the US. The PRP™ is used by MPI for Personalized Medicine. The DRP™ is used in Oncology Venture for drug development.

For further information, please contact

Ulla Hald Buhl, COO and
Chief IR & Communications
Mobile: +45 2170 1049
E-mail: uhb@oncologyventure.com

Or

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

This information is information that Oncology Venture Sweden AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, on January 9th, 2017.

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.